Technical Guide on Internal Audit of Pharmaceutical Industry (2023 Edition)

The Institute of Chartered Accountants of India
(Set up by an Act of Parliament)
New Delhi

Technical Guide on Internal Audit of Pharmaceutical Industry

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Board of Internal Audit and Management Accounting

The Institute of Chartered Accountants of India

(Set up by an Act of Parliament)

New Delhi

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Foreword

The Indian pharmaceutical industry ranks third globally in pharmaceutical production by volume and is known for its generic medicines and low-cost vaccines. Keeping the momentum going, the Indian Pharmaceutical industry is expected to grow further to generate opportunities across various sections of the pharmaceutical industry viz. Innovation and R&D, Healthcare delivery, Manufacturing and Global Supply Chain. Amidst the growing avenues, the challenge that lies here is the varied nature of resources and complex external environment that the industry deals with. This requires the need of optimised use of resources, a support-system to achieve the strategic objectives, assessment and improvement of existing controls and processes, assurance and advice on the governance, risk appetite, risk & control culture, and involvement in consulting activities that are of a problem-solving nature. Thus, Internal audit is a best tool for growth of pharmaceutical industry and Chartered Accountants are world class internal auditors. Chartered Accountants can provide credible and objective information and assess the requirements of best practices, recommend, and implement them.

I congratulate CA. Rajendra Kumar P., Chairman, CA. Charanjot Singh Nanda, Vice Chairman and other members of Board of Internal Audit and Management Accounting for bringing out this publication "Technical Guide on Internal Audit of Pharmaceutical Industry". This Technical Guide will provide the readers a crisp insight into various technicalities arising in the operations of pharmaceutical industry and covers the relevant issues which the internal auditors must be aware of.

I am sure that this Technical Guide will assist the members in discharging their professional responsibilities efficiently.

September, 04, 2023
New Delhi

CA. Aniket Sunil Talati
President, ICAI

Preface

Starting from a nascent position in 1960s, Indian pharmaceutical industry has emerged as the pharmacy of the world. The industry has played a key role in driving better health outcomes across the world through its affordable and high-quality generics drugs. The major challenges faced by the companies in pharmaceutical industry are regulatory compliances, Intellectual Property Rights Issues, price controls, innovation and infrastructure challenge, skilled workforce, global competition.

The Chartered Accountants can play a crucial role in helping Pharmaceutical Industry by planning and channelling risks into opportunities, as well as assisting management in taking further action.

Keeping this mind, the Board on Internal Audit and Management Accounting of ICAI is issuing this Technical Guide on Internal Audit of Pharmaceutical Industry to provide guidance to internal auditors in carrying out internal audit of companies operating in pharmaceutical industry. This Guide has been divided into various chapters that provide guidance on structure, history, regulatory framework, key drivers of this industry. This Guide, inter alia, provides guidance on aspects involved in various stages of pharmaceutical industry and regulatory framework. This Guide also describes risks associated with pharmaceutical industry and internal controls checklist for various processes. This Guide also contains illustrative checklist for internal audit of major areas of pharmaceutical industry.

We are immensely grateful to CA. Mohit Dhand and CA. Komal Dhand for sharing their experience and knowledge with us and review and revised Technical Guide.

We would like to thank CA. Aniket S. Talati, President, ICAI and CA. Ranjeet Kumar Agarwal, Vice President, ICAI for their continuous support and encouragement to the initiatives of the Board. We also thank the members of our Board who have always been a significant part of all our endeavours.

We also wish to express our sincere appreciation for CA. Arti Bansal, Secretary, Board of Internal Audit and Management Accounting, ICAI, Mr. Harish Dua, advisor and her team for their efforts in giving final shape to the publication.

We firmly believe that this publication would serve as basic guide for the members and other readers interested in the subject.

We will be glad to receive your valuable feedback at biama@icai.in. We also request you to visit our website https://internalaudit.icai.org/ and share your suggestions and inputs, if any, on internal audit and Management Accounting.

CA. Rajendra Kumar P
Chairman
Board of Internal Audit &
Management Accounting

CA. Charanjot Singh Nanda
Vice-Chairman
Board of Internal Audit &
Management Accounting

September 4, 2023
New Delhi

Foreword to the First Edition

Indian pharmaceutical industry has grown at a high pace during the last few years. The major challenges faced by the companies in the pharmaceutical industry are developing new products and services through research, shifting demographics, evolving governing regulations, transforming business models and increased expectations from stakeholders.

Risk is central to pharmaceutical companies as they are dependent on continuous research and development with long gestation periods, compliance issues with environmental laws, heavy capital investments as well as expenditures for environmental liabilities, management of their intellectual property rights, etc. Most innovative pharmaceutical companies are undergoing transition from their traditional business model and resort to diversification, mergers & acquisitions to deal with the growing competition for low cost generics.

The Chartered accountants can play a crucial role in helping pharmaceutical companies to address the said challenges presented by today's complex, competitive and risk driven environment by strategizing and channelizing the threats into opportunities and assist the management of the said companies in taking future course of action.

I congratulate CA. Rajkumar S. Adukia, Chairman, Internal Audit Standards Board of The Institute of Chartered Accountants of India and other members of the Board for bringing out this "Technical Guide on Internal audit of Pharmaceutical Industry" which is one of the rapidly growing industries of the country. This comprehensive publication would surely help the members to conduct value added internal audits and provide inputs that will help to improve operational efficiencies, risk management, capital allocation and market reach of the pharmaceutical companies in the country.

I am confident that the members and other interested readers will make best use of this publication.

February 4, 2013
New Delhi

CA. Jaydeep Narendra Shah
President, ICAI

Preface to the First Edition

The Indian Pharmaceutical industry is witnessing trends such as innovation in drugs at a faster pace, increasing investment, deeper penetration in rural markets, growth in insurance coverage and changing government regulations. These positive trends, along with favourable macro environment will help to propel the pharmaceutical industry to the next level of growth. Pharmaceuticals companies are facing competition and they need to optimally leverage financial, relational, technology and reputational capital to create strategies and provide value to consumers.

Keeping this in mind, the Internal Audit Standards Board is issuing the Technical Guide on Internal Audit of Pharmaceutical Industry, so as to provide guidance to internal auditors in carrying out internal audit of companies operating in pharmaceutical industry. The objective of this Technical Guide is to provide an insight into the functioning of the pharmaceutical industry, the key drivers of pharmaceutical industry, technical aspects peculiar to the industry and internal audit procedures with respect to certain processes which would help the readers in conducting internal audit of a pharmaceutical company. This Guide explains in brief the key drivers of Indian pharmaceutical industry which include low cost of manufacture, research & development, highly educated and specialized scientists, experience in international servicing, bio-pharmaceutical sector, etc. The Guide also covers in brief technical aspects of pharmaceutical industry which includes drug discovery and development solutions, exclusive synthesis and radiopharmaceuticals. The Guide also discusses regulatory framework for pharmaceutical industry in India especially, National Pharmaceuticals Pricing Policy, 2012. Internal audit aspects with respect to procurement to pay cycle, order to cash, statutory compliances, production and inventory management have been discussed in detail for each underlying activity alongwith it's controls objectives and the key controls to be verified in this regard.

At this juncture, I am grateful to Dr. Sanjeev Singhal and his study group members viz. C.A. R. Sankariah and C.A. Akshat Kedia for sharing their experiences and knowledge with us and preparing the draft of the Guide.

I wish to thank CA. Jaydeep N. Shah, President and CA. Subodh Kumar Agrawal, Vice President for their continuous support and encouragement to the initiatives of the Board. I must also thank my colleagues from the Council

at the Internal Audit Standards Board, viz., CA. Rajendra Kumar P., Vice-Chairman, IASB, CA. Amarjit Chopra, CA. Shiwaji B. Zaware, CA. Ravi Holani, CA. Anuj Goyal, CA. Nilesh Vikamsey, CA. Atul C. Bheda, CA. Charanjot Singh Nanda, CA. Pankaj Tyagee, CA. G. Ramaswamy, CA. J. Venkateswarlu, CA. Abhijit Bandyopadhyay, CA. S. Santhanakrishnan, Shri Prithvi Haldea, Smt. Usha Narayanan, Shri Gautam Guha, Shri Manoj Kumar and Shri Sidharth Birla for their vision and support. I also wish to place on record my gratitude for the co-opted members on the Board viz., CA. Porus Doctor, CA. Masani Hormuzd Bhadur, CA. Ghia Tarun Jamnadas, CA. Deepjee A Singhal, CA. Nitin Alshi, CA. Narendra Aneja and CA. Guru Prasad M and special Invitee, CA. Sumit Behl and CA. Sanjay Arora for their invaluable guidance as also their dedication and support to the various initiatives of the Board. I also wish to express my thanks to CA. Jyoti Singh, Secretary, Internal Audit Standards Board and CA. Arti Bansal, Sr. Executive Officer in giving final shape to the Technical Guide.

I am certain that this Technical Guide will help the members and others in efficiently discharging their responsibilities.

February 6, 2013
Mumbai

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Contents

Chapter 1

Objectives of Technical Guide

1.1 This technical guide aims to provide comprehensive information and guidance to internal auditors working in the domestic pharmaceutical industry. It aims to equip internal auditors with the knowledge necessary to effectively assess and evaluate the risk management and internal control systems, management processes and compliance frameworks specific to the pharmaceutical sector. The guide focuses on critical areas of concern and provides practical insights to enhance the efficiency, effectiveness and transparency of internal audit activities within pharmaceutical organisations.

1.2 The Guide briefly covers the following:

- History
- Current Scenario
- Key Drivers
- Technical Aspects
- Research & Development
- Regulatory Framework
- Risk Assessment and Internal Controls
- Internal Audit
    - Production Planning and Control (PPC)
    - Procure to Pay (P2P)
    - Order to Cash (O2C/OTC)
    - Hire to Retire (H2R)
    - Employee Expense Reimbursement
    - Expense Cycle
    - Fixed Asset
    - Financial Reporting Process

- Entity-Level Controls (ELC)
- IT General Controls and Audit

Chapter 2
History

2.1 Over the last few decades, the Indian Pharmaceutical (or “pharma”) industry has experienced rapid expansion which can be divided into four stages. We can consider the time before 1970 as the first stage of the pharma industry. At that time, the Indian market was dominated by foreign companies. The second stage covers 1970 to 1990, when several domestic companies began their operations. 1990 to 2010 is the third stage, where liberalisation led Indian companies to launch operations in foreign countries. The period after 2010 is seen as the fourth stage, where Indian pharma is moving rapidly into own research and development.

2.2 At the time of independence in 1947, the size of the Indian pharmaceutical sector was around Rs. 10 Crore. The Indian pharma market was dominated by western Multi National Corporations (MNCs) controlling between 80 to 90% of the market primarily through importation. Approximately 99% of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic drug prices were among the highest in the world. The need for import substitution by strengthening technological capability, reducing foreign dominance, building indigenous capacity, encouraging small-scale industries and reducing income inequalities was a necessity of the time.

2.3 The first Patent Act of independent India came into existence in 1970 on recommendations of Justice N Rajagopala Ayyangar Committee. However, the Act eventually came into existence only on April 20, 1972. It was indeed a national Patent Act wherein provisions were made to favour the domestic industry to a large extent. The immediate effect of the Patent Act, 1970 was seen in the number of patent applications filed subsequent to its enactment by Multi National Corporations (MNCs).

2.4 The Indian drug policy was formed on the recommendation of the Hathi Committee to ensure the production and distribution of essential drugs to poor populations. In the early 1960s, the MNCs had a monopoly in pricing in the country, where they kept the prices of non-essential medicines low and essential drugs high. To control monopoly in the market, the Government

created a price control regime known as the Drug Price Control Order (DPCO) in 1966 and by 1970 declared drugs to be essential commodities under the Essential Commodities Act, 1955. The DPCO regulated drug prices by allowing marked-up prices, including profits of 40% for life-saving drugs, 55% for essential drugs and 100% for less essential drugs. After that, DPCO was revised in 1979 and 1987.

2.5 The market share of foreign MNCs declined after India adopted the process patent. In 1980, the market share of foreign MNCs declined to 50% and by 2004, it further reduced to 23% as compared to domestic pharmaceutical industries. Subsequently, most foreign pharmaceutical manufacturers abandoned the Indian market due to the absence of legal mechanisms to protect their patented products. As the MNCs left the Indian market, local firms rushed into fill the void and by 1990, India was self-sufficient in the production of formulations and nearly self-sufficient in the production of bulk drugs

2.6 In 1991, India launched massive economic reforms, stepping into the era of globalisation. While India was jostling with her internal reform-driven economic reconstruction, the world was adapting to a new-trade order, the Trade-Related-Aspects of Intellectual Property Rights (TRIPs). Most of the signatory member states of the World Trade Organizations (WTO) adopted TRIPS, but this was in direct conflict with the Indian Patent Act, 1970. As a binding, India had to adopt the TRIPS agreement. Provisioning this adoption, the Indian Patent Act saw three landmark amendments, namely the Patent (Amendment) Act 1999, Patent (Amendment) Act 2002 and Patent (Amendment) Act 2005.

2.7 After 2005, government started developing clusters based on a public-private partnership model. Till October 2006, there were around 32 pharmaceutical and biotech Special Economic Zone (SEZs) received in-principal/formal approval, including 20 pharmaceutical industry and 12 biotechnology. The Government of India established the National Institute of Pharmaceutical Education & Research (NIPER) to cater to the long-standing demand for a dedicated nodal agency for quality higher education and advanced research in the pharmaceutical sciences. First NIPER, SAS Nagar was established in 1998 and later in 2007, Government established six more at Hyderabad, Ahmedabad, Hajipur, Kolkata, Guwahati and Rae Bareli.

2.8 The Department of Pharmaceuticals was formed on July 1, 2008, under the Ministry of Chemicals and Fertilisers to focus on the development of the pharmaceutical sector in the country and to regulate various activities related to the pricing and availability of medicines at affordable prices, Research & Development (R&D), the protection of intellectual property rights (IPR) and international commitments related to the pharmaceutical sector.

2.9 In 2009, India had more than 120 US Food and Drug Administration (FDA) approved plants and approximately 84 UK Medicines and Healthcare products. Regulatory Agency (MHRA) approved plants capable of manufacturing products with exceptional quality standards.

2.10 More recently, as India reeled under the impact of the Coronavirus pandemic (Covid-19), its healthcare sector (and the pharma industry in particular) rose to the occasion. It displayed the ability to manufacture and maintain supply chains even during the lockout period and exported medicines such as hydroxychloroquine and paracetamol to more than 150 countries, developing its image as the “Reliable Pharmacy of the World.” In January 2021, India rolled out the world’s largest vaccination drive to vaccinate around 300 million priority groups against the Covid-19. Initially, two vaccines, COVAXIN and COVISHIELD were considered by the Government of India and the Indian government provided them to large masses at almost free of cost.

Today, India is the largest provider of generic drugs globally. Indian pharmaceutical sector supplies over 50% of the global demand for various vaccines, 40% of the generic market in the US and 25% of all medicine in the UK.

Chapter 3
Current Scenario

3.1 India enjoys an important position in the global pharmaceuticals industry. India is the largest provider of generic drugs globally, known for its affordable vaccines and medications. The Indian Pharmaceutical industry is ranked 3rd in pharmaceutical production by volume and 14th by value after evolving into a thriving industry growing at a CAGR of 9.43% since 2013.

3.2 India has the most pharmaceutical manufacturing facilities that comply with the US Food and Drug Administration (USFDA) and has 500 API (Active Pharmaceutical Ingredient) producers, making up around 8% of the worldwide API market. The domestic pharmaceutical industry includes a network of over 3,000 drug companies and over 10,500 manufacturing units. Indian pharmaceutical firms supply over 80% of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome). India is rightfully known as the "pharmacy of the world" due to the low cost and high quality of its medicines.

3.3 According to the Indian Economic Survey 2021, the domestic market is expected to grow 3x in the next decade. India's domestic pharmaceutical market stood at US$ 42 billion in 2021 and is likely to reach US$ 65 billion by 2024 and further expand to US$ 130 billion by 2030. The Indian biotechnology industry was valued at US$ 70.2 billion in 2020 and expecting to reach US$ 150 billion by 2025.

3.4 India is the 12th largest exporter of medical goods in the world. India exports drugs to more than 200 countries with the US being the key market. Generic drugs account for 20% of the global export volume, making the country the largest provider of generic medicines globally. Indian drug & pharmaceutical exports stood at US$ 24.60 billion in FY22 and US$ 24.44 billion in FY21.

3.5 India's medical devices market stood at US$ 10.36 billion in FY20. The market is expected to increase at a CAGR of 37% from 2020 to 2025 to reach US$ 50 billion. As of August 2021, CARE Ratings expect India's pharmaceutical business to develop at an annual rate of ~11% over the next two years to reach more than US$ 60 billion in value.

3.6 The Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India launched the Jan Aushadhi Scheme in November 2008. Till May 2014, only 80 'Jan Aushadhi Stores' were in operation in selected States. The Government revamped the 'Jan Aushadhi Scheme' in September 2015 as 'Pradhan Mantri Jan Aushadhi Yojana' (PMJAY). It was again renamed as Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) to give further impetus to the scheme. Till 31st January 2022, 8675 PMBJP Kendras (or stores) are functioning across the country. The government has a target to open 10500 PMBJP stores in the country by 2025, but there are good chances that the actual number will exceed this target.

3.7 In the financial year 2020-21, the PMBI has made sales of Rs. 665.83 Crore, which led to savings of about Rs. 4000 Crore to the citizens compared to the branded medicines. In the financial year 2021-22 (till 31.01.2022), the PMBI has made sales of Rs. 751.42 Crore, leading to approximately Rs. 4500 Crore savings for the citizens.

3.8 More recently, on the retailing front, online pharmacies are becoming domestic bulk buyers from pharmaceutical industries. The revenue of the online retail sector stood at INR 38.15 Bn in 2020 and is likely to reach 317.87 Bn in 2026. Online Pharmacy offers a 10-20 % discount over offline or retail pharmacies. Online players are able to save various costs — real estate, inventory, employee salaries, utilities, intermediaries, etc., which allow them to offer these savings in the form of price discounts to the customers.

REFERENCE:

Ibef.org

Top 20 Listed Companies in India in terms of Net Sales (for the year ended 31st March 2022)

Sr. No.	Company Name	Net Sales (Rs.cr)
1	Sun Pharma	15,585.98
2	Dr Reddy's Labs	14,405.20
3	Cipla	13,091.79
4	Lupin	11,771.67

Sr. No.	Company Name	Net Sales (Rs.cr)
5	Aurobindo Pharm	11,287.14
6	Divis Labs	8,879.82
7	Alkem Labs	8,829.81
8	Glenmark	8,141.58
9	Zydus Life	7,981.90
10	Torrent Pharma	6,742.32
11	Ipca Labs	5,399.36
12	Alembic Pharma	5,035.41
13	Abbott India	4,919.27
14	Laurus Labs	4,707.04
15	Gland	4,400.71
16	Granules India	3,238.44
17	GlaxoSmithKline	3,217.51
18	Ajanta Pharma	3,140.64
19	Piramal Pharma	3,094.95
20	Sanofi India	2,956.60

Top 20 Listed Companies in India in terms of Market Cap (for the year ended 31st March 2022)

Sr. No	Company Name	Market Cap (Rs.cr)
1	Sun Pharma	2,47,263.47
2	Divis Labs	88,931.97
3	Cipla	86,041.04
4	Dr Reddy's Labs	71,790.01
5	Torrent Pharma	52,464.12
6	Abbott India	47,127.87

Sr. No	Company Name	Market Cap (Rs.cr)
7	Zydus Life	44,536.98
8	Alkem Lab	36,099.06
9	Lupin	34,361.71
10	Aurobindo Pharm	25,497.12
11	Gland	23,940.19
12	GlaxoSmithKline	22,154.92
13	Ipca Labs	22,092.56
14	Pfizer	19,327.96
15	Laurus Labs	19,232.53
16	JB Chemicals	15,124.20
17	Ajanta Pharma	15,083.53
18	Piramal Pharma	14,009.56
19	Sanofi India	13,037.64
20	Suven Pharma	12,632.79

Chapter 4
Key Drivers

4.1 Key drives of pharmaceutical industry are as follows:

General Key Drivers

Leading Pharma Producer

- Indian pharmaceutical industry expects to reach ~US$ 130 billion by 2030.
- India ranks 3rd worldwide for pharmaceutical production by volume and 14th by value.
- India is the largest producer of vaccines worldwide, accounting for ~60% of the total vaccines as of 2021.

One of the Highest Exports

- India is the world's largest provider of generic medicines; the country's generic drugs account for 20% of global generic drug exports.
- Indian drugs are exported to more than 200 countries with the US as the key market.
- India is the 12th largest exporter of medical goods.
- Indian drug & pharmaceutical exports stood at US$ 2,196.32 million in September 2022.

Among the Fastest-Growing Industries

- Indian pharmaceutical sector expects to grow at a CAGR of 22.4% soon and the medical device market expects to grow US$ 25 billion by 2025.
- India is the 2nd most significant contributor to the global biotech and pharmaceutical workforce.

Robust Growth in Biotech Industry

The biotechnology industry in India comprises ~600+ core biotechnology companies, ~2700+ biotech start-ups and ~100+ biotech incubators.

Rapidly Growing Healthcare Sector

Indian Healthcare is one of the fastest-growing sectors and expects to reach US$ 774 billion by 2030.

Economic Key Drivers

Cost Efficiency

- Low cost of production and R&D boosts the efficiency of Indian pharma companies, leading to competitive exports.
- As of 2019, India's cost of production is ~33% lower than that of the US.
- India's ability to manufacture high-quality, low-priced medicines presents a huge business opportunity for the domestic industry.

Policy Support

- In February 2021, the government approved a production-linked incentive (PLI) scheme for the pharmaceutical sector from FY21 to FY29. The scheme will attract investments of Rs. 15,000 crore, leading to incremental sales of Rs.2,94,000 crore and exports of Rs.1,96,000 crore.
- In March 2022, under the scheme SPI (Strengthening of Pharmaceutical Industry), a total financial outlay of Rs.500 crore for FY 2021-22 to FY 2025-26 was announced.

Increasing Foreign Direct Investments (FDI)

- The FDI inflows in the Indian drugs and pharmaceutical sector reached US$ 19.90 billion between April 2000-June 2022.
- The FDI inflows in the drugs and pharmaceuticals sector reached US$ 1,414 million in FY 2021-22.

- In September 2021, Schott, a pharmaceutical glass manufacturing company, said it would invest US$ 82 million to expand its tubing facility in Jambusar, Gujarat.

Supply-side Key Drivers

Launch of Patented Drugs

- After introducing product patents, India expects several multinational companies to launch patented drugs.
- According to Sagacious IP, in terms of patents filed by Indian companies, India ranks among the top 10 countries in Healthcare and Pharmaceutical sectors.
- The number of patents filed by Indian firms increased from 2,548 in 2015 to 7,399 in 2020.

Medical Infrastructure

- Pharma companies have increased spending to tap rural markets and develop better medical infrastructure.
- The hospitals market expects to increase in size by US$ 200 billion by 2024
- India's medical devices market stood at US$ 10.36 billion in FY20. The market is expected to grow at a CAGR of 37% from 2020 to 2025 to reach US$50 billion.

Scope in the Generics Market

- India's generic drugs account for 20% of global exports in volume, making it the largest provider of generic medicines globally.
- The generic drug market accounts for around 70% of the Indian Pharmaceutical Industry.

Over The Counter (OTC) Drugs

- India's OTC drugs market stood at US$7.62 billion in 2021 and is estimated to grow at a CAGR of 19.4% to reach US$ 18.49% billion in 2026, driven by a shift in consumer attitudes towards self-medication,

product advancements and pharmaceutical preferences for OTC drugs over prescription drugs.

Demand-side Key Drivers

Accessibility

- As per Mckinsey's report (July 2019), >US$ 200 billion will be spent on medical infrastructure in the next decade.
- New business models are expected to penetrate Tier 2 & 3 cities.
- Over 1,60,000 hospital beds will be added each year in the next decade.

Acceptability

- Rising levels of education to increase the acceptability of pharmaceuticals
- Patients are expected to show a greater propensity to self-medication, boosting the OTC market.
- Acceptance of biologics and preventive medicines is expected to rise.

Pradhan Mantri Bhartiya Janaushadhi Kendras

- The Government plans to provide free generic medicines to half the population at an estimated cost of US$ 5.4 billion.
- Affordable medicines under Pradhan Mantri Janaushadhi Kendras (PMBJKs) achieved impressive sales of Rs.100.40 crore in the first two months of FY21.

Epidemiological Factors

- The patient pool is expected to increase by over 20% in the next ten years (until 2030), mainly due to the population increase.
- New diseases and lifestyle changes boost demand.
- Increasing prevalence of lifestyle diseases

**Source: IBEF*

Chapter 5
Technical Aspects

Healthcare Segments

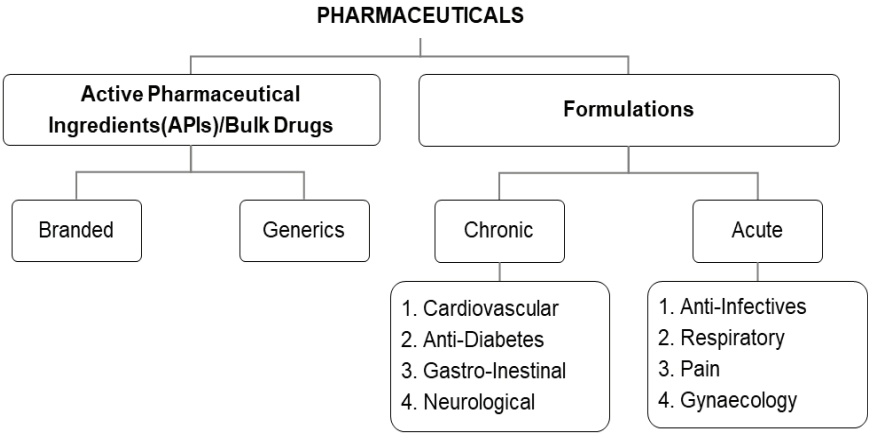
5.1 The healthcare market functions through five segments:

Segments	Details
Hospitals	Government hospitals – It includes healthcare
	Private hospitals – It includes nursing homes and mid-tier and top-tier private hospitals.
Pharmaceutical	It includes manufacturing, extraction, processing, purification and packaging of chemical materials for use as medications for humans or animals.
Diagnostics	It comprises businesses and laboratories that offer analytical or diagnostic services, including body fluid analysis.
Medical Equipment and Supplies	It includes establishments primarily manufacturing medical equipment and supplies, e.g. surgical, dental, orthopaedic, ophthalmologic, laboratory instruments, etc.
Medical Insurance	It includes health insurance and medical reimbursement facility, covering an individual's hospitalisation expenses incurred due to sickness.
Telemedicine	Telemedicine has enormous potential in meeting the challenges of healthcare delivery to rural and remote areas besides several other applications in education, training and management in health sector.

** Source: Hospital Market – India by Research on India*

5.2 The pharmaceutical industry is divided into various branches, representing different aspects and functions within the industry. These branches include research and development, manufacturing, marketing and sales, regulatory compliance, pharmacovigilance, health economics and outcomes research, medical affairs, supply chain and logistics, contract research organizations, pharmacy retail, health information technology, biotechnology and medical technology.

Each branch further expands into specific subcategories, highlighting the diverse areas and specialities within the pharmaceutical industry. This hierarchical tree visually represents the pharmaceutical industry's divisions, classifications and future directions.



Classification and Overview of the Pharmaceutical Industry

5.3 Overviews of areas under Pharmaceutical Industry in as follows:

Research and Development (R&D)

a. **Drug Discovery:** The process of identifying and developing new drug candidates, usually involving target identification, lead compound synthesis and optimization.

b. **Preclinical Development:** Involves laboratory testing and animal studies to assess the safety and efficacy of drug candidates before they can proceed to clinical trials.

c. **Clinical Trials:** Conducting controlled studies on human subjects to evaluate the safety, efficacy and dosage of new drugs or treatments.

d. **Regulatory Affairs:** Managing the regulatory requirements and interactions with health authorities to ensure compliance with regulations and obtain necessary approvals for drug development and commercialization.

Manufacturing

a. **Active Pharmaceutical Ingredients (API):** Production of the chemical compounds or substances that are the active components responsible for the therapeutic effects of drugs. An API is the component of an Over The Counter (OTC) or prescription medication that produces its intended health effects. If a prescription drug has a generic, its name is identical to its API. Combination therapies have multiple active ingredients, each of which may act differently or treat different symptoms.

   All drugs are made up of two core components:

   The API is the central ingredient produced from raw materials with a specified strength and chemical concentration.

   The excipient includes substances other than the drug that help deliver the medication to your system.

b. **Formulation Development:** Formulating APIs into dosage forms such as tablets, capsules, injections, or liquids, ensuring stability, bioavailability and appropriate drug delivery. India is the largest formulations exporter in volume, with a 14% market share and 12th in export value. Double-digit growth is expected over the next five years.

c. A biosimilar, or biosimilar drug, is a medicine that is very close in structure and function to a biologic medicine. It is a medicine made in a living system, such as yeast, bacteria, or animal cells. Biologics used in the treatment of cancer can work in many ways. For example, they might:

   - Help the body's immune system recognize and kill cancer cells more effectively.
   - Work against certain proteins in or on cancer cells to stop their growth.

- Help the body make more blood cells to replace the ones lost because of other cancer treatments.

d. **Packaging and Labelling:** Designing and producing pharmaceutical products' packaging materials and labels, including ensuring compliance with regulatory requirements.

e. **Quality Control and Assurance:** Implementing processes and systems to ensure the quality, purity and safety of pharmaceutical products through testing, inspections and adherence to quality standards.

f. **Supply Chain Management:** Overseeing the planning, sourcing, procurement, production and distribution of pharmaceutical products to ensure their availability and timely delivery.

Marketing and Sales

a. **Branded Medications:** Promoting and selling drugs developed and marketed under a specific brand name, typically protected by patents and associated with research, development and marketing investments.

b. **Generic Medications:** Marketing and selling drugs that are bioequivalent to brand-name drugs but are produced and sold without patent protection, usually at lower prices.

c. **Medical Devices:** Marketing and sales of medical equipment, devices, instruments, or diagnostic tools used for medical purposes.

d. **Over the Counter (OTC) Products:** Marketing and selling non-prescription medications, health products and supplements directly to consumers.

Therapeutic Areas and Specialized Medicine

a. **Acute Therapy:** Treatment of short-term and severe medical conditions or illnesses

b. **Chronic Therapy:** Treatment of long-term or persistent medical conditions or illnesses

c. **Personalized Medicine:** Customizing medical treatment based on an individual's genetic and biomarker information

d. **Drug Delivery Systems and Nanomedicine:** Techniques and technologies for targeted drug delivery and improved efficacy

e. **Pharmacovigilance:** Monitoring and assessing the safety and efficacy of pharmaceutical products throughout their lifecycle

Regulatory Compliance

a. **FDA Compliance:** Ensuring adherence to regulations and guidelines set by the U.S. Food and Drug Administration (FDA) regarding drug development, manufacturing, labelling and marketing.

b. **International Regulations:** Complying with regulatory requirements and guidelines of other countries and regions where pharmaceutical products are distributed or marketed.

c. **Good Manufacturing Practices (GMP):** Following the standards and guidelines for manufacturing processes, facilities and quality control to consistently produce safe and effective pharmaceutical products.

Pharmacovigilance and Drug Safety

Monitoring and evaluating the safety and effectiveness of drugs throughout their lifecycle, including detecting, assessing and preventing adverse effects and other drug-related issues.

Contract Research and Manufacturing Services (CRAMS)

Contract research and manufacturing services (CRAMS) is one of the fastest-growing pharmaceutical and biotechnology industry segments. The pharmaceutical market uses outsourcing services through contract research organizations (CROs) and contract manufacturing organizations (CMOs). Increasing costs of R&D, coupled with low productivity and poor bottom lines, have forced major pharmaceutical companies worldwide to outsource part of their research and manufacturing activities to low-cost countries like INDIA.

a. **Clinical Research:** Conducting clinical trials on behalf of pharmaceutical companies, including protocol development, patient recruitment, data collection and analysis.

b. **Data Management:** Collecting, processing and managing clinical trial data to ensure accuracy, quality and regulatory compliance.

c. **Regulatory Support:** Assist pharmaceutical companies with regulatory submissions, documentation and compliance throughout drug development.

Core and Non-Core Processes in the Pharmaceutical Industry

5.4 A Comprehensive Overview

Procure to Pay	Manufacturing	Supply Chain Management	Order to Cash	Sales/ Marketing Expenses
Procurement plan	Statutory compliance	Demand forecasting and planning	Pricing	Field force reimbursement
Vendor identification and selection	Production operations	Warehousing	Customer master management	Salesforce effectiveness
Vendor master updating/maintenance	Material management	Inventory management	Sales order management	Marketing expenses
Order management	Quality controls	Logistics and distribution	Discount/Schemes	Sample/Free drug
GRN processing	Waste disposal	Network planning and optimisation	Invoicing and collection	SRN processing
Invoice processing	Plant maintenance	Reverse logistics	Sales return	Invoice processing
Vendor payments	FDA/GMP standards		Institutional business	Vendor payments
Vendor evaluation	Scrap management		Credit Management	Vendor evaluation

Hire to Retire	Financial Reporting	Regulatory and Safety	Other support areas
Recruitment	Financial statement closure process	Regulatory strategy and plan	Insurance
Employee onboarding	Management reporting	Filing and submission	Corporate Social Responsibility
Employee master	Accounts payable and receivable	Product information management	Related party management
Compensation and benefits	Capex and projects	Compliance tracking & reporting	Entity Level Controls
Payroll management	Loans and advances	Adverse event and safety data management	IT General Controls
Loans/Advances	Treasury and banking	Licensing	Information Security
Employee separation	Fixed asset		
Contract labour management	Taxation & Statutory dues		

Forms of Medicines

5.5 Pharmaceutical manufacturing units produce a wide variety of medicines in different forms to meet the needs of patients. Some of the common forms of medications produced in pharmaceutical manufacturing units include:

Tablets: These are solid dosage forms that for oral intake. Tablets can be coated or uncoated and designed to release the active ingredient immediately or over a prolonged period.

Capsules: These are also solid dosage forms for oral intake. Capsules comprise a shell filled with powder, granules, or liquid.

Injectables: These are liquid or powder dosage forms administered by injection. Injectables are used for various purposes, including delivering medicines directly into the bloodstream or a specific tissue or organ.

Topicals: These are creams, ointments, gels and lotions applied directly to the skin or mucous membranes. Topicals treat skin conditions, pain, inflammation and infections.

Inhalers: These are devices that deliver medication directly to the lungs. Inhalers treat respiratory conditions like asthma and chronic obstructive pulmonary disease (COPD).

Suppositories: These are solid dosage forms inserted into the rectum or vagina. Suppositories deliver medication that cannot be taken orally or must be delivered directly to a specific body area.

Drops: These are liquid dosage forms administered by dropping the medication into the eyes, ears, or nose. Drops treat infections, allergies and other conditions.

These are just a few examples of medicines that pharmaceutical manufacturing units can produce in different forms. The specific forms produced depend on the market's needs and the manufacturing unit's capabilities.

Commonly Produced Medicines

5.6 Medicines include a wide range of products used to prevent, treat, or cure diseases and health conditions. Some examples of medicines that are commonly produced in pharmaceutical plants include:

1. **Antibiotics:** These are medicines that treat bacterial infections.
2. **Antivirals:** These are medicines that treat viral infections.
3. **Antifungals:** These are medicines that treat fungal infections.
4. **Antihypertensives:** These are medicines that treat high blood pressure.
5. **Antidiabetics:** These are medicines that treat diabetes.
6. **Analgesics:** These are medicines that relieve pain.

7. **Anti-inflammatory drugs:** These are medicines that reduce inflammation.
8. **Hormones:** These are medicines that regulate the body's hormonal balance.
9. **Cardiovascular drugs:** These are medicines that treat heart and blood vessel diseases.
10. **Chemotherapy drugs:** These are medicines that treat cancer.

These are just a few examples of the many medicines produced in pharmaceutical plants. The specific medicines produced will depend on the market's needs and the plant's capabilities.

Chapter 6
Research and Development

Drug Research and Development Process

Research and Development

6.1 Recently, the government has undertaken a greater push for research and innovation to boost India's medical tech industry. India has a strong presence in generic formulation, but it lags in research & innovation for complex molecules and high-end medical devices.

India's expenditure on research & development and innovation is significantly less. India spends about 0.7% of its GDP on research, whereas other countries spend 2.5-3%. Even if you see the investment by companies, it is approx. 7% and global companies spend 15-20%. This low investment is because research is expensive and, at the same time, unpredictable. Developing a product may take 8-10 years, but the outcome is uncertain. It is a high-risk activity. The government has recognized this and plans to boost product research and innovation through centres of excellence.

Never-the-less, India has improved its ranking in the Global Innovation Index (GII) 2021 to climb to 46th from 81st in 2015, according to the World Intellectual Property Organization (WIPO).

Drug Approval Process in India

6.2 India has reformed the clinical trial approval process to speed up the drug approval processes for prescription and orphan drugs. India's regulatory authority, the Central Drugs Standard Control Organisation (CDSCO), has improved transparency and accountability and promoted ethical and scientific clinical research and development of new drugs. This has resulted in a high number of waivers for local phase 3 clinical trials and a new conditional approval pathway for new drugs already approved and licensed by health authorities in the EU, US, Australia, Canada, or Japan. In addition, intellectual property protection is made more robust by implementing new rules in 2019, making India an attractive marketplace for proprietary biopharmaceutical companies to register their new products.

CDSCO implemented the 2019 New Drugs and Clinical Trials Rules (2019 new rules), the drug approval process has been made faster and more innovative medicines and orphan-designated medicines for rare diseases are now available. Under the new regulations, companies may abbreviate the clinical trials to approve orphan-designated medicines. Sponsors of orphan drugs can apply to the CDSCO for an expedited review process, waiving the requirement for local clinical trials in recognition of significant unmet medical needs.

The rules have aimed several other measures at reducing timelines for the approval of clinical trials and expediting the new drug approval process. As a result, many vaccines and drugs were approved in India, backed by pandemic-related accelerated regulatory processes and plans outlined by the Indian government to increase biotech and pharmaceutical innovation. This regulatory flexibility is needed to make India an attractive market to sponsors of new, innovative drugs and biologics and pharmaceutical companies eager to expedite the launch of their medicines and expand globally.

Under the new 2019 rules, applicants may apply to the licensing authority for an expedited review process in which they have established the clinical safety and efficacy evidence, even if the drug has not completed all the normal clinical phases. This rule will accelerate the application review and the clearance process to initiate a clinical trial, facilitate earlier entry of effective new drugs to the market and reduce the costs associated with development. These new provisions aim to encourage more indigenous research and development for diseases affecting patients in India. In addition, the flexibility and expedited processes will help position India as one of the major markets in Asia for pharmaceutical companies to market their drugs. India is well-suited as a venue for this plan. It is a developing country with a population of approximately 1.4 billion, about 17.7% of the world's population and there is considerable untapped research and manufacturing potential. In addition, many medical needs for critical diseases such as diabetes, cancer, tuberculosis and AIDS are unmet, creating a demand for therapies. For example, the government has implemented a national strategic plan for rapidly reducing tuberculosis-related morbidity and mortality in India by 2025. The plan is facilitated by supportive government policies integrated into the four strategic pillars of "detect, treat, prevent and build."

In India, a sponsor may apply to the licensing authority for an expedited review of new drugs developed for use in a disaster or for defence in an extraordinary situation (e.g., war or radiation exposure) when specific, rapid preventive and treatment strategies are required in circumstances in which a real-world clinical trial may not be possible. Permission for the manufacture of a new drug may be granted if the following conditions are satisfied:

1. Preclinical data makes a case for claimed efficacy;
2. There is no possibility of obtaining informed consent from a patient or patient's legally acceptable representative regarding inclusion and exclusion criteria and protocol adherence by each participant;
3. There is no established management or therapeutic strategy available, hence making a proposed intervention has clear possible advantages; and
4. Such approval can be used only once. Subsequent approval will be granted after a detailed efficacy report of such intervention has been generated.

Sponsors of orphan drugs can also apply for an expedited review, waiving the requirement for local clinical trials in recognition of significant unmet medical needs. In India, an "orphan drug" is intended to treat a condition affecting fewer than 500,000 patients. A drug already approved by the central licensing agency (CLA) for specific claims and proposed to be marketed with modified or new claims, including indication, route of administration (e.g., a novel drug delivery system), dosage and dosage form, is a subsequent "new drug." A subsequent new drug also includes a new drug already approved in the country. In these instances, the pharmaceutical company must receive prior permission from the CLA before obtaining the manufacturing license from the state licensing authority for the new drugs.

Drugs Versus New Drugs

6.3 Under the 2019 New Drugs and Clinical Trials Rules, a "new drug" is:

a. A drug that either has not been approved or is already approved in India for specific claims and proposed to be marketed with modified or new claims.

b. A fixed-dose combination of two or more drugs;

c. A modified- or sustained-release form of a drug or novel drug delivery system of any drug approved; or

d. A vaccine, rDNA-derived product, living modified organism, monoclonal antibody, stem-cell–derived product, gene therapeutic product, or xenograft intended to be used as a drug.

Under Section 3(b) of the 1940 Drugs and Cosmetics Act, "drugs" are:

a. Medicines and devices intended for use in the diagnosis, treatment, mitigation, or prevention of any disease or disorder in humans or animals;

b. Substances intended to affect the structure or any function of the human body; and

c. Substances intended for use as drug components, including empty gelatine capsules.

These categories of drugs shall continue to be new drugs for four years from the date of their permission granted by the CLA.

Central Drugs Standard Control Organisation (CDSCO) : Structure, Strategy and Responsibilities

Structure

6.4 Drug regulation falls under the Constitution of India. The Central Drugs Standard Control Organisation (CDSCO) is the national regulatory and licensing authority for approving drugs in India. The implementing authorities are the central government, through CDSCO and state governments, through the state drug licensing authorities.

Regulatory Strategy

6.5 CDSCO oversees regulatory strategy. It issues guidelines for manufacturing regulatory pathways and quality aspects for drugs. These guidelines also address regulatory requirements for marketing authorization. The regulatory environment in India has expanded during the past five years, with numerous regulatory measures introduced to streamline processes and promote ethical, science-based new drug approvals and clinical trials.

Responsibilities

6.6 The primary responsibilities of the CDSCO include:

a. Approval of new drugs and clinical trials in India;

b. Establishing drug control standards for the quality of imported drugs;

c. Coordinating the activities of state drug control organizations;

d. Providing expert advice in the enforcement of Drugs and Cosmetics Act; and

e. Issuing amendments to laws, rules and pharmacovigilance.

Regulatory Framework

6.7 The new drug approval process in India falls under the 2019 new rules. The new rules and regulations apply to all types of new drugs, INDs for human use, clinical trials, bioavailability/bioequivalence (BA/BE) studies and ethics committees, further streamlining the approval process. New clinical trial regulations have also been implemented to expedite the registration of orphan-designated and innovative medicines.

The drug approval process involves two steps – application to the regulatory authority to conduct a clinical trial and application for drug marketing authorization.

Advantages and Disadvantages of the New Rules

Advantages

6.8 Under the 2019 new rules, the drug approval process accelerates the market entry of advanced new treatments. There are also provisions for improving transparency and accountability and promoting ethical and scientific research.

These allow for a waiver of local clinical trials, resulting in faster approval times and stronger intellectual property protection in India, an additional attraction for companies wanting to register new drugs.

The qualifying products can now be launched in India without companies conducting phase 3 clinical trials to test for efficacy and safety in the Indian population, provided the associated global studies include Indian patients. In

addition, there is now a new conditional approval pathway for innovative and orphan-designated medicines approved in Europe, the US, Australia, Canada and Japan. This may result in a waiver of local clinical trials.

All the applications are submitted online in the electronic common technical document format. These reforms of the clinical trial approval process expedite the approval processes for these products.

Disadvantages

6.9 The sponsors or biopharmaceutical companies must commit to conducting post-market phase 4 trials to evaluate the long-term effects of the approved product, which may present a challenge for companies.

In addition, the authority's review documents and summary of the approval process for new drugs are not available in the public domain. This makes it challenging to gather regulatory intelligence and understand the authority's expectations for certain new dosage forms.

Regulatory Pathways

6.10 All drug substances and products intended to be launched in India fall under the "new drug" category. A new drug must undergo extensive non-clinical and clinical trials to prove its safety and efficacy before being considered for marketing authorization.

The choice of a regulatory pathway for new drug approval depends on numerous factors. These include:

a. The nature of a drug substance and/or drug product, for example, a vaccine, rDNA-derived product, living modified organism, monoclonal antibody, stem-cell–derived product, gene therapeutic product, or xenograft intended to be used as a drug, is considered a new drug. These types of drug substances or products must undergo extensive nonclinical and clinical trials to prove their safety and efficacy;

b. Type of formulation, for example, modified- or sustained-release forms of a drug or a novel drug delivery system of any drug approved by the CLA, are considered a new drug and must undergo a clinical trial and/or BA/BE study before consideration for marketing authorization; • Whether the drug has already been approved in India;

c. Whether the IND requires extensive research and trials, both clinical and non-clinical;

d. Whether the drug is designated as an orphan drug. Various requirements for orphan drugs may be waived on a case-by-case basis but will require approval from the CLA and a pre-submission meeting with the CDSCO to discuss and agree upon the required pathway.

e. Drug products with new molecules, combinations, dosage forms, indications, dosages, or routes of administration must undergo clinical trials and/or BA/BE studies before consideration for marketing authorization.

Regulatory Strategy

6.11 Sponsors are required to obtain permission from Indian regulators to conduct BA/BE studies and clinical trials. Data must be submitted for an unapproved new drug, including dosage form, composition, master manufacturing formula and stability study data. Drugs already approved in India will require the same information as for a phase 3 clinical trial. The clinical trial for a new drug may be conducted only after obtaining permission from the licensing authority. If the clinical study protocol or outcome is inadequate, the licensing authority may consider granting permission, provided the applicant meets the conditions set by the licensing authority.

The following are the phase-appropriate applications for permission to conduct clinical trials:

a. For phase 1 trials, applications should be submitted to the Licensing Authority in Form 44, accompanied by a fee and required data under Schedule Y;

b. For exploratory clinical trials (phase 2), applications should be made based on the data from the phase 1 trial, accompanied by a fee; and

c. For confirmatory clinical trials (phase 3), applications should be made based on the data from phase 1 and phase 2, accompanied by a fee.

No fees are required with the application to manufacture a new drug after the phase 1-3 clinical trials have been completed successfully in India under the 2019 new rules.

Citation ***Sengupta A.*** Accelerating drug development and approvals in India. Regulatory Focus. Published online 30 November 2022.

Overview of Drug Approval Process for US, Europe and India

6.12 The focus of this technical guide is Primarily on domestic formulation pharma companies, a comprehensive analysis of the approval processes in three major regions: United States, Europe and India is shared for understanding purposes. By examining the similarities and differences among these regions, companies and Internal Auditors can develop a clear understanding of the regulatory requirements, timelines and crucial considerations involved in introducing a new drug to the relevant market.

Table 1: Principal differences between US, EU & INDIA

Requirements	US	EU	INDIA
Agency	One Agency USFDA	Multiple Agencies • EMEA • GHMP • National Health Agencies	One Agency DCGI
Registration Process	One Registration Process	Multiple Registration Processes • Centralized (European Community) • Decentralized (At least 2 member states) • Mutual Recognition (At least 2 member states) • National (1 member state)	One Registration Process

TSE/BSE Study data	Not Required	Required	Required
Braille code on labelling	Not Required	Required	Not Required
Post-approval changes	Post-approval changes in the approved drug: • Minor changes • Moderate changes • Major changes	Post-variation in the approved drug: • Type Internal Auditor Variation • Type IB Variation • Type II Variation	Post approval changes in the approved drug: • Major quality changes • Moderate quality changes

Table 2: Administrative Requirements

Requirements	US	EU	INDIA
Application	ANDA / NDA	MAA	MAA
Debarment Classification	Required	Not Required	Not Required
Number of Copies	3	1	1
Approval Timeline	~18 months	~12 months	12-18 months
Fees	Under $2 million – NDA Application $51,520 – ANDA Application	National fee (including hybrid applications): £103,059 Decentralised procedure where UK is CMS: £99,507	50,000 INR
Presentation	eCTD & Paper	eCTD	Paper

Table 3: Finished Product Control Requirements

Requirements	US	EU	INDIA
Justification	ICH Q6A	ICH Q6A	ICH Q6A
Assay	90 - 100%	95 - 105%	90 - 110%
Disintegration	Not Required	Required	Required
Colour Identification	Not Required	Required	Required
Water Content	Required	Not Required	Not Required

Table 4: Manufacturing & Control Requirements

Requirements	US	EU	INDIA
Number of Batches	1	3	1
Packaging	A minimum of 1 lakh units	Not Required	Not addressed
Process Validation	Not required at the time of submission	Required	Required
Batch Size	1 pilot scale or minimum of 1 lakh units whichever is higher	2 pilot scale plus 1 lab batch or minimum of 1 lakh units whichever is higher	Pilot scale batch

Table 5: Stability Requirements

Requirements	US	EU	INDIA
Number of Batches	3 Pilot Batch or 3 Pilot Batch & 1 Small scale	2 Pilot Scale (If API stable) 3 Primary Batches (If API unstable)	2 Pilot Scale/ Production Scale (If API stable) 3 Primary Batches (If API unstable)

Condition: Long term stability, Accelerated stability	**Long Term:** 25°C/60%RH **Accelerated:** 40°C/75%RH (0,3,6 months) **Intermediate:** 30°C/65%RH	**Long Term:** 25°C/60%RH **Accelerated:** 40°C/75%RH (0,3,6 months) **Intermediate:** 30°C/65%RH	**Long Term:** 30°C/70%RH **Accelerated:** 40°C/75%RH (0,3,6 months)
Minimum time period of Submission	6 months Accelerate & 6 months Long Term	6 months Accelerate & 6 months Long Term	6 months Accelerate & 6 months Long Term
Container orientation	Inverted & upright	Do not address	Upright & inverted
Clause	21 CFR part 210 & 211	Volume 4 EU Guidelines for medicinal products	ICH Q1F
QP Certification	Not Required	Required	Required

Table 6: Bioequivalence Requirements

Requirements	US	EU	INDIA
CRO (Audits)	Audited by FDA	Audited by MHRA	CDSCO
Reserve sample	5 times the sample required for analysis	No such requirement	-
Fasted / Fed	Must be as per OGD recommendation	No such requirement	As CDSCO recommendation
Retention of samples	5 years from date of filling the application	No such requirement	3 years from date of filling the application
BE study for generic drugs	Against US RLD in any country. To	Against EU reference product	Against US/EU/Australia

	refer 'BE recommendations' in FDA site for guidance.	(ERP) in any country	RLD in any country except Thailand, where BE to be done locally against local reference product.

Chapter 7
Regulatory Framework

7.1 The growth of the pharmaceutical industry in the last two decades has been notable; the reason behind the same is the size of the Indian market since India has a population of around 1.4 billion people, which makes it a home for many diseases. In such cases, it becomes crucial to regulate the pharmaceutical industry as essential medicinal drugs must be made available at affordable rates, keeping in mind the economic divide present in India. The growth of the pharmaceutical industry is also dependent upon regulatory legislation and systems apart from various other factors. Therefore, it becomes vital to understand the regulatory processes in the Indian pharmaceutical sector.

The Regulatory Authorities

7.2 Regulatory bodies which are working as pillars to hold the regulatory infrastructure of the pharmaceutical industry of India are as follows:

The Central Drug Standards and Control Organization (CDSCO)

CDSCO comes under the umbrella of the Ministry of Health and Family Welfare. The CDSCO prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country. It also regulates the market authorization of new medicines and clinical trials standards and supervises drug imports and approves licenses to manufacture the above-mentioned products.

The Drug Controller General of India (DCGI)

This body is the head of CDSCO and its responsibility is to perform licensing and controlling functions of CDSCO.

The National Pharmaceuticals Pricing Authority (NPPA)

The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing the prices of bulk and formulation of drugs within the National List of Essential Medicines (NLEM). It was instituted in 1997 under the Department of Chemicals and Petrochemicals, which fixes or revises the prices of

decontrolled bulk drugs and formulations at judicious intervals; Periodically updates the list under price control through inclusion and exclusion of medicines per established guidelines; Maintains data on production, exports and imports and market share of pharmaceutical firms; And enforces and monitors the availability of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.

The Directorate General of Health Services (DGHS)

The DGHS is responsible for providing technical help and advising on matters of public health. It ensures the implementation of National Health Programs across all the states through its regional offices. It has to make sure that companies comply with International Health Regulations.

The Indian Council of Medical Research (ICMR)

The major functions of ICMR are to formulate, coordinate and promote biomedical research & Ethical Principles.

Genetic Engineering Approval Committee (GEAC)

To Manufacture, Use and Import Hazards Microorganisms/Genetically Engineered Organisms or Cells.

Department of Biotechnology

It promotes transgenic research, molecular biology of human genetic disorders, brain research and commercialising diagnostic kits and vaccines for communicable diseases.

Atomic Energy Review Board (AERB)

Promotes Radio therapy & Research, Safety review for Gamma Irradiators (Devices).

Bhabha Atomic Research Centre (BARC)

Promotes Isotopes application in Medicine & also monitoring usage of radioactive materials

Drug Technical Advisory Board (DTAB)

To advise Central & State Govt. on Technical Matters arising out of the Drugs & Cosmetics

Review Committee on Genetic Manipulation (RCGM)

No Objection Certificate for Clinical Trial & also r-DNA strains

Drug Consultative Committee (DCC)

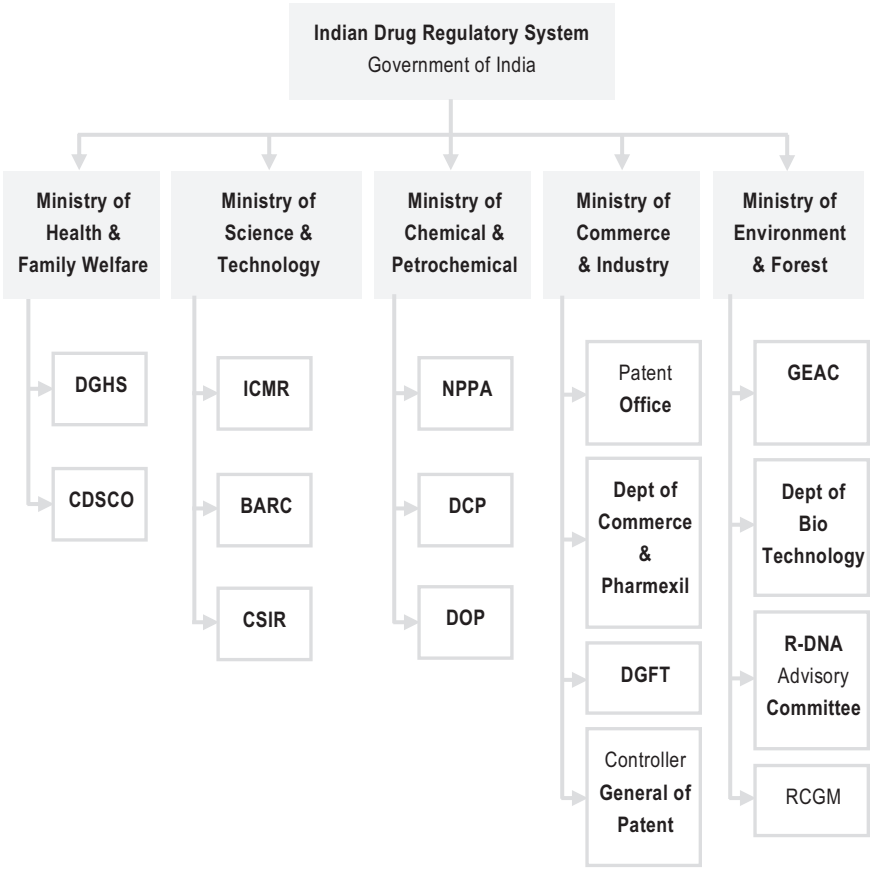
It is an advisory Committee to DTAB and Central & State Govt. for uniform implementation of various provisions of the Act.

Department of Pharmaceutical (DOP)

It was formed in 2008 under the Ministry of Chemicals and Fertilisers. The MoHFW examines pharmaceutical issues within the larger context of public health, while the DoP focuses on industrial policy.

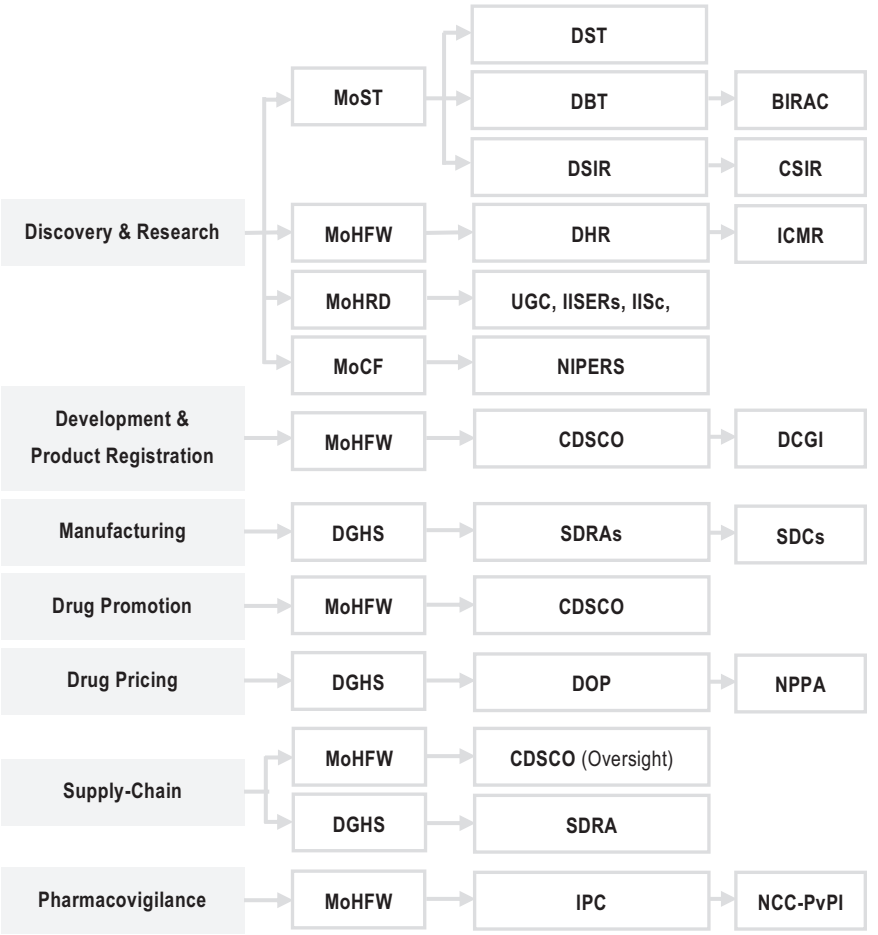
Central Drug Authority (CDA)

The CDA was established as an advisory body in terms of the Prevention of and Treatment for Substance Abuse Act (Act No. 70 of 2008) and is mandated to assist in the fight against substance abuse in the country. The primary function of the CDA is to monitor the implementation of the NDMP. CDA ensures coordination, facilitates the integration of the work of different departments and reports to parliament through the minister for social development



[Abbreviations: DGHS: Directorate General of Health Services, **CDSCO:** Central Drugs Standard Control Organisation, **ICMR:** Indian Council of Medical Research, **BARC:** Bhabha Atomic Research Centre (Radioactive), **CSIR:** Council of Scientific & Industrial Research, **NPPA:** National Pharmaceutical Pricing Authority, **DCP:** DCP, **DOP:** Dept of Pharmaceuticals, **GEAC:** Genetic Engineering Approval Committee, **RCGM:** Review Committee on Genetic Manipulation]

Existing scenario of drug regulatory setup in India



[**Abbreviations: MoST:** Ministry of Science & Technology, **MoHFW:** Ministry of Health & Family Welfare, **MoHRD:** Ministry of Human Resource Development, **MoCF:** Ministry of Chemicals & Fertilizers, **SDH:** State Department of Health, **DST:** Dept of Science & Technology; **DBT:** Dept of Biotechnology, **DSIR:** Dept of Scientific & Industrial Research, **DHR:** Dept of Health Research, **UGC:** University Grants Commission, **IISER:** Indian Institutes of Science Education and Research, **IISC:** Indian Institute of Science, **IIT:** Indian Institutes of Technology, **NIPER:** National Institute of Pharmaceutical Education and Research, **SDRA:** State Drug Regulatory Authority, **IPC:** Indian Pharmacopoeia Commission, **BIRAC:** Biotechnology Industry Research Assistance Council, **DCGI:** Drugs Controller General of

India, **SDC:** State Drug Controller, **NCC-PvPI:** National Coordination Centre – Pharmacovigilance Programme of India]

CDSCO	SDRA
• Approval of new drugs & clinical trials • Import Registration & Licensing • License approving of blood banks, LVPs, vaccines, r-DNA products & medical devices • Amendment to D&C Act and Rules • Banning of drugs & cosmetics • New drug testing • Oversight & market surveillance over & above state authority	• Manufacturing Licensing • Inspections • Regulation Enforcement • Fixed Dose Combination (FDC) Manufacturing Licensing • Testing of samples

The division of responsibilities between CDSCO and SDRAs is a consequence of 'health' being a subject matter under the State List. Overall functioning of SDRAs rests with the state. This has led to great disparity in the way the Drug & Cosmetics (D&C) Act is interpreted and enforced across states.

[***Source:*** *CDSCO website, N. Chowdhury et al, Administrative Structure and Functions of Drug Regulatory Authorities in India – working paper 309, 2015*]

Overview of Legislation

The Drugs and Cosmetics Act, 1940

7.2 Overview of legislation applicable to Pharmaceutical Industry are as follows:

This act provides the primary legal framework for regulating the import, manufacture, distribution and sale of drugs and cosmetics in India. It covers licensing, quality control, labelling and packaging requirements.

Drugs and Cosmetics Rules, 1945

These rules provide detailed guidelines for implementing the Drugs and Cosmetics Act. They specify requirements related to drug manufacturing, importation, clinical trials, licensing, packaging, labelling and advertisement of drugs.

Schedule M

Schedule M of the Drugs and Cosmetics Rules provides guidelines for pharmaceutical manufacturing units' Good Manufacturing Practices (GMP). It covers premises, equipment, quality control, documentation and personnel.

Indian Pharmacopoeia

The Indian Pharmacopoeia (IP) is an official compendium of standards for pharmaceutical substances, dosage forms and pharmaceutical testing procedures. It is published by the Indian Pharmacopoeia Commission (IPC) and serves as a reference for drug quality and testing in India.

Intellectual Property Rights (IPR)

India also has laws and regulations on intellectual property rights, including patents, trademarks and copyrights. The Patents Act 1970 and the Trademarks Act, 1999 govern the protection and enforcement of intellectual property rights in the pharmaceutical sector.

The Essential Commodities Act, 1955 and Drugs (Price Control) Order, 2013

It lays down rules for regulating the prices of drugs and procedures to fix the cost of medicines and methods for enforcing the prices that the Government has decided.

Various Laws applicable to a Pharmaceutical Company

7.3 The pharmaceutical industry in India operates within a complex regulatory landscape and the applicability of specific laws may vary based on factors such as the nature of the pharmaceutical product, it's listing status, geographical location and other relevant considerations.

Additionally, specific regulations may apply to aspects such as clinical trials, export/import of drugs, narcotic drugs, controlled substances and medical devices. Pharmaceutical companies need to comply with these laws and stay updated with any amendments or additions to the regulatory framework.

The following list of laws is suggestive of the applicable legal framework for the pharmaceutical industry in India:

Table 1: Central Government Laws applicable to a Pharmaceutical Company

Sr. No.	Act Name	Applicability of Act
1	Food Safety and Standards Act, 2006, read with Food Safety and Standards Regulations	This Act applies to the persons involved at any stage in activities related to manufacturing, processing, packaging, storage, transportation, distribution of food, Import and includes food services, catering services and sale of food or food ingredients.
2	Cigarettes and other tobacco products (prohibition of advertisement) Act-2003 & prohibition of smoking in public rules-2008	This Act applies to those engaged in the supply and distribution of products to prohibit advertising and regulate trade and commerce of cigarettes and other tobacco products.
3	Environment (Protection) Act, 1986, read with Batteries (Management and Handling) Rules, 2001	These rules apply to every consumer and bulk consumer involved in the sale, purchase and use of batteries or their components.
4	Disaster Management Act read with relevant Guidelines	This Act provides for the effective management of disasters by the State and Central Government.
5	Companies Act, 2013, read with relevant Rules.	This Act applies to companies incorporated under this Act.
6	Securities and	This Regulation applies to entities which

Sr. No.	Act Name	Applicability of Act
	Exchange Board of India Act, 1992, read with Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015	have listed any of the following designated securities on a Stock Exchange in India (e.g., NSE, BSE etc.): 1. Specified Securities listed on the mainboard or SME Exchange Innovators Growth Platform 2. Non-Convertible Debt Securities, Non-Convertible redeemable preference shares, perpetual debt instruments, perpetual non-cumulative preference shares 3. Indian Depository Receipts 4. Securitized Debt Instruments 5. Security Receipts 6. Units issued by Mutual Funds 7. Any other securities as may be specified by the Board It applies to listed entities based on market capitalization criteria and shall continue to apply to them even if they fall below such thresholds.
7	Depositories Act, 1996 read with Securities and Exchange Board of India Act, 1992 and Securities and Exchange Board of India (Depositories and Participants) Regulations, 2018	This Act applies to regulations of depositories, Issuer, Beneficial Owner, Participants and Registered Owner in Securities.
8	Securities and Exchange Board of India Act, 1992, read with Securities and Exchange Board of India	This Regulation applies to Companies with securities listed or proposed to be listed on any Stock Exchange in India.

Sr. No.	Act Name	Applicability of Act
	(Prohibition of Insider Trading) Regulations, 2015	
9	Securities and Exchange Board of India Act, 1992 read with Securities and Exchange Board of India (Substantial Acquisition of Shares and Takeovers) Regulation, 2011	This Regulation applies to the direct and indirect acquisition of shares or voting rights in or controls over the target company.
10	Securities Contract (Regulation) Act, 1956 and Securities and Exchange Board of India Act, 1992, read with Securities Contracts (Regulation) (Stock Exchanges and Clearing Corporations) Regulations, 2018 and Securities Contracts (Regulations) Rules, 1957	An Act to preclude adverse securities transactions by regulating the trading of securities and providing for certain related things.
11	Master Direction – Direct Investment by Residents in Joint Venture (JV) / Wholly Owned Subsidiary (WOS) Abroad	These directions lay down the modalities for how the foreign exchange business must be conducted by the Authorized Persons with their customers/ constituents to implement the regulations framed.
12	SEBI (Share-based employee benefits) Regulations, 2021	1. The provisions of these regulations shall apply to the following: a. Employee Stock Option Schemes

Sr. No.	Act Name	Applicability of Act
		b. Employee Stock Purchase Schemes c. Stock Appreciation Rights Schemes d. General Employee Benefits Schemes e. Retirement Benefit Schemes 2. The provisions of these regulations shall apply to any company whose shares are listed on a recognized stock exchange in India and has a scheme: a. For the direct or indirect benefit of employees b. Involving dealing in or subscribing to or purchasing securities of the company, directly or indirectly c. satisfying, directly or indirectly, any one of the following conditions: i. The Scheme is set up by the company or any other company in its group ii. The Scheme is funded or guaranteed by the company or any other company in its group iii. The Scheme is controlled or managed by the company or any other company in its group.
13	SEBI (Registrars to an Issue and Share Transfer Agents) Regulations, 1993	It applies to every person and body corporate who is engaged and wants to engage in the activities related to the Registrar to an issue or the Share transfer agent prescribing the provisions to the registration and dealing with all matters connected with the transfer and redemption of securities.
14	Prevention of Corruption	This Act applies to the whole of India and

Sr. No.	Act Name	Applicability of Act
	Act, 1988	all citizens of India outside India.
15	Master Direction - External Commercial Borrowings, trade Credits, Structured Obligations and relevant regulations	This direction applies to all eligible borrowers seeking borrowings from foreign countries. It also applies to all Authorized Dealer Category - I Banks and Authorized Banks.
16	Foreign Exchange Management Act, 1999 read with Master Direction on Export of Goods and Services issued by RBI and Foreign Trade Policy (2015-2020)	This Master Direction applies to all Authorized Dealer Category-I Banks and Authorized Banks. Category-I Banks have an RBI License to buy and sell foreign exchange for specified purposes.
17	Foreign Exchange Management Act, 1999 read with Foreign Exchange Management (Transfer or Issue of Foreign Security) Regulations, 2004 and Master Direction – Direct Investment by Residents in Joint Venture (JV) / Wholly Owned Subsidiary (WOS) Abroad.	These Regulations apply to the following willing to transfer or issue any foreign security by way of direct investment outside India: 1. Any Person resident in India 2. Any Indian Party such as a company incorporated in India or a Body created under an Act of Parliament or a Partnership firm registered under the Indian Partnership Act, 1932, or a Limited Liability Partnership (LLP_) as defined under these regulations and any other entity in India as may be notified by the Reserve Bank 3. Mutual Funds 4. Venture Capital Funds 5. Trust 6. Society

Sr. No.	Act Name	Applicability of Act
18	Foreign Exchange Management Act, 1999 read with Foreign Exchange Management (Non-Debt Instruments) Rules, 2019 and Foreign Exchange Management (Mode of Payment and Reporting of Non-Debt Instruments) Regulations, 2019	This Act applies to all branches, offices and agencies outside India of person resident in India and to contravention committed outside India by any person to whom the act applies.
19	Micro, Small and Medium Enterprises Development Act, 2006 read with Micro, Small and Medium Enterprises Development (Furnishing of Information) Rules, 2016	This act applies to enterprises engaged in the manufacturing or production of goods and engaged in providing or rendering services with the following turnover threshold: **Manufacturing Enterprise** — **Micro** — **Small** — **Medium** Investment in Plant & Machinery or Equipment — < Rs.1 Crore — < Rs.10 Crore — < Rs.50 Crore **Service Rendering Enterprises** — **Micro** — **Small** — **Medium** Annual Turnover — < Rs.5 — < Rs.50 — < Rs.250
20	Reserve Bank of India Act, 1934 read with Introduction of Legal Entity Identifier Code for Participation in Non-Derivative Markets	This Act applies to all Market Participants undertaking transactions in the markets regulated by the Reserve Bank of India.

Sr. No.	Act Name	Applicability of Act
21	Income tax Act, 1961 and income tax rules, 1962	This act applies to all individuals and entities that vary with respective income or profits.
22	The Customs Act, 1962	This Act applies to every organization importing and exporting goods during its business.
23	The Foreign Trade (Development & Regulations) Act, 1992, read with Foreign Trade Policy Procedure (Handbook of Procedure) and Appendices	This Act applies to every Importer and Exporter. This Act incorporates the Export and Import Policy by laying down simple, transparent and EDI (Electronic Data Interchange) compatible procedures that are easy to comply with and administer for efficacious foreign trade management.
24	The Public Liability Insurance Act, 1991	This Act applies to a person, firm, association, or company that owns or controls handling any hazardous substance.
25	Employees' Provident Fund and Miscellaneous Provisions Act,1952 read with Employees Provident Funds Scheme,1952, Employees' Pension Scheme, 1995, Employees' Deposit-Linked Insurance Scheme, 1976	This act applies to every establishment employing 20 or more and provides for the institution of provident funds, pension funds and deposit-linked insurance funds for employees in factories and other establishments.
26	Employees' State Insurance Act, 1948, read with Employees' State Insurance (Central) Rules, 1950	ESI Act applies to all Factories and other establishments as defined in the Act with ten or more persons employed in such establishments.

Sr. No.	Act Name	Applicability of Act
	and Employees' State Insurance Regulations, 1950	
27	Child and Adolescent Labor (Prohibition and Regulation) Act, 1986, read with Child Labor and Adolescent Labor (Prohibition and Regulation) Rules, 1988	This act applies to all the occupations which engage children or any hazardous process or occupation which engages adolescents across India.
28	Equal Remuneration Act 1976 read with Equal Remuneration Rules 1976	This act applies to employers of establishments employing male and female workers not to discriminate against its workers based on gender in matters of wage fixing, transfers, training and promotion. It provides equal remuneration to men and women workers for the same work or work of similar nature and prevents discrimination against women in employment matters.
29	Payment of Bonus Act, 1965, read with Payment of Bonus Rules, 1975	This act applies to establishment which employs 20 or more employees on any day during an accounting year.
30	Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act 2013 read with Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Rules 2013	This act applies to every employee employed at a workplace for any work on a regular, temporary, ad hoc, or daily wage basis either directly or through an agent, including a contractor with or without the knowledge of the principal employer.

Sr. No.	Act Name	Applicability of Act
31	Transgender Persons (Protection of Rights) Act, 2019, read with The Transgender Persons (Protection of Rights) Rules, 2020.	The Act provides compliance related to Discrimination against transgender Persons and the Grievance redressal mechanism.
32	Information Technology Act 2000 (To be read with applicable rules)	This act applies to the whole of India, including any offence committed outside India, if such contravention involves a computer, computer system, or computer network located in India.
33	Copyright Act, 1957, read with Copyright Rules, 2013	This act applies to every person who intends to or has a copyright and intends to use copyrighted material.
34	Trademarks Act, 1999, read with Trademarks Rules, 2017	This Act applies to businesses and services to provide registration, better protection of trademarks for goods and services and the prevention of the use of fraudulent marks.
35	The Patents Act, 1970, read with The Patents Rules, 2003	This Act applies to Every Corporation, Enterprise, Industry, Organization, or Individual for registration of Patents or protection regarding the same.
36	Uniform Code for Pharmaceuticals Marketing Practices	This is a voluntary code of marketing practices for the Indian Pharmaceutical Industry.
37	List of Compliances under various Acts which prohibit Advertisements of certain products and services	The List applies to companies that use their platform to advertise products and services of others, being print, broadcasting, e-commerce, websites, etc.

Table 2: Central Government Laws applicable to Pharma Manufacturing unit

Sr. No.	Act Name	Applicability of Act
1	The Drugs and Cosmetics Act, 1940, read with Relevant Rules	This Act applies to every pharm company or entity regulating the import, manufacture, distribution and sale of drugs and cosmetics.
2	Essential Commodities Act, 1955, read with Drugs (Price Control) Order 2013	This order regulates the drug distribution and the ceiling price of a scheduled formulation of specified strengths and dosages.
3	The Narcotic Drugs and Psychotropic Substances Act, 1985	This Act provides stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances, to provide for the forfeiture of property derived from or used in the illicit trafficking of narcotic drugs and psychotropic substances and implement the international convention on Narcotic Drugs and Psychotropic Substances.
4	The Medicinal and Toilet Preparations (Excise Duties) Act, 1955, read with Relevant Rule	This Act levies and collects excise duties on medicinal and toilet preparations containing alcohol.
5	The Petroleum Act read with The Petroleum Rules, 2002	This Act applies to establishments that import, transport and store petroleum.
6	The Explosives Act read with the Gas Cylinder Rules, 2016	This Act applies to every industry and its various industrial establishment manufacturing, storing, filling and transporting gas cylinders and valves.
7	The Explosives Act read with The Static and Mobile Pressure Vessels (Unfired) Rules, 2016	This Act applies to all entities involved in the manufacture, possession, use, sale, transport, import and export of Pressure Vessels and Explosives.
8	The Electricity Act 2003 read with Intimation of	This Act applies to Every person/company that generates,

Sr. No.	Act Name	Applicability of Act
	Accidents (Form and Time of Service of Notice) Rules, 2004 and Central Electricity Authority (Measures relating to Safety and Electric Supply) Regulations, 2010 and Central Electricity Authority (Installation and Operation of Meters) Regulations, 2006 and National Electrical Code, 2011	transmits, distributes, trades and uses electricity.
9	Environment Protection Act, 1986 with Environmental Impact Assessment, 2006	This Act applies to every individual, organization, or Industry that setup the Category A and/or Category B types of projects requiring environmental clearance.
10	Apprentices Act, 1961 read with Apprenticeship Rules, 1992	This act applies to every employer who employees one or more other persons to do any work in an establishment for remuneration and includes any person entrusted with the supervision and control of employees in such establishment.
11	The Indian Wireless Telegraphy Act, 1933	This Act applies to all persons having wireless telegraphy apparatus in possession.

Table 3: Common State Government Laws applicable

Sr. No.	Act Name	Applicability of Act
1	Goods and Service Tax Act, 2017, read with State Goods and Service Tax Rules, 2017 (Combined	This Regulation applies to the listed entities which have listed any of the following designated securities:

Sr. No.	Act Name	Applicability of Act
	with CGST & IGST)	1. Specified Securities listed on the mainboard or SME Exchange Innovators Growth Platform 2. Non-Convertible Debt Securities, Non- Convertible redeemable preference shares, perpetual debt instruments, perpetual non-cumulative preference shares 3. Indian Depository Receipts 4. Securitized Debt Instruments 5. Security Receipts 6. Units issued by Mutual Funds 7. Any other securities as may be specified by the Board It applies to listed entitles based on market capitalization criteria that shall continue to apply to such entities even if they fall below such thresholds.
2	The Motor Vehicle Act read with the Motor Vehicle Rules	This Act applies to industries to provide legislative provisions regarding licensing of drivers/conductors, registration of motor vehicles, control of motor vehicles through permits, special requirements relating to state transport undertakings, traffic regulation and insurance policies.
3	Environment Protection Act 1986 read with Solid Waste Management Rules 2016	This rule applies to every domestic, institutional, commercial and non-residential outgrowth in urban agglomerations, urban local bodies and census towns declared by the registrar general.
4	Environment (protection) Act, 1986, read with Plastic Waste Management Rules,	This rule applies to every waste generator, local body, gram panchayat, manufacturer, importer and producer.

Sr. No.	Act Name	Applicability of Act
	2016	
5	Environment (protection) Act, 1986, read with Bio-Medical Waste Management Rules, 2016	These rules shall apply to all persons who generate, collect, receive, store, transport, treat, dispose or handle bio-medical waste in any form, including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, Ayush hospitals, clinical establishments, research or educational institutions, health camps, medical or surgical camps, vaccination camps, blood donation camps, first aid rooms of schools, forensic laboratories and research labs.
6	Environment (protection) Act, 1986, read with Hazardous Waste Management Rules	This Rule shall apply to the Management of Hazardous and other wastes as specified in the Schedules to these rules.
7	The Private Security Agencies (Regulation) Act, 2005, read with the State Private Security Agencies Rules, 2009	This Act applies to the person or body of persons forming departments or organizations engaged in providing private security services to any industrial or business undertaking or a company or any other person or property.
8	The Energy Conservation Act read with Energy Conservation (The Form and Manner for Submission of Report on the Status of Energy Consumption by Designated Consumer)	This applies to any user or class of energy users in energy-intensive industries and other establishments for efficient use of energy and its conservation.

Sr. No.	Act Name	Applicability of Act
	Rules, 2007 and Energy Conservation (Energy Consumption Norms and Standards for Designated Consumers, Form, Time within which and Manner of Preparation and Implementation of Scheme, Procedure for Issue of Energy Savings Certificate and Value of Per Metric Ton of Oil Equivalent of Energy Consumed) Rules, 2012	
9	The Electricity (Duty) Act, 1952	This Act applies to every person generating, transmitting, distributing and supplying electricity to levy a duty on the consumption of electrical energy in the respective state.
10	The Legal Metrology Act read with The Legal Metrology Rules	This Act applies to every person and body corporate who wants to engage in activities related to weights and measures, prescribing the provisions to trade and commerce in weights, measures and other goods sold or distributed by weight, measure, or number.
11	Industries (Development and Regulation) Act 1951 read with The Registration and Licensing of Industrial Undertakings Rules, 1952	This Act applies to all the Industrial Undertakings carried on one or more factories by any person.
12	The Water (Prevention &	This Act applies to Industries to provide

Sr. No.	Act Name	Applicability of Act
	Control of Pollution) Act – 1974	for the prevention and control of water pollution and the maintaining or restoring of wholesomeness of water, for the establishment, to carry out the purposes aforesaid, of boards for the prevention and control of water pollution for conferring on and assigning to such boards powers and functions related thereto.
13	Air (Prevention and Control of Air Pollution) Act, 1981	This act applies to industries/establishments to provide for the prevention, control and abatement of air pollution.
14	The Industrial Development Act, 1961, read with State Industrial Development Rules, 1962	This Act is to make special provisions for securing the orderly establishment in industrial areas and industrial estates of industries in the respective state and for generally assisting in the organization and establishing an industrial development corporation.
15	Environment (Protection) Act, 1986 & Construction and Demolition Waste Management Rules, 2016	This Rule applies to every waste resulting from the construction, re-modeling, repair and demolition of any civil structure of an individual, organization, or authority that generates construction and demolition waste such as building materials, debris, or rubble.
16	Environment Protection Act, 1986 r/w Manufacture, Storage, Import of Hazardous Chemicals Rules, 1989	This Rule shall apply to: • An Industrial Activity in which a hazardous chemical is involved • Isolation storage in which a threshold quantity of a hazardous chemical is above a certain limit.
17	Lift and Escalators Act read	This Act regulates the installation,

Sr. No.	Act Name	Applicability of Act
	with Lifts and Escalators Rules	maintenance and safe working of electric lifts, escalators and all machinery and apparatus in the respective state.
18	Fire Prevention & Fire Safety Act, 2005, read with State Fire Prevention & Fire Safety Rules, 2005	An Act to provide for the maintenance of a Fire Service Force in the respective state.
19	The Environment (Protection) Act, 1986, read with Noise Pollution (Regulation and Control) Rules, 2000	These Rules shall apply to all Industrial activity, construction activity, generator sets, loud-speaker, public address terms, music systems, vehicular horns and other mechanical devices that have mysterious effects on human health and the psychological well-being of the people.
20	Environment (protection) Act, 1986, read with The Environmental Rules, 1986	An Act to provide for the protection and improvement of the environment and matters connected therewith.
21	Indian Boilers Act, read with The Boilers Rule	This Act applies to every person who owns boilers to provide mainly for the safety of life and property of persons from the danger of explosions of steam boilers and for achieving uniformity in registration and inspection during the operation and maintenance of boilers in India.
22	The Factories Act 1948 read with The Factory Rules, 1963	This Act applies in the following: • Factories having ten or more workers/employees and manufacturing process is being carried out with the aid of power • Factories with 20 or more workers are employed and the process is carried out

Sr. No.	Act Name	Applicability of Act
		without power.
23	Employee Compensation Act, 1923 read with State Workers' Compensation Rules, 1924	This act applies to establishments that compensate workers or their dependents in case of an injury/accident resulting from employment resulting in disablement or death.
24	Contract Labor (Regulation and Abolition) Act, 1970, read with State Contract Labor (Regulation and Abolition) Rules, 1975	This act applies to every establishment where 50 or more workers are employed or were employed on any day of the preceding 12 months as contract labour.
25	Inter-State Migrant Workers (Regulation of Employment and Conditions of Service) Central Act, 1979 to be read with Inter-State Migrant Workers (Regulation of Employment and Conditions of Service) Central Rules, 1980	This Act is intended to regulate the employment of inter-state migrant workers and to provide for their conditions of service, where: • Every establishment in which five or more interstate migrate (Whether or not in addition to other workers) are employed or who were employed on any day of the preceding 12 months. • Every Contractor who employs or employed five or more interstate migrant workers (Whether or not in addition to other workers) on any day of the preceding 12 months.
26	Employment Exchanges (Compulsory Notification of Vacancies) Act, 1959, read with Employment Exchanges (Compulsory Notification of Vacancies) Rules, 1960	This Act applies to all compulsory notifications of vacancies to employment exchanges by all establishments in the Public Sector and such establishments in the Private Sector as are engaged in non-agricultural activities and employing 25 or more workers.
27	Maternity Benefit Act, 1961, read with State Maternity	This act applies to establishments where ten or more persons are

Sr. No.	Act Name	Applicability of Act
	Benefit Rules, 1967	employed or were employed on any day of the preceding 12 months.
28	Minimum Wages Act, 1948, read With State Minimum Wages Rules, 1950	This act applies to persons engaged in Scheduled Employments (Including Employment in Shop and Commercial Establishments) or specified classes of work for which minimum wages have been fixed.
29	Payment of Gratuity Act, 1972, read with State Payment of Gratuity (central) Rules, 1972	This act applies to establishment which employs ten or more employees on any day of the preceding 12 months.
30	Payment of Wages Act, 1936, read with State Payment of Wages Rules, 1937	This Act applies to persons employed in any factory, to persons employed otherwise than in a factory, in which wages payable to employees do not exceed Rs. 24000 per month or other higher sum, based on figures of the consumer expenditure survey published by the National Sample Survey Organization.
31	Labor Welfare Fund Act, 1987 read with State Labor Welfare Fund Rules, 1988	This Act applies to the following establishments: 1. A Factory 2. A Tramway or Motor omnibus service or a motor transport undertaking to which the Motor Transport Workers Act, 1961 applies 3. Any establishment within the meaning of the Assam Shops and Establishments Act, which employs, or on any working day during the preceding 12 months, five or more

Sr. No.	Act Name	Applicability of Act
		persons are employed.
32	The Industrial Employment (Standing Orders) Act, 1946	This act applies to every industrial establishment wherein 50 or more workers are employed or on any day of the preceding 12 months.
33	Industrial Dispute Act, 1947 & Central Rules/State Rules	This Act applies to every industrial establishment or undertaking for any investigation and settlement of industrial disputes between employers and employers, between employers and workers, or between workers and workers, which is connected with the employment or non-employment or the terms of employment or the conditions of labour.
34	The Building and other Construction Workers' (Regulation of Employment and Conditions of Service) Act, 1996, read with The Building and other Construction Workers' (Regulation of Employment and Conditions of Service) Rules, 1998	This Act applies to every establishment which employs or has employed on any day of the preceding 12 months ten or more building workers in any building or other construction work.
35	The Building and Other Construction Workers' Welfare Cess Act, 1996	An Act to provide for the levy and collection of a Cess on the cost of construction incurred by employers to augment the resources of the Building and Other Construction Workers' Welfare Boards constituted under the Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996.

Sr. No.	Act Name	Applicability of Act
36	Right of Persons with Disabilities Act 2016 read with Rights of Persons with Disabilities Rules, 2007	This Act applies to establishments employing 20 or more employees to give effect to the United Nations Conventions on the Right of Persons with Disabilities and to encourage establishments to have a disabled-friendly workplace.
37	The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017, read with The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Rules, 2017	This Act applies to every company or body corporate registered within India or outside India.
38	Environment Protection Act, 1986 read with E-waste (Management and Handling) Rules, 2016	This act applies to every consumer, the bulk consumer involved in the sale, transfer, purchase, collection, storage and processing of e-waste or electrical and electronic equipment, including their components, consumers, parts and spares that make the product operational.

Note: It is important to note that the applicability of state and central law, specific requirements and procedures may vary depending on the nature of business, products, scale, geography, state or municipality within India. Therefore, it is advisable to consult the local authorities or refer to state guidelines for accurate and up-to-date information.

Chapter 8

Risk Assessment and Internal Controls

Risk Assessment and Internal Controls

8.1 There are several important aspects of risks and internal controls that Internal Auditor may consider while conducting Internal Audit. However, the Internal Auditor first needs to recognise the inter-relationship between risk and internal controls.

As per the Standard on Internal Audit (SIA) 130 “Risk Management”, as issued by the ICAI Risk can be defined as the probability of a threat exploiting vulnerability of business assets or processes or controls by occurrence of an event causing significant impact to the business operations and continuity and which could prevent the organization from achieving its goals and objectives.

Similarly, Standard on Internal Audit (SIA) 120 “Internal Controls”, as issued by the ICAI explains Internal Controls as systemic and procedural steps adopted by an organisation to mitigate risks, primarily in the areas of financial accounting and reporting, operational processing and compliance with laws and regulations”.

This means that to mitigate any risk, management needs to design and implement one or more Internal Controls effectively indicating that Internal Controls are merely risk mitigation steps.

Risk Assessment

8.2 Risk assessment identifies and assesses potential risks that may impact an organization's objectives. An Internal Auditor should may consider the following aspects of risk assessment:

Identification of risks: Internal Auditor may assess whether the organization has identified all relevant risks that could impact its objectives. This involves reviewing risk sources and interviewing key stakeholders to identify potential risks.

Risk evaluation: Internal Auditor may evaluate the potential impact and likelihood of each identified risk and determine whether the organization has appropriate controls in place to mitigate the risks.

Monitoring and reporting: Internal Auditor may assess whether the organization is monitoring its risks and reporting on them regularly to ensure they are managed effectively. This involves reviewing risk management reports, attending risk management meetings and identifying deficiencies or improvement areas.

Internal Controls

8.3 Internal controls are the policies, procedures and systems established by an organization to safeguard its assets, ensure the accuracy and completeness of financial reporting and promote compliance with laws and regulations. An Internal Auditor may consider the following aspects of internal controls:

Design and implementation: Internal Auditor may assess whether the internal controls are designed and implemented effectively to achieve the organization's objectives. This involves reviewing policies and procedures, testing the effectiveness of controls and identifying any gaps or weaknesses.

Monitoring and evaluation: Internal Auditor may evaluate whether the internal controls are being monitored and evaluated regularly to ensure they remain effective. This involves assessing whether the organization has appropriate monitoring processes in place, such as regular audits and whether any deficiencies identified are being remediated in a timely manner.

Documentation: Internal Auditor may review the documentation of internal controls, such as policies, procedures, risk control matrix (RCM) and training materials, to ensure they are accurate and up to date.

By identifying any gaps or weaknesses in internal controls and assessing the effectiveness of risk management processes, the Internal Auditor can help the organization improve its operations and reduce the risk of negative impacts on its objectives.

Risks in Pharmaceutical Industry

8.4 The pharmaceutical industry faces various risks including product safety, quality, efficacy, regulatory compliance, reputational risk and supply

chain risks. Effective internal controls are essential to mitigate these risks and ensure pharmaceutical products' safe and effective production, distribution and use.

Some core risks and internal controls in the pharmaceutical industry include:

Areas	Risk	Internal controls
Product safety, quality and efficacy	Failure to ensure the safety, quality and efficacy of pharmaceutical products can lead to serious health consequences for patients and damage to the organization's reputation.	The organization may consider having a comprehensive quality management systems, including product testing procedures, quality assurance and risk management. These systems should be regularly reviewed and updated to ensure they remain effective.
Regulatory compliance	Failure to comply with regulatory requirements can result in fines, product recalls and reputational damage.	The organization should have policies and procedures to ensure compliance with all applicable laws and regulations, including monitoring and reporting requirements. The organization might also maintain a strong relationship with regulatory agencies and stay up to date with regulation changes.
Reputational	Reputational risk can result from negative publicity, product recalls, or failure to meet customer expectations.	The organization should have a comprehensive communication strategy to manage its reputation, including procedures for handling complaints and crises. The organization should regularly monitor social media and other channels to identify potential reputational risks.
Supply chain	Supply chain disruptions or quality	The organization should have robust supply chain management

Areas	Risk	Internal controls
	issues can lead to delays or shortages of critical pharmaceutical products.	systems, including supplier selection criteria, supplier performance monitoring and contingency plans for supply chain disruptions. The organization should maintain strong relationships with key suppliers and review supply chain risks regularly.

The pharmaceutical industry is subject to various risks and effective internal controls are essential to mitigate these risks and ensure the safe and effective production, distribution and use of pharmaceutical products. The organization should have robust quality management, regulatory compliance, reputational risk and supply chain management systems in place to ensure it operates effectively and efficiently while minimizing risks.

8.5 An illustrative list of risks in various areas in the pharmaceutical industry are as follows:

Sr. No	Audit Areas	Risk Categories	Risks
1	Statutory Compliance	Compliance and Regulations	Drug Quality Issues
			Product recall issues
			Medical/ Clinical Validity Challenges
			Quality concerns
			Trademark Infringement issues
			Drug Price Control Order (DPCO)
2	Production Planning & Control (PPC)	Manufacturing	Quality, Timely Delivery, RM, Cost
			Material Management

Sr. No	Audit Areas	Risk Categories	Risks
			Production inefficiencies, low yield
3	Procure To Pay (P2P)	Supply chains, outsourcing and service provider	Third Party Risk
4	Order To Cash (O2C)	Climate change and Environmental Sustainability	Expired Drugs Disposal
		Communications and Reputation	Spurious Drugs
5	Hire To Retire (H2R)	Culture, Behaviour & Soft Controls	Employee Online Behaviour
			Employee Suicide
			Workplace Discrimination
		Staff Well-being and Talent Management	Field force protests
			POSH non-compliance/ Sexual Harassment
6	Plant Audits	Climate change and environmental sustainability	Waste Disposal
			Pollution issues
			Fire Hazard
		Staff Well-being and talent Management	Labour unrest/ Work Stoppage
			Workforce illness spread
7	IT General Controls	Cybersecurity and data security	Privacy Issues, Access Control
		IT Infrastructure	Disaster Recovery,

Sr. No	Audit Areas	Risk Categories	Risks
			Backups
8	Enterprise Risk Management Framework	Communications and Reputation	Stock price fall / Market Capitalization
			Rumours
			Partnership break-off
		Compliance and Regulations	Unauthorized/ ill-equipped health camp tests
			Adverse Drug Reactions Complaints

Good Manufacturing Practices (GMP) and U.S. Food and Drug Administration (FDA) Risks in Indian Pharma Industry

8.6 GMP and FDA risks are particularly relevant for pharmaceutical companies in India due to the complex regulatory landscape and global market presence. Striking a balance between operational efficiency and regulatory compliance is essential. Robust quality control measures, accurate documentation, comprehensive employee training and proactive reporting practices are indispensable to mitigate these risks.

By emphasizing the importance of adhering to GMP principles and FDA regulations, pharmaceutical companies in India can ensure product quality, patient safety and a strong reputation in the competitive global pharmaceutical market.

8.7 Good Manufacturing Practices (GMP) and U.S. Food and Drug Administration (FDA) risks that pharmaceutical companies in India might face are as follows:

GMP Risk

GMP refers to the comprehensive set of guidelines and practices aimed at ensuring that pharmaceutical products are consistently produced and controlled according to quality standards. In the context of pharmaceutical companies in India, adherence to GMP is critical to maintain product quality, safety and efficacy. Deviations from GMP can lead to substandard products, compromised patient health, regulatory non-compliance and reputational damage.

Risk Example:

Scenario: A pharmaceutical company in India decides to introduce a new generic drug to the market. Due to intense competition and market pressures, they expedite the manufacturing process without adequately validating the changes.

Risk: The rushed manufacturing process might not adhere to GMP principles, leading to inconsistent product quality. The lack of proper validation can result in variations in drug potency, stability, or dissolution rates, potentially impacting patient outcomes and regulatory approvals.

Controls through Process Validation: Thoroughly validate any changes in manufacturing processes to ensure consistent product quality and compliance with GMP.

Documentation: Maintain comprehensive documentation of manufacturing processes, quality controls and validation procedures.

Employee Training: Continuously train manufacturing staff on GMP principles and the importance of following established processes.

FDA Risk

The FDA is a regulatory body that oversees the safety, efficacy and quality of pharmaceutical products sold in the U.S. market. For pharmaceutical companies in India looking to export products to the U.S., compliance with FDA regulations is crucial. Failure to meet FDA requirements can lead to import bans, warning letters, recalls and legal actions, significantly impacting market access and reputation.

Risk Example:

Scenario: A pharmaceutical company in India receives FDA approval for a new drug and begins exporting it to the U.S. market. However, they fail to report adverse events promptly to the FDA as required.

Risk: Non-compliance with FDA reporting requirements can result in delayed identification of potential safety concerns. This can trigger FDA investigations, warnings and erode the company's credibility, leading to reduced market trust and regulatory scrutiny.

Controls through Adverse Event Reporting: Establish clear processes for promptly reporting adverse events to the FDA in compliance with regulatory guidelines.

Monitoring: Implement systems to continuously monitor and analyze safety data to identify and address potential issues swiftly.

Risk Assessment in the Pharmaceutical industry

8.8 Risk assessment in the pharmaceutical industry uses a structured approach to identify, evaluate and prioritize potential risks that could impact pharmaceutical products' safety, quality and efficacy. The following are some steps typically involved in risk assessment in the pharmaceutical industry:

Identify potential risks: The first step in risk assessment is to identify all the potential risks that could impact the organization's objectives. This involves reviewing all aspects of the pharmaceutical product lifecycle, including manufacturing, distribution, storage and use.

Evaluate the likelihood and impact of each risk: Once potential risks are identified; the next step is to evaluate the likelihood and impact of each risk. This involves assessing the probability of the risk occurring and the potential severity of the consequences.

Prioritize risks: After evaluating the likelihood and impact of each risk, risks should be prioritized based on their level of risk. The most significant risks should be addressed first.

Develop risk management strategies: The next step is to develop risk management strategies to mitigate the identified risks. This may include implementing new policies, procedures and controls and developing contingency plans for potential risk scenarios.

Implement risk management strategies: Once the risk management strategies are developed, they should be implemented and monitored for effectiveness. This involves regularly reviewing the effectiveness of the strategies and adjusting as necessary.

Communicate risks: It is also essential to communicate the identified risks to stakeholders, including regulators, healthcare professionals, patients and employees. This helps ensure everyone understands the potential risks and the organization's management approach.

Overall, risk assessment in the pharmaceutical industry is critical to ensure the safe and effective production, distribution and use of pharmaceutical products. Organizations can develop effective risk management strategies that minimize the likelihood and impact of adverse outcomes by identifying, evaluating and prioritizing potential risks.

Responsibility of Internal Auditor Relevant

8.9 Responsibility of Internal Auditor as per Standard on Internal Audit (SIA) 130 Risk Management issued by ICAI are as follows:

"5.1 Unless specially excluded from the audit approach, the Internal Auditor shall plan and conduct risk based internal audits. This requires the application of risk management concepts to ensure that the audits are prioritised in areas of importance, appropriate resources are allocated effectively where needed most, audit procedures are designed to give due attention to important matters and issues identified and reported as significant in nature.

5.2 The nature and extent of audit procedures to be conducted in risk management is dependent on the maturity of the risk management processes and the framework in place. Where management has implemented a risk management framework, the Internal Auditor shall plan and perform audit procedures to evaluate the design, implementation and operating effectiveness of the organisation's risk management framework to provide independent assurance to management and those charged with governance.

6.2 **Audit objectives on Risk Management Framework:** The Internal Auditor shall perform audit procedures over the risk management framework with an overall objective to review the organisation's ability to:

(a) identify all risks;

(b) assess them objectively;

(c) respond to them through controls or other mitigations;

(d) ensure unmitigated risks are within the tolerance level; and

(e) monitor and report their status in a timely manner, to enable achievement of organisational objectives.

6.3. Auditing the Risk Management Framework: Where there is a formal risk management framework in place, the work of the Internal Auditor shall be directed to ensure that the organisation has amongst others:

(a) Designed the framework consistent with best-in-class and globally recognised frameworks, such as, COSO or ISO 31000, etc.,

(b) Implemented various enabling mechanisms, such as:

  (i) Issued risk management policies and implemented supporting procedures;

  (ii) Set the right culture with supporting messages and activities;

  (iii) Designed risk management structure, established a risk management committee, appointed risk officers and assigned each risk to a specific "risk owner";

  (iv) Identified all risks applicable to the entity (created a database), assessed each for importance and priority and undertaken appropriate mitigation steps or implement controls;

  (v) Conduct training programs for risk officers and owners, covering knowledge and competency;

  (vi) Implemented robust risk management systems, deploying technology (where possible), to monitor their progress and track their status, to document timely mitigation steps and to allow timely escalation in case of any slippage;

  (vii) Continuously tracks performance against risk appetite, along with sufficient reviews and oversight mechanisms;

  (viii) Established timely communication and periodic reporting systems and protocols.

The Internal Auditor will review the risk management system and processes in place to evaluate whether they are operating in an effective and efficient

manner and help to ensure full compliance. Any shortcoming highlighted shall result in recommendations for improvement and suggestions on how to make the risk management framework more efficient and effective in line with stated objectives.

5.3 Where no formal risk management framework exists, the Internal Auditor shall design and conduct audit procedures with a view to highlight any exposures arising from weak or absent risk management activities, make recommendations to implement and strengthen related processes and thereby improve risk management.

5.4 Where the independent assurance requires the issuance of an audit opinion over the design, implementation and operating effectiveness of risk management, this shall be undertaken in line with the requirements of Standard on Internal Audit (SIA) 110, "Nature of Assurance", especially with regard to the need to have a formal Risk Management Framework in place, which shall form the basis of such an assurance.

6.5 Independent Assurance ones Risk Management: Where a written assurance report is being issued, the Internal Auditor shall also consider the following as a basis for audit opinion:

a. The linkage of the risk management framework with the system of CEO and CFO certification on Internal Controls; and

b. Certificates of self-compliance from owners of key risks to support a system of continuous compliance.

5.5 "The Internal Auditor shall not assume any responsibility to manage the risks or to execute risk management decisions. It is not responsibility of the Internal Auditor to mitigate or resolve the risks."

Internal Control Questionnaire (ICQ)

8.10 The Internal Control Questionnaire (ICQ) is a structured questionnaire that serves as a tool for internal auditors to systematically assess the design and effectiveness of internal controls within an organization. It consists of a series of control questions that cover various aspects of an organization's operations. The ICQ aims to identify control gaps, weaknesses and areas of non-compliance that need to be addressed. By using the ICQ, auditors can obtain a comprehensive view of an organization's internal control environment and provide recommendations for improvement.

There are numerous benefits of using ICQ in internal audits within the pharmaceutical industry. It provides a standardized framework for evaluating controls and risk management practices, ensuring audit consistency and comparability. The ICQ also helps auditors to focus on critical risk areas, such as compliance with FDA regulations, data integrity and supply chain security. Additionally, the ICQ facilitates communication between auditors and management by providing a common language and understanding of control objectives.

Internal Control Questionnaire in the Pharmaceutical Industry

8.11 In the pharmaceutical industry, numerous unique risks and challenges must be addressed through internal audits. When applying the ICQ, auditors should pay particular attention to the following areas:

Regulatory Compliance: The pharmaceutical industry is heavily regulated, with organizations needing to comply with various regulations such as FDA regulations, Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP). The ICQ should include control questions related to regulatory compliance, including documentation, training and quality control processes.

Quality Management Systems: Internal audits should assess the effectiveness of an organization's quality management systems, such as Standard Operating Procedures (SOPs), change control processes, validation activities and quality assurance programs. The ICQ should cover control activities to ensure product quality, safety and efficacy.

Drug Safety and Pharmacovigilance: Auditors should focus on controls related to adverse event reporting, risk management plans, safety monitoring and signal detection. The ICQ should include questions about the processes to identify, evaluate and manage drug safety issues.

Data Integrity and Cybersecurity: Given the increasing reliance on digital systems and electronic data in the pharmaceutical industry, auditors should assess controls related to data integrity, data security and data governance. The ICQ should cover data access controls, backups, validation processes and cybersecurity measures.

Supply Chain Management: The pharmaceutical supply chain is complex and vulnerable to risks such as counterfeit drugs, product diversion and supply disruptions. Auditors should evaluate controls related to supplier management, inventory management, transportation security and product traceability.

Research and Development Processes: Internal audits in the pharmaceutical industry should assess the effectiveness of controls in research and development activities, including clinical trial management, data integrity in research studies and compliance with ethical guidelines.

Financial Controls and Fraud Prevention: The ICQ should cover controls related to financial transactions, including revenue recognition, expense management, procurement processes and fraud prevention measures.

Human Resources and Training: Auditors should evaluate controls related to employee competence, training programs, segregation of duties and adherence to the organization's code of conduct and ethical standards.

Internal Control Questionnaire Development and Administration

8.12 Developing an effective ICQ for the pharmaceutical industry involves several steps. Auditors should conduct a risk assessment to identify key control objectives and risks specific to the organization. They should gather information through interviews, document reviews and process walkthroughs to understand the existing control environment. Based on this information, auditors can design control questions that are relevant, specific and tailored to the organization's operations and risks.

Scoring and evaluating control activities within the ICQ require auditors to establish assessment criteria. These criteria can be based on regulatory requirements, industry best practices, or internal policies and standards. The assessment process may involve assigning a score or rating to each control question to measure the effectiveness of controls. The scoring can be qualitative (e.g., high, medium, low) or quantitative (e.g., percentage compliance).

Reporting and documenting ICQ findings are essential for effective communication and follow-up. Documentation should include the ICQ

questionnaire, assessment results, supporting evidence and management's response to audit findings. The audit report should identify control weaknesses, gaps and recommendations for improvement.

Internal Control Questionnaire Best Practices

8.13 To ensure the successful implementation of ICQ in pharmaceutical Internal auditors should consider the following best practices:

Maintain independence and objectivity: Internal auditors should maintain an independent and objective mindset throughout the audit process. They should assess controls and risk management systems with professionalism and scepticism.

Stay current with regulations and industry standards: Auditors must stay informed about evolving regulations, industry guidelines and best practices in the pharmaceutical sector. This knowledge will help auditors design relevant and effective control questions within the ICQ.

Foster collaboration with management: Auditors should establish open lines of communication with management to thoroughly understand the organization's operations, risks and control environment. Collaboration with management ensures that the ICQ is tailored to the organization's needs and risks.

Use a risk-based approach: Prioritize control areas based on their significance and potential impact on the organization's objectives. Focus more attention on areas with higher risks and vulnerabilities. This approach ensures efficient and effective allocation of audit resources.

Continuously improve the internal audit function: Internal audit should be seen as a value-added function contributing to the organization's success. Auditors should seek feedback, learn from previous audits and continuously enhance their skills and knowledge.

Chapter 9
Internal Audit

Standards on Internal Audit (SIAs)

9.1 Preface to the framework and Standard on Internal Audit as issued by the ICAI mention that :

The Standards on Internal Audit (SIAs) are a set of minimum requirements that apply to all members[1] of the ICAI while performing internal audit of any entity or body corporate.

9.2 As per Section 138 of Companies Act, 2013, the Board of a Company may, besides a Chartered Accountant, appoint a cost accountant or any other professional to conduct Internal Audits. The ICAI recommends the adoption of the SIAs by non-members of the ICAI who are performing internal audits so as to ensure a consistent approach and quality in the discharge of their professional duties

7.4 The Standards on Internal Audit are classified and numbered in a series format, as follows:

(i) 100 Series: Standards on Key Concepts

(ii) 200 Series: Standards on Internal Audit Management

(iii) 300–400 Series: Standards on the Conduct of Audit Assignments

(iv) 500 Series: Standards on Specialised Areas

(v) 600 Series: Standards on Quality Control

(vi) 700 Series: Other/ Miscellaneous Matters

100 Series : Standards on Key Concepts

SIA 110: Nature of Assurance

SIA 120: Internal Controls

SIA 130: Risk Management

1

SIA 140: Governance

SIA 150: Compliance with Laws and Regulations

200 Series : Standards on Internal Audit Management

SIA 210: Managing the Internal Audit Function

SIA 220: Conducting Overall Internal Audit Planning

SIA 230: Objectives of Internal Audit

SIA 240: Using the Work of an Expert

SIA 250: Communication with those Charged with Governance

300-400 Series : Standards on the Conduct of Audit Assignments

SIA 310: Planning the Internal Audit Assignment

SIA 320: Internal Audit Evidence

SIA 330: Internal Audit Documentation

SIA 350: Review and Supervision of Audit Assignments

SIA 360: Communication with Management

SIA 370: Reporting Results

SIA 390: Monitoring and Reporting of Prior Audit Issues

500 Series : Standards on Specialised Areas

SIA 520: Internal Auditing in an Information Technology Environment Third

SIA 530: Third Party Service Provider

Standards issued upto July 1, 2013

SIA 5: Sampling

SIA 6: Analytical Procedures

SIA 7: Quality Assurance in Internal Audit

SIA 11: Consideration of Fraud in an Internal Audit

SIA 18: Related Parties

Risks, Key Controls various Process

9.2 Risks and Conrols for following processes is given below:

(i) Production Planning and Control (PPC)

(ii) Procure to Pay (P2P)

(iii) Order to Cash (O2C/OTC)

(iv) Hire to Retire (H2R)

(v) Employee Expense Reimbursement

(vi) Expense Cycle

(vii) Fixed Asset

(viii) Financial Reporting Process

(ix) Entity-Level Controls (ELC)

(x) IT General Controls and Audit

Production Planning and Control (PPC)

The pharmaceutical industry's production planning and control (PPC) process involves managing and coordinating various activities to ensure efficient and effective production operations. It encompasses demand forecasting, capacity planning, material planning, scheduling and monitoring production processes. While PPC is crucial for meeting production targets and ensuring the timely availability of pharmaceutical products, it is also associated with certain risks. Internal auditors play a vital role in identifying and mitigating these risks to safeguard the PPC process's integrity, reliability and compliance.

Here is an overview of the PPC process in the pharmaceutical industry including its key sub-processes:

Sr. No	Process	Sub-process
1	Production and Material Requirement Planning and Procurement	Sales Forecasting
		Production Planning in Head Office (HO)
		In-House Manufacturing V/s Contract Manufacturing
		Production Indent for In-House Production
		Sales Order creation in ERP (Indent at the factory)

Sr. No	Process	Sub-process
		Material Requirement Planning
		Material Purchase Requisition
		Purchase Order generation and approval
		Preparation of Goods Received Note (GRN)
		Quality Check of Material Received
2	Production Planning and Execution	Daily Production Plan based on Monthly Production Indent
		Batch Creation
		Creation of Batch Manufacture Record and its approval
		Material Requisition by Production to Stores and Dispensing of the same
		Manufacturing Process
		Creation of Batch Packing Record
		Packing Process
		Factory Manpower Planning
		Machine Availability
3	Dispatch of Goods	Delivery of Finished Goods to Central warehouse (**CWH**)
		Receipt of material at Central warehouse (**CWH**)
		Stock Transfer of finished goods to Clearing and Forwarding agent (**CFA**)
4	Miscellaneous	Material Returns
		Scrap Sales
		Batch Costing
		Plant and Machinery Maintenance

Below is a detailed explanation on PPC cycle in the Pharmaceutical Manufacturing industry:

Sr. No	Process/ Sub Process	Brief Narration
A.	**Production and Material Requirement Planning and Procurement**	
1	Sales Forecasting	The first step in the PPC cycle is forecasting, which involves predicting the demand for pharmaceutical products. This step is critical as it helps the organization plan its production schedules and inventory requirements. Generally, Sales Planning Executives prepare the sales forecast for the next 2-3 months based on the average sale of the last few months. Once the demand forecast is established, the next step is to align production plans with sales plans. This is done through Sales and Operations Planning (S&OP), which involves integrating sales, marketing and production plans to create a unified production plan.
2	Production Planning	The master production schedule (MPS) is the detailed plan that outlines the production schedule for each product over a specific period. It considers the forecasted demand, production capacity and inventory levels. The MPS is a critical input for the production process as it determines the quantity of materials and resources required to meet the production targets. Based on the below factors, Production is prepared by Planning Senior and sent to Sourcing Team for procurement and production: 1. Current Stock Level 2. Minimum Stock Level (Approx. 2-3 Months) 3. Expected returns from expiry/ sales returns

Sr. No	Process/ Sub Process	Brief Narration
		4. Sales Forecast 5. In-process production
3	In-House Manufacturing V/s Contract Manufacturing	Basis the Production Plan, Capacity, Availability of License / Approval to manufacture the Product and facility available in the Factory, decisions are made to produce the product in-house or outsource the same to the approved Third-Party Manufacturer. The Work Orders are created by the procurement team on the Specified Contractors based on the terms as per the agreement. The decision to make it in-house or to outsource the production is taken based on the following parameters: 1. Production Capacity 2. Equipment Availability 3. Feasibility Study 4. Manpower Availability 5. Other local factors Projected sales volumes are also considered for the decision to manufacture or outsource and higher volume products are preferably manufactured in-house.
4	Issuance of Sales Order to factory - For Production	On approval of the Production Plan by the Planning Head, the sales orders are issued to the factory to produce the product. The Sales Order captures the following details: Product Name, Formulation, Harmonized System Of Nomenclature (HSN) Code, Delivery Date, Quantity, Rate, etc.
5	Material Requirement Planning (MRP)	According to the MPS, the material requirement planning (MRP) process determines the raw materials and components required to manufacture the

Sr. No	Process/ Sub Process	Brief Narration
		products. The MRP system calculates the required quantity of each raw material and component, considering the production schedule, inventory levels and lead times. The planning & Sourcing Team initiates the calculation of materials requirements in the system after the factory receives the sales order. Generally, in the industry ERPs are used which auto-calculates the quantity of Raw Materials and Packing Materials required for production based on the Sales Order and product (BOM) (Master Formula Record & Master Packing Record). Based on the stock levels, the system creates a procurement plan considering the minimum pack quantity and other factors. The procurement process is covered in more detail in Procure to Pay processes.
B.	**Preparation of Goods Received Note (GRN)**	
1	Goods Receipt Note	As a general process, on receipt of materials, the received material is entered in the Gate Inward Register before transferring the goods to stores. Stores at the receiving Station create Goods Receipt Notes (GRN). Documents reviewed at the time of the creation of GRN are PO/ Invoice/ Test Report from Vendors etc.
2	Quality Check of Material Received	Goods are received at the factory gate along with the test reports for analysis of material done at the vendor's end. The Stores Executive sends samples of these materials for re-test to Quality Control (QC) Department since there can be

Sr. No	Process/ Sub Process	Brief Narration
		variations in the test reports due to the time involved in transporting API Materials. Based on the results of tests, the inward material is classified as: • Quarantine (when the material is waiting for sampling) • Under Test (requisition issued and sample with QC for testing) • Approved or Hold &Rejected. The QC Department prepares a Certificate of Analysis (CoA); only the materials with approved COAs are available for issuance. If the test of the incoming material is not done in-house, the Testing Vendor will be informed and the sample will be sent in the designated manner (e.g., Cold chain/ Temperature/ Moisture, etc.)
C.	**Production Planning and Execution**	
1	Daily Production Plan based on Monthly Production Indent	Based on the Sales Order, the Planning/ Production team prepares detailed monthly and daily process-wise plans for the next month. Further, the daily plan can be modified and reviewed per the need.
2	Batch Creation	Based on the Sales order, daily/monthly plan and availability of RM/PM, the new batch is created by Production Executive and the QA Head approves it after verification. Sales Order reference is used as a base to trace the batch with the plan. Batch creation includes the following details: Product Name/ Batch No/ Mfg. Date/ Expiry Date/ Batch Size/ MRP/ Start Date/ Target

Sr. No	Process/ Sub Process	Brief Narration
		Date
3	Creation of Batch Manufacture Record and its approval	After approval of batch creation, Batch Manufacture Record (BMR) is prepared by QAM (Quality Assurance Manager), reviewed by Production and verified by the QA head. BMR is created based on the master document MFR (Master Formula Record) • BMR is a complete documentation for a batch manufactured covering all processes from raw material to dispensing to the final reconciliation of the product manufactured. • BMR documents all the aspects of production for a batch of a product, for example - Details of equipment to be used for all the production processes, standard time for completion of each process, the standard material requirement at each process, storage instructions for raw material, intermediaries and semi-finished goods, etc. • Processes are documented in the checklist and test results are recorded in the prescribed formats after each sub-process. This is checked by the Production Process owner and approved by the QA team. • Actual Yield is recorded by the Production executive after every process/sub-process, compared with the standard yield and documented in BMR. Variations from the standard yield are investigated and reviewed by the QA Team and are documented in the BMR.

Sr. No	Process/ Sub Process	Brief Narration
4	Material Requisition by Production to Stores and Dispensing of the same	Based on the Bill of Material (BOM as per MFR - Master Formula Record), the production executive creates the material requisition to stores. Generally, Material Requisition can be created only when the requirement list is per the MFR. Based on the requisition received, a Raw Material Dispensing Slip is generated and the Stores Executive dispenses material to the Production department under the supervision of QC. The prerequisites to dispense the material as per GMP norms are listed in the BMR and the same is followed during the process. At the end of the process, shortages/excess Raw Material (RM) quantity is reconciled.
5	Manufacturing Process	The process of manufacturing depends on the type of the product. However, the below sub-processes are followed in general for tablets manufacturing: 1. Dispensing of Raw Material (Materials are issued for manufacturing as per Bill of Material given in Batch Record) 2. Pre-manufacturing Operations, Control and Precautions (Ensuring all the requirements as per GMP are met) 3. Granulation (Granulation step involves mixing of specified API with other excipients using Rapid Mixer Granulator (RMG). Then dry mixed material is Granulated using water or a specified binder in RMG) 4. Compression (During the compression

Sr. No	Process/ Sub Process	Brief Narration
		process, the lubricated granules are compressed into tablets as per predefined specifications) 5. Coating (During Coating, the compressed tablets are coated as per predefined specifications) 6. Inspection (Visual inspection is done for sorting and removal of tablets with any physical defect) 7. In-process checks 8. Final Reconciliation 9. Batch History and signing off BMR
6	Creation of Batch Packing Records	After completion of the manufacturing process, Batch Packing Record (BPR) is prepared by QAM, reviewed by Production and verified by the QA head. BPR is created based on the master document MPR (Master Packing Report). • BPR is the complete documentation for a product's packing covering all aspects, from dispensing packing material to final reconciliation. • BPR records the physical return of excess PM from manufacturing to the stores. • BPR documents the details of equipment used and any deviations from those described in the MPR
7	Packing Process	Packing process consists of the following Sub process: 1. Dispensing slip of Packing Material. 2. Instructions to be followed for dispensing as mentioned in the BPR.

Sr. No	Process/ Sub Process	Brief Narration
		3. Stereos issuance and destruction. 4. Line clearance for coding machine. 5. Over-printed cartons in-process check. 6. Primary area prerequisites before packing commencement. 7. Line clearance instruction and approval of the same. 8. In-process checks. 9. Limit setting for carton and shipper weighing. 10. Packing material reconciliation slip.
8	Factory Manpower Planning	This process involves planning and scheduling the production process to ensure that there is enough manpower available to meet production targets. The process must be documented to ensure sufficient coverage and that the production process runs smoothly. Basis the production Plan, the Shifts are decided and the decision is taken for the recruitment of manpower or taking the causal workers on a contract basis.
9	Machine Availability	The production team considers machine availability, usage and maintenance plans while making the detailed monthly/daily plan.
D.	**Dispatch of Goods**	
1	Delivery of Finished Goods to CWH (Central Ware House)	Once the Finished Goods production process is complete and on approval from the Quality Assurance Team, the Factory Production Department generates Production Slip for requesting the transfer of FG from the production floor to the factory stores. After the generation of Production Slips,

Sr. No	Process/ Sub Process	Brief Narration
		samples are taken by Quality Control (QC) team for testing of the finished goods produced. Once QC approves the FG, it releases the goods to the store, Package Product Release (PPR) after checking the BMR & BPR. Generally, PPR is created by the QC Executive and is approved by the QC Head. Goods are shifted to the Factory warehouse/ Central warehouse.
2	Receipt of material at CWH	On receipt of Stock at CWH, the consignment is matched with the Delivery Challan and stacked Division wise.
3	Stock Transfer of finished goods to CFA (Carrying and Forwarding Agent)	Now the finished goods can be sold or transferred to CFA locations from CWH.
E.	**Miscellaneous**	
1	Material Returns	Raw Materials are dispensed as per the requisition and in absolute quantity; however, packing materials are usually dispensed to the Production Department in full packs rather than the actual material requirement. The excess material is returned to stores upon completion of the production process. The Production department creates a Material Return Note and then QA Team checks and approves it.
2	Scrap Sales	The scrap generated at the factory primarily consists of leftover raw material and packaging material. The Scrap is sold to the preferred scrap vendors at the agreed rates. The company must ensure that scrap sales comply with all applicable laws, regulations

Sr. No	Process/ Sub Process	Brief Narration
		and industry standards, including environmental regulations, data privacy laws and anti-bribery laws.
3	Batch Costing	Once the batch is closed, Generally, the ERP/system automatically calculates the costing for RM and PM and Intermediate goods consumed in the production of the particular batch. Overheads need to apportion to the batch at the end of the month/defined period based on the adopted costing methodology and assumptions to arrive at the batch costing. The Compression cost is derived from the allocation of overheads to the batch.
4	Plant and Machinery Maintenance	Plant and machinery maintenance is a critical aspect of pharmaceutical manufacturing as it ensures that the equipment used in the manufacturing process functions optimally, produces high-quality products and complies with regulatory requirements. Here are some steps involved in the maintenance process for plant and machinery in pharmaceutical manufacturing: • Schedule maintenance activities: • Conduct regular inspections • Perform preventive maintenance • Address corrective maintenance issues • Keep records of maintenance activities • Implement an equipment management system
5	Review of the Reports - Production	The production reports must be reviewed to ensure that the production process runs smoothly and that any issues are identified

Sr. No	Process/ Sub Process	Brief Narration
		and addressed promptly. These reports must be documented and reviewed by the Production Process owner and approved by the QA team. The yields should be analyzed to see if the production output is expected as planned.
6	Waste Disposal	Waste disposal is a crucial aspect of pharmaceutical manufacturing, as it involves properly handling, treating and disposing of various waste streams generated during manufacturing. There are several types of waste generated in pharmaceutical manufacturing, including: **Chemical waste:** This includes solvents, reagents and other chemicals used in the manufacturing process. These wastes can be hazardous and must be handled and disposed of appropriately. **Biological waste:** This includes waste generated from microorganisms, such as bacteria, viruses and fungi. Proper handling and disposal of these wastes are critical to prevent the spread of infections. **Solid waste:** This includes packaging materials, expired drugs and other solid waste generated during manufacturing.To manage waste disposal in pharmaceutical manufacturing, following applicable laws and regulations, including those related to hazardous waste, solid waste and air emissions, is vital. This may involve obtaining permits, implementing waste management plans and working with professionals to ensure proper handling and

Sr. No	Process/ Sub Process	Brief Narration
		disposal. Some standard waste management practices in pharmaceutical manufacturing include: • Segregation of waste streams to prevent contamination and ensure proper handling and disposal. • Treatment of hazardous wastes, such as incineration, chemical, or biological treatment. • Recycling and reuse of materials, where possible, to reduce waste generation and conserve resources. Use pollution prevention strategies, such as reducing hazardous materials, improving manufacturing processes and implementing waste reduction programs.

Potential Risks in Production Planning Control Process

Inaccurate Demand Forecasting: Inadequate market demand forecasting can lead to overproduction or underproduction of pharmaceutical products, resulting in excess inventory or stockouts. This risk can impact financial performance and customer satisfaction. Internal auditors should assess the accuracy and reliability of demand forecasting methods and recommend improvements if necessary.

Insufficient Capacity Planning: Inadequate capacity planning can lead to resource constraints, production delays and inability to meet market demand. Internal auditors must evaluate the effectiveness of capacity planning processes, assess the adequacy of resources and identify any gaps or bottlenecks that may hinder production efficiency.

Ineffective Material Planning/supply chain Interruption: Improper planning and management of raw materials, packaging materials and other supplies can disrupt production. Internal auditors should assess the adequacy of inventory management systems, review material planning

processes and ensure proper controls are in place to prevent stockouts, wastage, or obsolescence of materials.

Inefficient Scheduling: Poor production scheduling can result in inefficient utilization of resources, increased setup times and production delays. Internal auditors should review the scheduling process, evaluate the effectiveness of scheduling tools and methodologies and recommend enhancements to optimize resource utilization and minimize production downtime.

Lack of Process Monitoring: Inadequate monitoring of production processes can lead to quality issues, deviations from standard operating procedures (SOPs) and non-compliance with regulatory requirements. Internal auditors should assess the effectiveness of process monitoring mechanisms, including real-time monitoring, data analysis and performance tracking, to identify and address potential deviations or non-conformities.

Yield Risk: Variations in actual yield compared to the standard yield during the manufacturing process may result in production inefficiencies and financial implications. Internal auditors should assess yield monitoring systems, review yield calculations, identify potential causes of yield deviations and recommend process improvements to optimize yield.

Product Failure Risk: Failure to meet product specifications, resulting in quality issues, customer complaints, product recalls and reputational damage. Internal auditors should evaluate the effectiveness of product testing protocols, review quality assurance measures, ensure adherence to approved manufacturing processes and verify compliance with regulatory requirements.

Stability Risk: Inadequate product stability studies lead to potential product quality, efficacy and safety changes over time. Internal auditors should assess the design and execution of stability testing programs, review documentation of stability studies, ensure adherence to predetermined testing intervals and verify compliance with regulatory guidelines.

Third-Party Risk in Manufacturing: Dependence on third-party manufacturers for production poses quality control issues, supply chain disruptions and inadequate oversight. Internal auditors should evaluate the vendor selection and qualification process, review quality agreements with third-party manufacturers, assess monitoring and control mechanisms and ensure compliance with regulatory requirements.

Maintenance Risk: Inadequate maintenance practices and equipment failures lead to production delays, quality issues and potential safety hazards. Internal auditors should assess maintenance protocols, review preventive maintenance schedules, evaluate equipment calibration and validation processes and recommend improvements to ensure operational reliability and minimize downtime.

Safety Risk: Occupational health and safety hazards, inadequate safety protocols and non-compliance with safety regulations, potentially leading to accidents, injuries and legal liabilities. Internal auditors should review safety policies and procedures, assess workplace safety measures, evaluate employee training programs and verify compliance with occupational health and safety regulations.

Cost overrun Risk: The risk of cost overruns due to various factors such as fluctuating raw material prices, inefficient resource utilization, production delays and unexpected expenses. Internal auditors should evaluate cost estimation and monitoring processes, review budgeting practices, assess procurement strategies for raw materials and identify areas for cost optimization and efficiency improvement.

On-time Delivery Risk: The risk of delays or non-delivery of raw materials or finished goods, which can disrupt production schedules, impact customer satisfaction and lead to financial losses. Internal auditors should assess supplier management processes, review supply chain practices, evaluate contingency plans for alternative suppliers and monitor delivery performance to ensure the timely availability of materials and finished products.

Narcotics Products Handling Risk: In pharmaceutical companies dealing with narcotics or controlled substances, specific risks are associated with the handling, storage and transportation of these sensitive products, including the potential for theft, diversion, or non-compliance with regulatory requirements. Internal auditors should evaluate security measures for narcotics handling, review inventory management controls, assess access controls to restricted areas and verify compliance with applicable regulations, such as controlled substance licensing and reporting.

Expiry of Raw Materials: The risk of raw materials reaching their expiry dates before they can be used in production, leading to waste, increased costs and potential disruptions in the manufacturing process. Internal auditors should assess inventory management practices, including proper

storage, FIFO (first-in, first-out) handling and regular monitoring of raw material expiration dates. They should also review processes for supplier notification and returns of expired materials.

Risk of Raw Material Shelf-Life Management and Batch Expiry Alignment: The risk of using raw materials with a shorter shelf life in production may result in finished products with limited expiration dates or batch expirations that do not align with market demand. Internal auditors should review the process of linking raw material shelf life with batch production planning, assess the adequacy of shelf-life tracking systems, ensure proper communication between production and quality control teams and monitor batch expiration dates to avoid product wastage and expiry-related issues.

Compliance and Environmental Risks in the Pharmaceutical Industry - PPC

The pharmaceutical industry is subject to various compliance and environmental risks due to its highly regulated nature and the potential impact of its operations on public health and the environment.

Regulatory Compliance Risk: Applicable Acts and Regulations: Drug and Cosmetics Act, 1940; Drugs and Cosmetics Rules, 1945; Schedule M requirements, etc. Risks can be – Non-compliance with regulatory requirements, such as Good Manufacturing Practices (GMP), labelling regulations, licensing requirements and product registrations.

Quality and Safety Risk: Applicable Acts and Regulations: Good Manufacturing Practices (GMP), Pharmacopoeia standards, Quality Management Systems (QMS), etc. Risks can be – Quality control failures, substandard or counterfeit drugs, inadequate product testing and deviations from quality and safety standards.

Environmental Risk: Applicable Acts and Regulations: Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2016; Air (Prevention and Control of Pollution) Act, 1981; Water (Prevention and Control of Pollution) Act, 1974, etc. Risks can be – Improper handling and disposal of hazardous materials, emissions and effluents impacting air and water quality and non-compliance with environmental regulations.

Data Privacy and Security Risk: Applicable Acts and Regulations: Information Technology Act, 2000; Personal Data Protection Bill (expected to

be enacted soon), etc. Risks can be – Unauthorized access of production/product data, data breaches, inadequate data privacy controls and non-compliance with data protection laws.

Key Control in Production Planning Control Process

The following table gives a brief description of various activities, control objectives and key controls in production planning control cycle:

Sr. No.	Activity	Risk	Control Objective	Key Controls
A.	**Assignment of Authority & Responsibility**			
1	Segregation of Duties	Inadequate segregation of duties and unauthorized and inappropriate user access resulting in fraudulent and incorrect production activities.	Adequate segregation of duties and appropriately authorized access controls are maintained for all activities related to book closure.	Implement a robust system of segregation of duties and access controls to ensure that authorized individuals perform respective production activities in a controlled and monitored environment.
B.	**Dispatch of Goods**			
a	Delivery of Finished Goods to CWH	1. Finished Goods may be dispatched to Central Warehouse without adequate documentation 2. Excess/ Short is delivered to	To ensure accurate and complete documentation of finished goods dispatched to the Central Warehouse (CWH),	**Documentation Control:** Implement standardized documentation processes for finished goods and require proper forms to be completed

Sr. No.	Activity	Risk	Control Objective	Key Controls
		CWH 3. All FG Dispatched from the factory may not be captured in the system at CWH	prevent excesses or shortages during delivery and ensure that all dispatched goods are properly recorded in the system at CWH.	and signed off by authorized personnel. **Physical Verification and Reconciliation:** Conduct regular physical verification and reconciliation of dispatched goods at CWH **System Integration and Data Capture:** Implement an integrated system that captures all finished goods dispatched from the factory in real-time and updates inventory records at CWH.
b	Quality Check of FG before dispatch to CWH	Finished Goods are dispatched to CWH without Quality Check	Ensure that finished goods dispatched to CWH undergo a proper quality check	Implement a robust quality control process for finished goods dispatched to

Sr. No.	Activity	Risk	Control Objective	Key Controls
			to maintain product quality and customer satisfaction.	CWH, ensuring that all products meet the required quality standards.
c	Receipt of finished goods (FG) at CWH	Proper tracking of goods may not be in place to monitor the movement of goods	To establish a proper tracking system for monitoring the movement of goods and ensure accurate and timely information regarding their location and status.	Implement a robust and integrated goods tracking system to monitor and record the movement of goods throughout the supply chain, enabling real-time visibility and accurate tracking.
d	Stock Transfer of finished goods to CFA/CSA/Super Stockist	1. Goods may be dispatched to the wrong CFA 2. Goods packed for dispatch may not be as per the packing list 3. Invoice/Stock Transfer Note for goods to be dispatched may not be prepared, or maybe there is a delay in	To ensure accurate and reliable dispatch processes, including proper destination selection, packing as per packing lists and timely preparation of invoices for goods to be	• Destination Verification • Packing List Validation • Invoice Preparation and Timeliness • Documentation and Record-Keeping • Reconciliation and Audit • Automation

Sr. No.	Activity	Risk	Control Objective	Key Controls
		preparation.	dispatched.	and System Integration
C.	**Manufacturing Process**			
a	Dispensing of raw material	Dispensing Area may not be cleaned, which may result in remains of previous products/ material from the area.	Before initiation of production, cleanliness is maintained and room temperature is checked and monitored on a timely basis.	Implement a robust cleaning and sanitation protocol for the dispensing area to ensure it is thoroughly cleaned, free from residues and ready for the dispensing of new products through proper cleaning schedules, defining cleaning procedures, audits & inspection
b	Granulation, Blending, Compression, Coating and Inspection	1. In-process sample collection and quality control may not be happening or may not be as per the BATCH MANUFACTURE RECORD requirements 2.	To ensure proper in-process sample collection and quality control per the Batch Manufacturing Record (BMR) requirements and to monitor and authorize	Implement a robust control framework that includes adherence to Batch Manufacturing Record (BMR) requirements for in-process sample collection and

Sr. No.	Activity	Risk	Control Objective	Key Controls
		Reconciliation/ Yield may not be monitored or may not be authorized for deviations from standard tolerance levels	deviations from standard tolerance levels during reconciliation and yield calculations.	quality control, along with a well-defined reconciliation process to monitor and authorize deviations from standard tolerance levels in yield calculations. This involves proper training, documentation and review of in-process sample collection and quality control, establishing tolerance levels for deviations and implementing an authorization process for reconciliation deviations, with regular monitoring and reporting to identify and address significant variations.

Sr. No.	Activity	Risk	Control Objective	Key Controls
c	Packing Process, Creation of Batch Packing Record and its approval	Dispensing of packing raw material for Primary and secondary packing of the finished goods may not be done as per the Master packing Records.	To ensure the proper dispensing of packing materials for primary and secondary packing of finished goods per the Master Packing Records (MPR).	Implement robust control measures to ensure the accurate dispensing of packing raw materials for primary and secondary packing in strict adherence to the specifications outlined in the Master Packing Records (MPR). This includes implementing comprehensive SOPs, conducting dispensing validation and material verification, maintaining accurate batch record documentation, performing quality control checks and conducting regular reconciliations

Sr. No.	Activity	Risk	Control Objective	Key Controls
				and reporting to identify and address any discrepancies or deviations from the MPR requirements.
d	Policies and Procedures	The company is not compliant with the policies & procedures and applicable rules and regulations are not updated	To ensure compliance with company policies, procedures and applicable rules and regulations and to maintain up-to-date knowledge of regulatory requirements.	Implement a comprehensive compliance management system that includes regular review, updates and adherence to company policies, procedures and relevant rules and regulations.
D	**Production and Material Requirement Planning and Procurement**			
a	In-House Manufacturing V/s Contract Manufacturing	A feasibility study for taking on the decision of In-House Manufacturing Vs Contract Manufacturing may not be done or is inaccurate	To ensure that a thorough and accurate feasibility study is conducted to evaluate the decision of in-house manufacturing versus contract manufacturing.	Implement a structured and comprehensive feasibility study that assesses the advantages, disadvantages, costs, risks and capabilities of in-house manufacturing and contract manufacturing

Sr. No.	Activity	Risk	Control Objective	Key Controls
				options. This includes cross-functional collaboration, rigorous data collection and analysis, thorough risk assessment, financial analysis, evaluation of strategic alignment and clear documentation of the decision-making process, ensuring an informed and accurate assessment of the feasibility of each option.
b	Preparation of Goods Received Note (GRN)	1. GRN may not be generated for all goods received at the factory 2. There may be delays in the creation of GRN 3. GRN Qty or rate may not	To ensure accurate and timely generation of Goods Receipt Note (GRN) for all goods received at the factory, with quantities and	Implement a robust GRN process that includes regular monitoring and adherence to generate GRNs for all goods received, minimize delays

Sr. No.	Activity	Risk	Control Objective	Key Controls
		match with PO Qty and Rate or Invoice Qty and rate	rates matching the Purchase Order (PO) and Invoice.	in GRN creation and conduct thorough three-way matching to verify quantities and rates against the PO and Invoice. This includes establishing clear procedures and timelines for GRN generation, implementing automated systems and controls for accuracy, conducting regular reconciliations to identify discrepancies and promptly resolving any mismatches through investigation and communication with suppliers, procurement and finance

Sr. No.	Activity	Risk	Control Objective	Key Controls
				departments.
c	Production Indent for In-House Production	Information in production indents is inadequately captured and not as per the production plan.	To ensure accurate and comprehensive capturing of information in production indents that aligns with the production plan.	Implement a robust control process to capture information in production indents per the production plan accurately. This includes establishing clear guidelines for indent creation, verifying the alignment of indents with the production plan, conducting regular reviews and reconciliations to identify discrepancies, providing training to personnel involved in indent creation, implementing quality checks and approvals and maintaining effective

Sr. No.	Activity	Risk	Control Objective	Key Controls
				communication channels between production planning and indenting teams to ensure proper alignment and timely resolution of any issues or variances.
d	Quality Check of Material Received	Sub Standard material received/used. Quality check is not carried out or recorded	To prevent the acceptance and use of substandard materials and ensure the implementation of a robust quality check process that is carried out and properly recorded.	Implement a comprehensive control system to prevent the acceptance of substandard materials and ensure proper quality checks are conducted and recorded. This includes establishing clear quality standards and criteria for materials, conducting thorough inspections and testing procedures,

Sr. No.	Activity	Risk	Control Objective	Key Controls
				verifying supplier certifications and quality documentation, maintaining comprehensive records of quality checks performed, implementing a rejection process for non-compliant materials, providing training to personnel involved in quality checks and conducting regular audits to monitor compliance with quality standards and procedures.
e	Receipt of material at Factory	No records / Inadequate records may be maintained for keeping track of goods received	To ensure accurate and complete records are maintained to track and monitor goods received	Implement a standardized and centralized record-keeping process for goods received, conducting regular

Sr. No.	Activity	Risk	Control Objective	Key Controls
			effectively.	reconciliations, providing training, implementing controls, fostering communication and conducting periodic audits to ensure accurate and complete records are maintained for effective tracking.
f	Sales Order to factory	Sales Orders created are not approved.	To ensure sales orders are created system only after proper approval and to identify and address any variances.	Implement an approval workflow for sales orders, conduct regular reconciliations between sales orders and indent vouchers, document and investigate any variances, establish clear communication channels between relevant departments

Sr. No.	Activity	Risk	Control Objective	Key Controls
				and take corrective actions to align the sales orders with the indent vouchers and ensure accuracy and consistency in sales order processing.
g	Supply planning	Inaccurate sales forecast may lead to inaccurate production planning and incorrect procurement of materials Production plans are not documented as per the demand forecast	To ensure accurate sales forecasts for effective production planning and procurement of materials and to document production plans in alignment with demand forecasts.	Establish procedures for documenting production plans based on the demand forecast. Conduct regular reviews and reconciliations between sales forecasts and production plans to identify any discrepancies and take corrective actions
E.	**Production Planning and Execution**			
a	Batch Creation	• A batch may be created for unapproved products	Ensure that batches for production are created only	Implement a control process to ensure batches for

Sr. No.	Activity	Risk	Control Objective	Key Controls
		• A batch created for production may not be authorized • A batch may not be created on time or per the production head's plan.	for approved products, authorized by relevant stakeholders and created in a timely manner as per the production head's plan.	production are created only for approved products, authorized by relevant stakeholders and created on time as per the production head's plan.
b	Creation of Batch Manufacture Record and its approval	Batch Manufacture Records may not be created accurately, timely, or as per the system.	To ensure accurate, timely and system-aligned Batch Manufacture Records (BMRs) creation.	Implement a control process for accurate, timely and system-aligned creation of Batch Manufacture Records (BMRs) through clear guidelines, training, quality checks, automated systems, audits and effective communication
c	Daily Production Plan based on Monthly Production Indent	• Daily Production Plan may not be prepared based on the Sales Order created	To ensure the preparation of the Daily Production Plan based on Sales Orders	Control the preparation of the Daily Production Plan based on authorized

Sr. No.	Activity	Risk	Control Objective	Key Controls
		• Changes in Production Plan may not be authorized	created and the authorization of any changes made to the Production Plan.	Sales Orders and implement an authorization process for any changes made to the Production Plan.
d	Factory Manpower Planning	• Inadequate planning leads to excess or shortage of casual workers • Casual workers required by various departments may not be approved by their respective HODs	Ensure adequate planning and approval of casual workers to prevent excess or labour shortage in various departments.	Control the labour planning process to ensure adequate staffing of casual workers in various departments. Implement an approval workflow where HODs review and authorize hiring casual workers, maintain clear communication channels and monitor labour utilization to prevent excesses or shortages.
e	Machine Availability	Machines required for production may	To ensure the availability of machines	Control the availability of machines

Sr. No.	Activity	Risk	Control Objective	Key Controls
		not be available, leading to delays in the production process	required for production and minimize delays in the production process.	required for production through regular maintenance, preventive schedules, effective communication, spare parts inventory, backup plans, prompt issue reporting, operator training and proactive production schedule reviews.
F	**Miscellaneous**			
a	Batch Costing	1. Consumption of RM, PM, intermediary goods, wages and overheads are not recorded / inaccurately captured 2. The apportionment of overheads to arrive at the batch cost is inaccurate 3. There may be	To ensure accurate recording of material consumption, wages and overheads, accurate apportionment of overheads for batch costing and effective management of variances	Ensure accurate recording of material consumption, wages and overheads, accurate apportionment of overheads for batch costing and effective management of variances

Sr. No.	Activity	Risk	Control Objective	Key Controls
		a Variance between the standard cost / actual cost of the batch	between standard and actual costs.	through robust control processes, regular reconciliations, defined allocation methods, variance analysis and corrective actions.
b	Material Returns	1. Excess material issued for production/ packing may not be returned and may be lost if not tracked appropriately 2. Material received back from the floor may not be updated in the system	Excess material, if issued for production and which is not consumed, should be returned and adequate entries are passed into the system.	Ensure accurate recording of material consumption for batch and effective management of variances through robust control processes, regular reconciliations, variance analysis and corrective actions.
c	Plant and Machinery Maintenance	Plant and Machinery equipment may not be maintained	Ensure appropriate maintenance of plant and machinery	Implement preventive maintenance program for regular

Sr. No.	Activity	Risk	Control Objective	Key Controls
		appropriately, leading to frequent breakdowns. There may be delays in procuring the spare parts of machinery, leading to the production process coming to stand still.	equipment to minimize breakdowns and timely procurement of spare parts to prevent production delays.	inspection and maintenance of plant and machinery, establish efficient spare parts management process for timely procurement, prioritize and promptly address equipment breakdowns through effective repair and servicing procedures, maintain good vendor relationships for timely spare parts delivery and foster a culture of continuous improvement to prevent recurring issues.
d	Scrap Sales / Destruction of rejected RM/PM	1. Scrap generated in the factory is not	To ensure proper segregation,	Segregate scrap from other stocks,

Sr. No.	Activity	Risk	Control Objective	Key Controls
		segregated from other stocks 2. Scrap sold may not be approved by the appropriate authority and may not be properly supervised 3. Cash received from the sale of scrap may not be accounted/ accounted at lower levels 4. Destruction of rejected RM/PM is not done as per the approved guidelines	approval, supervision and accounting of scrap generated in the factory and adherence to approved guidelines for destroying rejected raw materials and packaging materials.	implement approval and supervision for scrap sales, ensure proper accounting of cash received and adhere to approved guidelines for destroying rejected materials.

Procure to Pay (P2P)

Procure-to-pay is a business cycle spanning from procurement functions for goods and services needed to receiving procedures, including verification, accounts payable and accounting functions. The cycle consists of various interconnected steps that must be executed accurately and efficiently to ensure the timely availability of goods and services required for the manufacturing process.

Below is a detailed explanation of the P2P cycle in the pharmaceutical manufacturing industry:

STEP 1: REQUIREMENT IDENTIFICATION: In this initial stage, various departments within the pharmaceutical company, such as Maintenance, Production, Sales and Distribution and Administration identify their specific

material requirements. They then create a document known as a Purchase Requisition (PR) or Purchase Request, which includes details such as material description, quantity, estimated cost, material requirement date and preferred or standard vendor.

STEP 2: PR AUTHORIZATION: The PR undergoes approval by the head or senior authority of the respective department. The authority may approve or return the PR to the originator for modifications.

STEP 3: FINAL PR APPROVAL/ROLE OF INVENTORY CONTROLLER: Once the user department authorizes the PR, it is passed on to the inventory controller or materials management department responsible for handling all materials within the organization. The inventory controller reviews the PR, checking for any open Purchase Orders (PO) or scheduled/planned deliveries for the material. If there are any existing orders or deliveries, the inventory controller may return the PR or request the user department to revise the quantity of the material if necessary. After the inventory controller approves, the PR moves to the Procurement department.

STEP 4: PROCUREMENT: After the final authorization of the PR and confirmation that there are no planned deliveries for the material, it is passed on to the procurement department. The department checks if there are any existing contracts for the material. If no contract exists, the procurement department initiates a supplier search and sends out inquiries. A call-out is generated and sent to the contracted supplier if a contract exists.

STEP 5: SUPPLIER IDENTIFICATION: If there are no pre-contracted suppliers, the procurement department collaborates with the user department to identify potential suppliers. This can be done through referrals, searching databases, or other means.

STEP 6: INQUIRY FLOATING: Once the suppliers are identified, the procurement department sends a Request for Quotations/Proposal (RFQ/RFP) to the suppliers based on the PR. The RFQ includes material description, technical specifications, quantity, terms and conditions, delivery date, submission deadline, quality standards and supplier offer validity.

STEP 7: RECEIPT OF TECHNICAL QUOTATIONS: The procurement department receives supplier quotations after sending the RFQ/RFP to vendors. These technical quotations contain information regarding the technical specifications of the material. Vendors are typically instructed to

submit their quotations in sealed envelopes with only the RFQ reference number mentioned. Quotations are analysed by the procurement department.

STEP 8: TECHNICAL QUOTATION EVALUATION: Quotations are forwarded to the technical department for evaluation based on technical specifications. The technical department shortlists the quotations based on these specifications.

STEP 9: RECEIPT OF COMMERCIAL QUOTATIONS: The procurement department requests shortlisted suppliers to provide commercial quotations once the technical evaluation is complete. The commercial quotation includes details about payment terms, discounts and other commercial aspects. The procurement department prepares a quotation comparison statement to compare all quotations and suppliers are shortlisted for further negotiations.

STEP 10: NEGOTIATION: Based on the commercial quotations, the procurement department selects suppliers and invites them for negotiations. The negotiation process covers various aspects, such as price reduction, quantity and price breaks, delivery terms and conditions, freight charges and payment terms.

STEP 11: VENDOR SELECTION: After negotiations with the selected vendors, revised quotations are prepared and the final vendor is chosen for contract award. The selection is based on evaluating commercial and technical parameters, previous vendor performance, delivery dates and other relevant factors.

STEP 12: CONTRACT AWARD: Once the vendor is finalized, a Letter of Intent (LOI) may be sent, requesting the vendor to provide security or a bank guarantee (if applicable) before signing the agreement. The agreement can be fixed or blanket, as mentioned in the RFQ.

STEP 13: PURCHASE ORDER (PO): The procurement department creates a purchase order based on the contracts and sends it to the supplier. The PO refers to the initial document created in the process, i.e., the PR. The PO includes terms and conditions, description of goods or services, quantity, unit price, total amount payable, expected delivery date and payment terms.

STEP 14: PO ACKNOWLEDGEMENT: Upon receiving the PO, the supplier acknowledges its receipt and sends the acknowledgement to the procurement department. The procurement department records this

acknowledgement. Suppliers can remotely download purchase orders and acknowledge if an Enterprise Resource Planning (ERP) system is used for procurement functions.

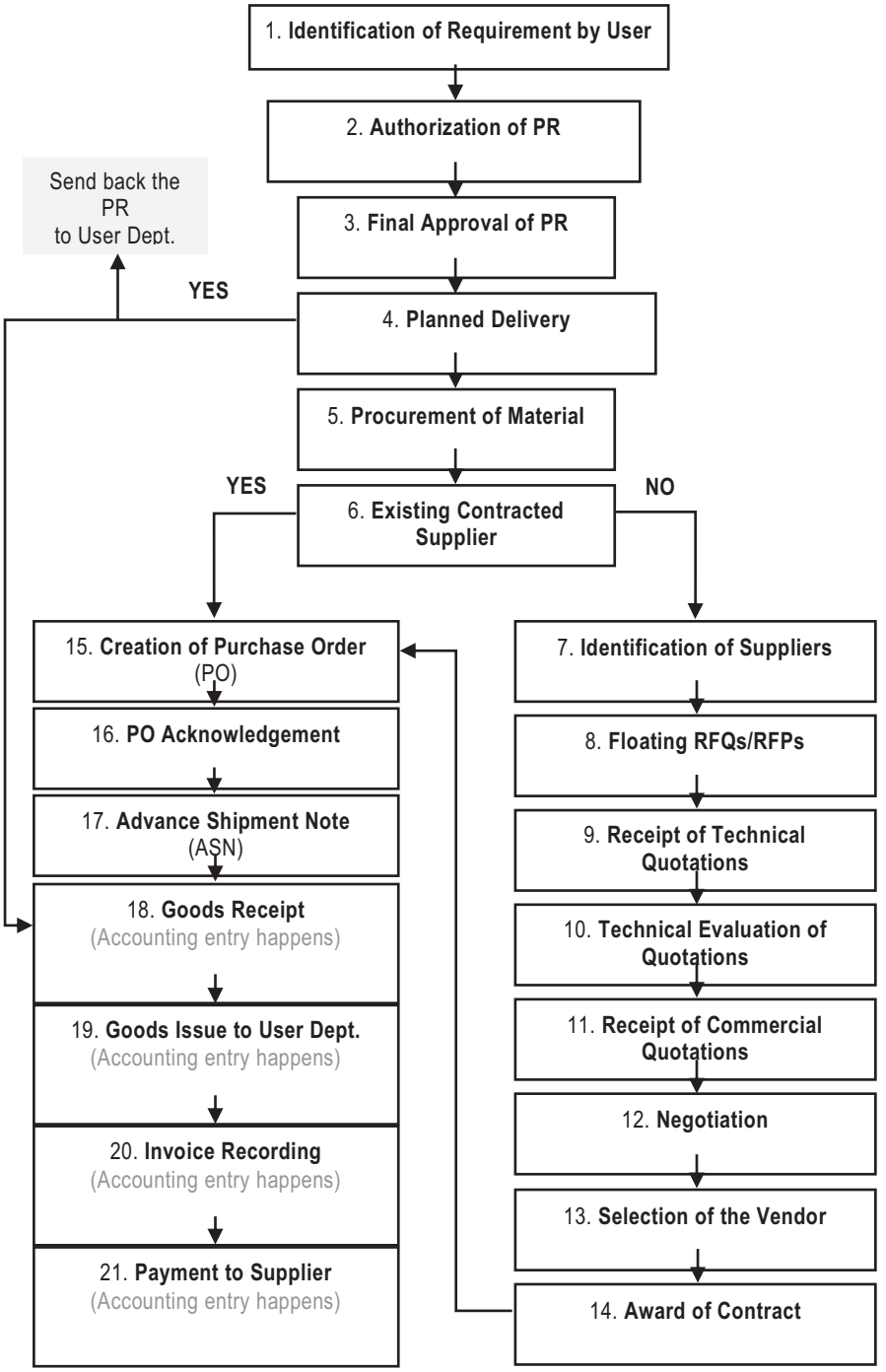
STEP 15: ADVANCE SHIPMENT NOTE (ASN): The supplier sends an Advance Shipment Note (ASN) to the procurement department when the material is shipped. The ASN includes the shipping date, transporter's name, airway bill number, package count, package weight, receiving location address and a description of the goods.

STEP 16: RECEIPT OF GOODS OR SERVICES: Upon delivery of the goods or completion of services, the receiving department matches the PO with the received goods or services. They verify that the quantity and quality of the goods or services align with the PO. Any discrepancies or shortages are reported to the purchasing department and the vendor is notified. After quantity verification, the material is placed at inspection locations and a material inspector is called for further inspection. If the inspector rejects the material, it is returned to the vendor, or the vendor is asked for rectification on-site. Acceptable material is moved to respective warehouse locations.

STEP 17: INVOICE PROCESSING: After verifying that the goods or services received match the PO, the vendor sends an invoice to the accounts payable department. The invoice includes details of the goods or services provided, quantity, unit price and the total amount payable. The accounts payable department verifies that the invoice matches the PO and the received goods or services.

STEP 18: PAYMENT: Once the invoice is verified, the accounts payable department pays the vendor based on the agreed-upon payment terms in the PO. Payments can be made through wire transfer, electronic funds transfer (EFT), or by issuing a check.

STEP 19: RECONCILIATION: The final step in the procurement-to-payment cycle involves reconciling accounts. This includes matching the payment made to the vendor with the invoice and the PO to ensure no discrepancies. The accounts payable department updates the company's financial records and records all transactions.


1. Identification of Requirement by User
2. Authorization of PR
Send back the PR to User Dept.
3. Final Approval of PR
YES
4. Planned Delivery
5. Procurement of Material
YES
6. Existing Contracted Supplier
NO
15. Creation of Purchase Order (PO)
16. PO Acknowledgement
17. Advance Shipment Note (ASN)
18. Goods Receipt (Accounting entry happens)
19. Goods Issue to User Dept. (Accounting entry happens)
20. Invoice Recording (Accounting entry happens)
21. Payment to Supplier (Accounting entry happens)
7. Identification of Suppliers
8. Floating RFQs/RFPs
9. Receipt of Technical Quotations
10. Technical Evaluation of Quotations
11. Receipt of Commercial Quotations
12. Negotiation
13. Selection of the Vendor
14. Award of Contract

Potential Risks in a Procurement process

A procurement process can have several potential risks compromising efficiency, effectiveness and integrity. Some common ones include:

1. **Supply chain risks:** Supply chain risks arise from the supplier's financial stability, the quality of the goods or services, or the delivery schedule. For instance, if the supplier is not financially stable, there is a risk that the organization will not receive the goods or services. Similarly, if the supplier does not deliver the goods or services on time, there is a risk that the organization cannot use them.

2. **Contract risks:** Contract risks are risks that arise from the terms and conditions of the contract. For instance, if the contract does not allow for enough flexibility, there is a risk that the organization cannot change the contract if necessary.

3. **Delivery risks:** Delivery risk is a procurement risk that arises from the delivery schedule. For example, if the goods or services are not delivered on time, there is a risk that the organization cannot use them.

4. **Lack of clear policies and procedures:** A procurement process without clear and well-defined policies and procedures leaves room for confusion, inefficiency and inconsistencies.

5. **Unethical supplier selection and management:** Biased/manipulated supplier selection and management can lead to a higher risk of fraud, waste and abuse of procurement funds.

6. **Inadequate contract administration:** A failure to properly administer contracts, including monitoring supplier performance and enforcing contract terms, can result in inferior goods and services and significant cost overruns.

7. **Lack of internal controls:** A lack of proper internal controls, such as segregation of duties, can increase the risk of fraud, waste and abuse.

8. **Inadequate documentation:** Poor documentation practices can lead to difficulties in tracking procurement activities, making verifying compliance with policies and procedures harder.

9. **Weaknesses in payment processes:** Payment processes that are not adequately controlled can result in overpayments, fraud and other financial losses.

It is essential to regularly assess and address these and other potential vulnerabilities in the procurement process to ensure that procurement activities are conducted in a manner that is consistent with the organization's goals and in compliance with relevant laws and regulations.

Internal Audit of Procurement Process

An internal audit of the procurement process is a systematic examination of the procedures and controls within an organization to ensure that the procurement of goods and services is conducted in a manner that is consistent with the organization's policies and objectives and that it complies with relevant laws and regulations.

The scope of the internal audit may include evaluating the procurement policies and procedures, supplier selection and management, contract administration, purchasing transactions and payment processes. The audit may also include a review of internal controls, such as the segregation of duties and documentation of transactions, to ensure that procurement activities are conducted with accuracy and integrity.

The objective of an internal audit of the procurement process is to assure the organization's management that the procurement process is operating effectively, efficiently and in compliance with relevant regulations and internal policies. The audit results may identify areas for improvement and help ensure that procurement activities support the organization's overall mission and objectives.

Control Objective from Internal Audit Perspective – P2P Process

Internal controls play a critical role in the P2P cycle in the pharmaceutical manufacturing industry. These controls may include ensuring that the requisition and PO are authorized by the relevant departments, maintaining an accurate inventory of goods and services, verifying that the goods or services received match the PO, verifying the accuracy of invoices received and ensuring timely payment to vendors. Effective internal controls help ensure that the P2P cycle is efficient, effective and compliant with regulatory requirements.

The internal auditor should have the following control objectives when auditing the procure-to-pay (P2P) cycle in the pharmaceutical industry:

Authorization and Approval: Ensure that the requisition and PO are authorized and approved by relevant departments before proceeding with the purchase. The auditor should verify that the approval process aligns with company policies and procedures.

Supplier Selection: Verify that the selection of vendors is based on objective criteria such as price, quality and delivery time. The auditor should also ensure that the vendor selection process is fair and transparent.

Organizations need to select reputable and ethical suppliers. A reputable supplier has an excellent track record of delivering goods and services on time and at a reasonable price. By selecting a reputable supplier, organizations can minimize the risks associated with procurement.

Use multiple suppliers: Dependency on a single supplier can create organizational risks. For instance, if the supplier cannot deliver the goods or services on time, the organization may be forced to purchase them from another supplier at a higher price. To avoid this, organizations should use multiple suppliers for their procurement needs. This will help ensure the organization has a backup plan if one supplier cannot meet its obligations.

Contract Management: Ensure the contract's terms and conditions align with company policies and procedures. The auditor should also verify that the contract includes clauses for service level agreements, quality standards and penalties for non-compliance.

Inventory Management: Ensure an accurate inventory of goods and services is maintained. The auditor should verify that the inventory system is regularly updated and reconciled with purchase orders, invoices and delivery notes.

Goods and Services Receipt: Verify that the receiving department matches the goods or services received with the PO and that any discrepancies are reported to the purchasing department. The auditor should also ensure that the receiving department thoroughly inspects the goods or services received.

Supplier performance: A process should be in place to periodically evaluate the performance of all suppliers. Various factors should be included in the evaluation criteria, such as quality, on-time delivery, service, contract compliance, responsiveness and Total Cost of Ownership (TCO). Any instances of non-performance should be noted in the information systems for future reference and reviewed during contract renewal.

Invoice Processing: Verify that invoices received are accurate and match the PO and goods or services received. The auditor should also ensure that the accounts payable department perform a three-way match between the PO, invoice and goods or services received.

Payment: Verify that payments are made on time and in line with the payment terms agreed upon in the PO. The auditor should also ensure that payments are made through authorized modes and that the payment process is secure.

Reconciliation: Verify that accounts are reconciled regularly to ensure no discrepancies. The auditor should also ensure that the accounts payable department maintains accurate and complete records of all transactions.

Implement effective controls throughout the process: Controls such as segregation of duties, approvals and reviews can help mitigate procurement risks. By implementing these controls, organizations can ensure the process is conducted fairly and transparently. For instance, if the organization requires approval from multiple individuals for each purchase, it can reduce the chances of fraud or corruption.

Procure to Pay (P2P)

The following table gives a brief description of various activities, control objectives and key controls in procurement to pay cycle:

Sr. No.	Activity	Risk	Control objective	Key Controls
A.	**Production and Material Requirement Planning and Procurement**			
a	Material Purchase Requisition	Material may be procured at high rates as compared to market rates	Ensure the best quote selection for materials to be procured	A quote comparison process should be built into the system to ensure the best quote selection for procuring materials.
b	Trade Payables	Excess Material or	Ensure that the materials	Material requirement

Sr. No.	Activity	Risk	Control objective	Key Controls
		incorrect material may be ordered, which may cause inventory build-up	are ordered in the correct quantity and specifications, received, inspected and stored properly to prevent excess inventory, reduce storage costs and minimize the risk of obsolete or expired inventory.	planning should be based on sales forecasts, production planning and inventory levels. The organization should implement key controls such as procurement policies and procedures, purchase order verification, inspection of goods received, inventory management and supplier performance evaluation.
c	Purchase Order generation and approval	Material ordered without approval from the Sourcing head; excess material ordered	Ensure that procurement decisions are made by authorized personnel and that materials are ordered per pre-approved purchase orders, contracts, or supplier	The organization should implement key controls such as procurement policies and procedures, authorization and approval processes, purchase order verification, contract management and procurement audit.

Sr. No.	Activity	Risk	Control objective	Key Controls
			agreements.	
d	Quality Check of Material Received	Sub Standard material may be allowed. Quality check is not carried out or recorded	Ensure that only materials that meet the organization's quality standards are accepted and any sub-standard materials are identified and rejected	The organization should implement key controls such as a quality management system that outlines the standards and procedures for purchasing materials, supplier selection and evaluation to ensure that suppliers have established quality control processes in place, regular quality checks at every stage of the procurement process and clear documentation of all quality-related information.
e	Receipt of material at Factory	No records / Inadequate records may be maintained for keeping track of goods received	Ensure that accurate records are maintained for all goods received and that the receipt of goods is	The organization should implement key controls such as establishing receiving procedures that require all goods to be properly documented,

Sr. No.	Activity	Risk	Control objective	Key Controls
			properly documented.	regular reconciliation of goods received with purchase orders, invoices and packing slips, clear documentation of any discrepancies and the use of an automated inventory management system.
B.	**Trade Payables**			
a	Recording Payables	Goods received by, or services rendered to, the entity are: 1. Not recorded in trade payables or other expenses 2. Recorded at the incorrect amount.	Ensure that all goods received and services rendered are properly recorded in the organization's financial records.	To achieve this objective, the organization should implement key controls such as the establishment and maintenance of procurement policies and procedures that outline the standards and requirements for recording expenses, the use of a centralized procurement system that captures all

Sr. No.	Activity	Risk	Control objective	Key Controls
				purchases, regular reconciliation of purchase orders, invoices and receipts and the implementation of an automated accounts payable system. Periodically, finance personnel should review, open purchase orders and record other expenses and accrued payables for goods received or services rendered for which a completed service order or vendor invoice has not been received
		Inventory and trade payables are recorded before receipt and/or title transfer of the inventory.	Ensure that all inventory and trade payables are accurately recorded in the organization's financial records.	The organization should implement key controls such as establishing clear policies and procedures that outline the requirements for recording inventory and trade payables,

Sr. No.	Activity	Risk	Control objective	Key Controls
				implementing an automated inventory management system that tracks inventory receipt and transfer and regular reconciliation of inventory records with physical inventory counts. Additionally, the organization should ensure that all trade payables are properly documented and verified before recording them in the financial records.
b	Recording Disbursements	Cash disbursements are: 1. Not recorded 2. Recorded in the general ledger when no cash disbursement has been made 3. Recorded	Ensure that all cash disbursements are accurately recorded in the organization's financial records.	The organization should implement key controls such as the segregation of duties between the personnel responsible for authorizing, recording and disbursing cash, the establishment of clear policies and procedures

Sr. No.	Activity	Risk	Control objective	Key Controls
		at the incorrect amount		that outline the requirements for recording cash disbursements and the implementation of an automated cash disbursement system that records all transactions in real-time. Additionally, the organization should regularly reconcile bank statements with cash disbursement records to detect discrepancies and ensure the accuracy of recorded transactions.
		BRS are not reconciled regularly	Ensure accurate and complete financial reporting	To achieve this, an organization should establish clear policies and procedures for preparing and reviewing bank reconciliations, ensuring segregation of duties between those responsible

Sr. No.	Activity	Risk	Control objective	Key Controls
				for the process and the custody of the organization's bank accounts. Regular reconciliations should be conducted for all bank accounts, including checking, savings and investment accounts and any differences should be identified, investigated and adjusted as necessary.
c	Recording Debit Memos	Inventory returned to suppliers is: 1. Not removed from the inventory and trade payables records 2. Recorded at the incorrect amount	Ensure accurate recording of inventory and trade payables to prevent any mistakes in financial statements and improve the accuracy and completeness of financial reporting.	Organizations should establish clear policies and procedures for recording returned inventory, including documentation requirements and reconciliation frequency. The organization should also ensure that all returned inventory is removed from the inventory and

Sr. No.	Activity	Risk	Control objective	Key Controls
				trade payable records and recorded at the correct amount. The personnel responsible for the process should differ from those responsible for inventory custody.
d	Recording Payables	The trade payables balance includes amounts due to unauthorized vendors	Ensure accurate and complete financial reporting	Organizations should establish clear policies and procedures for the selection and approval of vendors, including appropriate due diligence and verification of vendor information. The organization should also implement appropriate segregation of duties between those responsible for the vendor selection and approval process and those responsible for processing

Sr. No.	Activity	Risk	Control objective	Key Controls
				payments. All vendor invoices should be reviewed and verified for accuracy and legitimacy before being approved for payment and any discrepancies or suspicious activity should be investigated and resolved.
		Foreign trade payables are translated using an incorrect foreign exchange rate.	Ensure that foreign currency transactions are accurately recorded and translated and prevent any misstatement in financial statements.	An organization should establish clear policies and procedures for foreign currency translation, including appropriate guidance on selecting foreign exchange rates for translation. The organization should ensure that foreign currency transactions are recorded accurately and timely and that all applicable foreign exchange rates

Sr. No.	Activity	Risk	Control objective	Key Controls
				are obtained from reliable sources. All foreign currency transactions and translations should be reviewed and verified for accuracy and any discrepancies or errors should be investigated and resolved.
e	Discount negotiations	Volume or purchase discounts from suppliers are recorded in improper accounts (e.g., cost of sales, inventory) or at incorrect amounts.	Ensure that all discounts are accurately recorded, classified and allocated to the appropriate accounts to prevent any misstatement in financial statements.	Organizations should establish clear policies and procedures for accounting for volume or purchase discounts, including guidance on the appropriate accounts for recording such discounts. The organization should ensure that all discounts are properly authorized, supported by appropriate documentation and recorded promptly

Sr. No.	Activity	Risk	Control objective	Key Controls
				and accurately. All discounts should be reviewed and verified for accuracy and legitimacy before being approved for recording and any discrepancies or suspicious activity should be investigated and resolved.

Order-to-Cash Process in the Pharmaceutical Industry (O2C/OTC)

The pharmaceutical company's Order-to-Cash (O2C) cycle encompasses the entire process from receiving an order to collecting payment. It plays a crucial role in ensuring smooth and efficient operations. It involves multiple stakeholders, including sales and marketing, distribution, production, procurement and finance. Furthermore, O2C collaborates with quality control and regulatory compliance teams to enforce proper pharmaceutical product handling, storage and rotation.

It also holds leverage and responsibility in effectively managing inventory at each location to prevent working capital blockage. Moreover, it plays a critical role in reducing or avoiding product expiries, which can result in substantial financial losses for the organization.

To understand the O2C cycle better, let us understand the Ecosystem and Distribution model in the pharma industry:

Pharmaceutical Distribution: Drug distribution in India has witnessed a paradigm shift. Before 1990, pharmaceutical companies established their depots and warehouses. Now they have been replaced by clearing and forwarding agents (CFAs).

CFAs: Clearing and forwarding agents (CFAs) majorly help manufacturers/pharma companies provide reach for their products in the market. The CFAs are Custodians of Stocks as agents, Logistics service providers, storing and distributing products to Stockists for pharmaceutical companies. They maintain warehouses and transportation infrastructure. The transfer of goods from manufacturer to CFAs is on a goods transfer note and it's not the transfer of ownership, hence not recognized as sales in the books of manufacture. Based on the demand for products, CFA/Company mutually decides on how many Stockists to be maintained in CFAs jurisdiction. Most companies keep 1–3 CFAs in each Indian state. A company with PAN India distribution may work with 25–35 CFAs. The company pays the CFAs commission based on the percentage of the total turnover of products in its jurisdiction.

CSA (Clearing and Settlement Agent): Acts as an intermediary for financial transactions settlement between Stockists and pharmaceutical companies.

Super-stockists: Distributors purchasing products in bulk from pharmaceutical companies. Supplies products to Stockists or retailers, ensuring timely availability.

Stockist: Receives products from Super-stockists or pharmaceutical companies. Manages inventory, processes customer orders and distributes products to retailers. Stockist is the distributor of the pharmaceutical company, who can simultaneously handle more than one company (usually, 5–15 depending on the city area) and may go up to even 30–50 different manufacturers. They directly raise purchase orders in the pharma company's name and pay for the products in the pharmaceutical company's name; the logistics and distribution are done through CFAs.

Retail: End customers (pharmacies, medical stores) selling pharmaceutical products to patients or consumers. The retail pharmacy obtains products from the stockist or sub-stockist through whom it finally reaches the consumers (patients/Hospitals/Institutions etc.). They procure stock from the Stockists registered in the Association of Druggists and Stockists in India (AIOCD); manufacturers would not sell their products directly to retail chains or retailers.

Logistics are managed through cost-effective means at the central level by the pharma company. The distribution cost from the manufacturing plant to

the manufacturer bears the stockist. Price to Stockist (PTS) and Price to Retailers (PTR) are the terms used in the industry and revenue recognition at manufactures and stockist books, respectively.

Institutional Supplies

Institutional supplies are approximately 7% of the total drug sales in India. Distribution for institutions (divided into state-funded, centrally funded & large hospitals) happens through stockists or directly from the company CFAs. Companies bid for the tenders passed by these institutions like central PSUs (Public Sector Units), including NTPC, BHEL, etc.

Replenishment Model vs. Forecasting Model

For planning the distribution of drugs, Indian companies follow two models, 1) the Replenishment model and 2) the Forecast-based model.

Product sales are monitored daily from the supply nodes and based on the demand and availability; products are supplied in the replenishment model. In a forecast-based model, sales are forecasted based on the previous sales and the plan for the current year and then products are supplied periodically.

The replenishment model has disadvantages in tracking daily sales, inventory and frequent supplies. A forecasting-based model will work best for the company as sending the stock once a month or fortnight based on the stockist inventory will be much easier.

The main advantage of the replenishment model is that the retailer and the Stockists will be happy since their inventory space is saved and they can accommodate products from many different companies.

Sales Classification: Primary Sales: Initial sales from pharmaceutical companies to Stockists or Super-stockists.

Secondary Sales: Subsequent sales from Stockists, Super-stockists, or retailers to end customers.

Here is an overview of the OTC process in the pharmaceutical industry, including its key sub-processes, Activities and the role of stakeholders:

Sub Process	Activity	Primary Responsibility	Secondary Responsibility
Customer Master	Identification of Distribution Gap	Sales & Marketing	Distribution

Sub Process	Activity	Primary Responsibility	Secondary Responsibility
Maintenance & Credit Approval	Identification of potential Stockiest	Sales & Marketing	Distribution
	Evaluation of Potential Stockiest	Distribution	Sales & Marketing
	Collection of New Stockiest Documentation	Sales & Marketing	Distribution
	Stockiest File Creation	Distribution	-
	Stockiest Credit Limit Management	Sales & Marketing	Distribution
	Customer (Stockiest) Master Maintenance	Distribution	-
	Customer Master Review	Distribution	-
	Stockiest Discontinuation	Distribution	Sales & Marketing
	Credit Hold/ Extension	Distribution	-
	New Stockiest Credit Limit - Annual Review	Distribution	-
Inventory Movement (routine efforts of Distribution)	Ascertainment of Location-wise Inventory Requirements for Shipment	Sales & Marketing	Distribution
	CFA-wise Inventory Allocation Planning	Distribution	-
	Movement of Inventory to locations	Distribution	-
	Receipt of Inventory at Location	CFA	Distribution
Order Processing, Invoicing &	Order Receipt	CFA	Distribution
	Order Processing	CFA /Sales and Marketing	Distribution

Sub Process	Activity	Primary Responsibility	Secondary Responsibility
Despatch	Invoicing & Despatch of Orders	CFA	Distribution
	Cancellation / Closure of Sales Order	CFA	Distribution
	Processing of Request for Sample	Sales & Marketing	Distribution
	Goods in Transit	Management	Distribution
	Sales Cut-off	Management	Finance
Receivables Management	Collection Processing	CFA	Distribution
	Cheque Dishonour related Follow up	Finance	Distribution
	Review & follow up on Customer Dues	Distribution	CFA / Sales
	Balance Confirmation & Reconciliation	Finance	Distribution
	Provisioning & Write Off of Bad Debts	Management / Finance	Distribution
Sales Return Management	Return from Customers	CFA	Distribution
	CFA Activities upon receipt	CFA	Distribution
	Approval of Return Claim and Issue of Credit Note	Distribution	CFA
Physical Verification of Inventory at CFA	Physical Verification	CFA	Distribution
	Reconciliation with Books	CFA	Distribution
	Adjustment in Books	Distribution	-
	Updating of ERP for short expiry/expiry	Distribution	-
Expiry Management	Physical Verification of Expired Inventory at CFA	Distribution	-

Sub Process	Activity	Primary Responsibility	Secondary Responsibility
	Despatch to CWH	CFA	Distribution
	Receipt at Central Warehouse	CWH Stores In charge	Distribution
	Destruction	CWH Stores In charge	Distribution
CFA Expense Management	Commission	Finance	Distribution
	Freight Claim	Distribution	Finance

Potential Risks in the Order-to-Cash (O2C) Process in the Pharmaceutical Industry

Inaccurate Customer Master Data: Incorrect customer information or credit terms can lead to billing errors, delayed payments and disputes.

Sales Order Errors: Incorrect order details, pricing, or product quantities can result in delivery delays, customer dissatisfaction and revenue leakage.

Non-compliance with Regulatory Requirements: Failure to comply with pharmaceutical regulations, labeling requirements and drug distribution laws can result in legal and regulatory penalties.

Inventory Management Issues: Inaccurate inventory records, stockouts, or excess inventory can lead to customer dissatisfaction, revenue loss and increased carrying costs.

Credit and Receivables Management: Non-payment or delayed payment by customers can impact cash flow and increase bad debt risk.

Sales Returns and Expiry Management: Inadequate management of sales returns and expired products can result in financial losses and regulatory non-compliance.

Non-compliance with Anti-Bribery and Corruption Laws: Engagement in unethical practices, bribery, or corruption can lead to legal consequences and damage the company's reputation.

Distribution Risk: Issues in the distribution network can lead to delays in product delivery, stockouts, or incorrect order fulfilment, impacting customer satisfaction and revenue.

Logistics Risk: Inefficient logistics operations can result in transportation delays, product damage, or loss, affecting order fulfilment and customer service.

Scheme and Discounts Risk: Inadequate control over promotional schemes and discounts can result in revenue leakage, incorrect pricing and potential misuse.

Breakage and Pilferage: Breakage (damage during handling) and pilferage (theft or loss) of pharmaceutical products can lead to financial losses and inventory discrepancies.

Insurance Risk: Insufficient insurance coverage for pharmaceutical products can lead to financial losses in case of damage, theft, or other unforeseen events.

Expiry Risk: Inadequate expiry management can lead to the sale or use of expired pharmaceutical products, resulting in potential harm to patients and regulatory non-compliance. Inappropriate sales and distribution planning may lead to the expiry of products.

Storage Risk and Temperature Control: Inadequate storage conditions and temperature control can compromise pharmaceutical products' quality, potency and stability.

Inventory Management and Expiry Reduction Process

Below are Key performance matrices which can help in "Inventory Management and Expiry Reduction Process":

Participants: Sales & Marketing, Distribution, Production, Procurement and Finance

Description	Input	Output	Key Performance metrics
To **reduce the high inventory coverage** and improve the production plan, processes need to be defined and	SKU-wise demand forecasting by the sales team • Production plan for the	• Approval of production plan based on the current inventory levels and the inventory to be	Sales forecast accuracy for the previous month • Existing Inventory levels

Description	Input	Output	Key Performance metrics
implemented; Key metrics need to be monitored periodically	month • Existing SKU Stock levels • Last 6-month SKU sales • Forecasting accuracy of previous months • Machine Availability • Maintenance Schedules • Product-wise/SKU-wise manufacturing lead times • Material Lead Times	maintained • Approval plan Procurement plan based on the current inventory levels and the inventory to be maintained	• Forecasted inventory levels • Expiry % 1. SKU wise 2. Region wise 3. Stockist wise • Average Months taken for the batch to be sold out • On time In Full Delivery (Service levels)
The process needs to be **implemented for the sales team to identify the stock nearing expiries**, discuss the **solutions to liquidate** the same stock and initiate inventory transfer from one stockist to	Inventory Analysis of the stockist every month to identify • Slow moving inventory • Near to expiry inventory • Inventory lying with stockist for more than six months	Discuss the following points with the stockiest during monthly interactions: Plan to liquidate the slow-moving stocks • Support required to liquidate the slowing-moving stocks	Plan to liquidate the slow-moving stocks • Support required to liquidate the slowing-moving stocks • Assess the demand for the product in the market • If the stockist

Description	Input	Output	Key Performance metrics
another		• Assess the demand for the product in the market	is unable to liquidate the slow-moving SKU, analyse the demand for the same SKUs with another stockist in the region and transfer the stock to another stockist who can liquidate the stock in the market
The sales team needs to Identify the SKUs with **high expiry by region and by stockists** each quarter, Reduce the supply order size, or block specific SKUs to stockists facing high expiries	• Identify the SKUs with a Higher expiry ratio. • Identify the regions / cities with higher expiry ratio of the SKUs shortlisted in step 1 • Identify whether all the expiry ratio is higher in the case of all Stockists If	• All stockists in the city/region facing high expiries in select SKUs • Few stockists in the city/region facing high expiries in select SKUs	Few stockists in the city/region facing high expiries in select SKUs • Identify the reasons for low demand in the region/city • Keep minimum inventory in respective CFAs to cater to emergency demands • Block the SKU

Description	Input	Output	Key Performance metrics
	step 3 is not the case, • identify stockists with higher expiry ratio as compared to other stockists • Analyse inputs the reasons for high expiry		or reduce the order size for all stockists for at least three months or till the stockist places the order • Block the SKU or reduce the order size for stockist with higher expiry for at least three months or till the stockist places the order

Key Controls in Order to Cash (O2C) Process

The following table gives a brief description of various activities, control objectives and key controls in order to cash cycle:

Sr. No.	Activity	Risk	Control objective	Key Controls
1	**Revenue from operations**			
a	**Appointment of Stockist/ CFAs**	Agreements with Customer: 1. Onboarding of Stockist without an adequate requisition from	To ensure proper onboarding of stockists and timely execution of stockist agreements in	Ensure onboarding of stockists is supported by adequate requisition from sales and execute stockist

Sr. No.	Activity	Risk	Control objective	Key Controls
		Sales 2. Stockist Agreements are executed after Invoicing for the new Stockists	alignment with sales processes and invoicing	agreements before invoicing for new stockists.
		Stockist Master: 1. Stockist Master is created without adequate documentation 2. Master data does not remain pertinent	To ensure the accurate and relevant creation and maintenance of stockist master data.	Create stockist masters with adequate documentation and regularly review and update the data to ensure accuracy and relevance.
b	**Recording of Sales**	Sales and trade receivables recorded: • do not relate to valid sales/ dispatches • At the incorrect amount • In the incorrect period.	Ensure accurate sales and trade receivables are recorded, including valid sales/dispatches, correct amounts and proper period allocation.	Validate sales and trade receivables for validity, accuracy of amounts and correct period allocation
		Goods are	Ensure that	Ensure goods are

Sr. No.	Activity	Risk	Control objective	Key Controls
		dispatched to customers without invoicing or recording thereof.	goods dispatched to customers are properly invoiced and recorded in the system.	not dispatched to customers without proper invoicing or recording by implementing controls that mandate creating and approving invoices before release and conducting regular reconciliations between orders and invoices.
		Sales are not classified appropriately as per Schedule III of the Companies Act, 2013	To ensure proper classification of sales as per Schedule III of the Companies Act, 2013	Ensure sales are appropriately classified as per Schedule III of the Companies Act, 2013 through clear guidelines, review and approval processes and cut off procedures are considered revenue recognition.
		Customer Credit Limit: Invoicing is done to the customer	Ensure invoicing is done per customer credit limits and only for authorized	Establish a control process to monitor customer credit limits before invoicing. Conduct periodic

Sr. No.	Activity	Risk	Control objective	Key Controls
		without considering the Credit Limits assigned to them. Invoices are issued and recorded for dispatches to non-customer offsite locations.	customer locations.	reviews of customer credit limits to ensure their accuracy and appropriateness. Implement controls to verify and authorize non-customer offsite locations before issuing invoices.
c	**Sales Returns and Credit Memos**	Goods returned are noted in the Sales Return by the CFA after receiving goods. CFA physically checks the material received with the Invoice (with Batch and whether any scheme was applied).	To ensure accurate recording and processing of sales returns and credit notes for goods returned by customers	Implement a control process where the CFA verifies returned goods against the original invoice, fills out a Sales Return capturing relevant details and establishes monitoring at the Head Office to review and authorize credit notes, ensuring accurate recording and processing of sales returns.
		The Claims for Sales Returns are checked at	To ensure accurate verification and	Implement a control process where the CFA

Sr. No.	Activity	Risk	Control objective	Key Controls
		the receipt location and the CFA verifies the receipt of goods. After proper Batch verification and confirmation of the Invoice rate (PTS/ Discounted), the accounting is done and credits are passed on.	processing of claims for sales returns, including batch verification, invoice rate confirmation and proper accounting of credits.	performs verification of sales return claims at the receipt location. This involves checking the returned goods, verifying the batch details and confirming the invoice rate (PTS/Discounted) . Accounting for the sales returns and passing on credits should only be done after the proper batch verification and confirmation of the invoice rate.
		The Credit Note review and approval mechanism is based on the Batch reference, so the Invoice is appropriately mapped against the Credit Note.	To ensure proper review and approval of credit notes by mapping them appropriately to the corresponding invoice based on the batch reference.	Implement a control mechanism where the review and approval of credit notes are based on batch reference. This involves cross-referencing the credit note with the corresponding invoice to ensure

Sr. No.	Activity	Risk	Control objective	Key Controls
				accurate mapping. The review process should include verifying the batch details to ensure consistency between the credit note and the original invoice.
		The promotional rates are approved and accordingly, the Sales Order is prepared at the discounted rate itself.	To ensure proper approval and implementation of promotional rates for a defined timeframe, accurate entry of discounted rates in the system and automatic restoration of pre-scheme prices after the promotional period.	Implement a control mechanism where promotional rates are approved, entered accurately in the system and automatically restored to pre-scheme prices after the defined timeframe. This ensures proper authorization, accurate system configuration and timely restoration of prices.
		The Credit Note review and approval	To ensure the accurate capture of	Implement a control process where credit

Sr. No.	Activity	Risk	Control objective	Key Controls
		mechanism is based on the Invoice and Batch matching reference so that the Invoice rate is appropriately captured during the generation of the Credit Note.	invoice rates in credit notes by implementing a review and approval mechanism based on invoice and batch-matching references.	notes are reviewed and approved based on matching the invoice and batch references. The review process should include validating the batch details and confirming that the credit note captures the correct rate from the original invoice.
		The Management estimates the expiry returns based on business judgment and the past trend of expiries and returns quarterly and provides for the same accordingly.	To ensure accurate estimation and provision for expiry returns based on business judgment and historical trends	Implement a control process where the management performs quarterly estimation and provision for expiry returns. This involves utilizing business judgment and considering past trends of expiries and returns to arrive at a reasonable estimate. The control

Sr. No.	Activity	Risk	Control objective	Key Controls
				mechanism should include thorough analysis, documentation and review of relevant data and factors influencing expiry returns.
		Provision for Sales Returns is recorded periodically based on the percentage derived by the Management estimates.	To ensure accurate recording of sales return provisions based on percentage estimates derived by management.	Implement a control process where provisions for sales returns are recorded based on management's estimated percentage. This involves documenting the estimation methodology, reviewing and approving the provision calculation and monitoring actual returns for adjustments as needed.
2	**Trade Receivables**			
a	**Recording of Trade**	Goods or services	To ensure accurate	Perform regular reconciliations

Sr. No.	Activity	Risk	Control objective	Key Controls
	receivables	rendered to the entity are: • Not recorded in trade receivables • Recorded at the incorrect amount	recording of goods or services rendered to the entity in trade receivables, with correct amounts.	between sales records and trade receivables to identify and address any discrepancies
b	**Provision for doubtful trade receivables**	At each quarter end, the Distribution Team reviews the Accounts Receivable ageing before sharing it with the finance team.	To ensure the accuracy and reliability of the Accounts Receivable ageing report by implementing a review process conducted by the Distribution Team before sharing with the finance team at each quarter end.	The Distribution Team should review the report, verifying the accuracy and completeness of the customer account balances, ageing categories and overall data integrity.
		The Distribution Team identifies old non – recoverable dues on a case-to-case basis and the same is intimated to the	To identify and address old non-recoverable dues	The distribution head should assess the collectability of these dues based on factors such as customer communication, ageing and historical

Sr. No.	Activity	Risk	Control objective	Key Controls
		Finance Team.		payment patterns.
c	**Recoveries of Trade receivable**	Recoveries of trade receivables previously written off are improperly recorded in the Statement of Profit and Loss.	To ensure proper recording of recoveries of trade receivables previously written off in the Statement of Profit and Loss	Establish clear approval procedures and documentation for write-offs, monitor and track written-off receivables, identify and record recoveries accurately and conduct regular reconciliations and reviews to validate the recorded amounts.

Hire to Retire

The hire-to-retire process, or the employee lifecycle, encompasses all the stages an individual goes through during their employment with an organization, from the initial hiring to their retirement or separation from the company. Here's a detailed breakdown of each phase:

Manpower Planning & Budgeting: Manpower planning and budgeting involve forecasting and allocating resources to efficiently meet the organization's workforce needs. It includes analysing staffing requirements, determining the optimal number of employees, developing hiring plans and budgeting for recruitment, training and development.

Recruitment and Selection: The recruitment and selection process involve identifying hiring needs, creating job descriptions, sourcing candidates through various channels, screening applications, conducting interviews, assessing candidate skills and performing reference and background checks to select the most qualified candidate for the job ultimately.

Onboarding: Onboarding integrates new employees into an organization, including paperwork, training, introductions and setting performance expectations.

Performance Management: Performance management is setting goals, evaluating performance, providing feedback and fostering employee development.

Compensation and Benefits: Compensation and benefits involve the financial and non-financial rewards provided to employees for their work and include salary, bonuses, health insurance, retirement plans and other perks

Payroll Processing: Collecting and verifying employee time and attendance data, calculating gross and net pay, withholding taxes, processing deductions for benefits or garnishments and issuing pay-checks or direct deposits.

Statutory Dues: Statutory deductions include income tax, social security contributions and retirement fund contributions, as well as compliance with labour laws related to minimum wages, overtime pay and employee benefits. Ensuring timely and accurate payment of these statutory dues is crucial to maintaining legal compliance and fulfilling the organization's obligations towards its employees.

Employee Engagement and Retention: Employee engagement and retention are strategies to create a positive work environment, boost employee satisfaction and retain top talent. It involves fostering open communication, providing growth opportunities, recognizing achievements and addressing employee concerns.

Career Development and Training: Career development and training focus on enhancing employee skills, knowledge and growth through programs, training initiatives and opportunities for advancement within the organization.

Separation and Retirement: Separation and retirement refer to the processes involved when an employee leaves the organization voluntarily or reaches the end of their career. It includes activities such as conducting exit interviews, processing necessary paperwork, transitioning responsibilities and supporting retirement planning.

Organizations should comply with relevant labour laws throughout the hire-to-retire process, maintain accurate employee records and prioritize employee well-being and satisfaction to create a positive and productive work environment.

PLANNING

Workforce Planning	Travel Budget Planning	Project Planning
Organization generates a plan by modelling the demand for talent	Budgets are planned and assigned	Individual project planners identify needs

STAFFING

Source contingent workers	Recruit new hires	Identify internal hires
Open requisitions, create a PO, work with suppliers	Open requisitions, find candidates, make offers	Search for existing resources with the required skills

ONBOARDING

Complete paperwork and receive equipment	Receive training, meet team members and so on

WORKING

Monitor deliverables, costs (including travel) and margins and close quarter end	Deliver ongoing training and development	Provide feedback and complete ongoing skills assessments	Submit and approve timesheets	Approve expenses: Request, book, travel, capture receipts and monitor against policies

PAYING

Pay internal employees through payroll and reimburse for travel	Process invoices from suppliers for contingent workers and travel agencies; pay corporate cards

STAFFING

Offboard internal and external resources	Submit final time and expenses and close impact	Update financial statements and make corrections as needed

Potential Risks in a Hire to Retire process

Risk management in HR means assessing and dealing with the potential risks of having a workforce. These risks are related to how you hire, retain and manage employees and other types of workers and employee behaviour.

1. **Workforce risks:** Employee turnover, employee burnout, employee relations, workplace conflict and harassment and lack of employee engagement can negatively impact the company and prevent it from thriving.

2. **Employee data management:** Cybersecurity and data privacy are crucial responsibilities for every organization. Security breaches or misuse of personal information can leave companies vulnerable to lawsuits and brand damage.

3. **Compliance:** Human Resources activities and policies must align with many laws and regulations across states and countries. Laws related to equal employment opportunity, labor laws, wage and hour regulations, employee classification, data privacy and other legal requirements.

4. **Compensation and Benefits Risk:** Errors in payroll processing, inaccurate calculation of wages, or non-compliance with tax and benefits regulations can result in financial losses, employee dissatisfaction and potential legal consequences.

5. **Training and Development Risk:** Insufficient employee training and development investment can result in skill gaps, outdated knowledge and

decreased employee performance. This can hinder organizational growth and limit competitiveness.

6. Separation and Retirement Risk: Mishandling employee separations and retirements can lead to legal disputes, improper payments and a negative impact on employee morale and reputation.

Staff Well-being and Talent Management

Insufficient measures for staff Well-being and Talent Management lead to risks such as - Inadequate mental health and safety policies, poor communication and management practices, limited participation in decision-making or low control over one's area of work, low levels of support for employees, inflexible working hours, unclear tasks or organizational objectives, workplace discrimination, employee unrest and field force protest.

1. Storage of Critical Skills: Not having the right talent with the expertise and proficiency required to compete, grow, or innovate can severely hamper a company's future.

2. Behaviour and Ethics: The topmost risk for a business is an ethical violation. It is advisable to draft a code of conduct by establishing an ethics panel or community in the organisation.

3. Misuse or Loss of Intellectual Property: If your business deals with sensitive information, which can be misused or losing employee data (e.g., compensation details) can hurt your business.

4. Mergers & Acquisitions (M&A) Risks: Many risks pertaining to M&A can backfire on HR in the long run. Any risks or threats related to employment law, diligence, etc., would bounce back to the human resource department.

5. Regulation and Compliance: Violating any regulatory or statutory compliance could cost your entire business. Again, it all comes down to processes and policies.

HR Risk Management Techniques

- HR Risk Mitigation Checklist
- Complying with Rules and Regulations
- Develop a Risk Management Strategy
- Stay Updated with the Legal Guidelines

- Initiate Training
- Respond to Significant Circumstances
- Monitoring & Evaluation
- Quick action
- Review

Control Objective from Internal Audit Perspective – Hire to Retire Process

From an internal audit perspective, the following control objectives are typically relevant for the hire-to-retire process:

1. Compliance: Ensure compliance with applicable employment laws, regulations and internal policies throughout the hire-to-retire process.

2. Recruitment and Selection: Verify that recruitment and selection processes are fair, objective and aligned with equal employment opportunity principles.

3. Onboarding: Confirm that onboarding procedures are comprehensive and effective, ensuring new employees receive the necessary information, training and support for a smooth transition.

4. Performance Management: Assess the effectiveness and fairness of performance management processes, including goal setting, performance evaluations and feedback mechanisms.

5. Compensation and Benefits: Validate the accuracy and integrity of payroll processing, benefits administration and tax and labour laws compliance.

6. Employee Engagement and Retention: Evaluate initiatives to foster employee engagement, job satisfaction and retention, such as recognition programs, career development opportunities and work-life balance initiatives.

7. Training and Development: Assess the effectiveness of training programs to enhance employee skills and knowledge and ensure alignment with organizational objectives.

8. Separation and Retirement: Verify that separation and retirement processes are properly documented, comply with legal requirements and include appropriate exit interviews and procedures.

9. Data Security and Privacy: Evaluate controls in place to protect employee data, including personal and confidential information, to ensure compliance with data protection and privacy regulations.

10. Record-keeping and Documentation: Ensure accurate and complete record-keeping throughout the hire-to-retire process, including employee files, contracts, performance evaluations and other relevant documentation.

These control objectives help guide internal audit activities in assessing the hire-to-retire process's effectiveness, efficiency and compliance and identify improvement and risk mitigation areas.

HR RISK MANAGEMENT

1	Identify key HR risks within your organization
2	Assess the risks & prioritize your actions
3	Design & implement your solutions by using risk management techniques
4	Set up a continuous HR risk monitoring process
5	Strengthen the risk management skills within your team

Key Controls in Hire to Retire Cycle

The following table gives a brief description of various activities, control objectives and key controls in hire to retire cycle:

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
1	Manpower Budget and Monitoring	1. Excess Manpower cost 2. Absence of manpower planning leading to unauthorized recruitment	1. To restrict excess cost on manpower 2. Manpower budgets are prepared and approved	Annual budgeted department-wise manpower requirements (in terms of count and other costs) should be fixed and approved by the Management after considering the existing manpower, additional requirements due to new projects/expansion and estimated separations during the year.
2	Employee Master	Fictitious/ 'Ghost'/ Duplicate/ Dummy employee creation leading to fictitious payroll disbursals/ Unauthorized salary processing	To maintain a database of employee	Employee master should be created with a compensation structure in the system by the HR department based on an approved Appointment Letter and verified by the Payroll department.
3	Employee	Unauthorized	Authorized	Any amendment to

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	Master	changes to the employee master lead to salary manipulation.	access to the database	the employee master (Retirement / Resignation / Confirmations / Increments / Transfers / Promotions / etc.) should be done only on approval of the Administrative Director by the HR department and verified by the Payroll department.
4	Recruitment	Inadequate personal information and documentation impact the sourcing of the right candidates.	To ensure receipt of all required documents.	A standard checklist of documents to be obtained from employees is defined and documents are collected with verification of 'Original copies'. Track of pending documents is kept and followed up with the employees.
5	Recruitment	The absence of formal acknowledgement of an Appointment Letter from employees may	To obtain confirmation from new joiners	An appointment letter with appropriate employment clauses (such as the structure of remuneration, date

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		lead to disputes.		of joining, designation, confidentiality clause, etc.) and reference to adherence to the company's personnel policies are issued to the candidate and acceptance is obtained.
6	Performance Appraisal / Confirmations/ Increment / Promotions / Transfer	Incorrect increment/ promotions/ transfer	To ensure increment/ transfer/ promotions as per policy and appropriate approvals	Increment/Promotion letters are issued to employees as per the guidelines defined by Business HR and approved as laid down in the Delegation of Authority Manual.
7	Loans and advances	Loans are not approved and authorized as per the policy.	To avoid unapproved loans to employees	Loan applications are duly authorized and sanctioned as per the company's policy.
8	Loans and advances	Non-recovery of outstanding dues from employees	Timely recovery of loans and advances to employees	The loans/advances recovery schedule is updated in the Payroll system by the Payroll department based

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				on the Loans approved by the appropriate authority.
9	Reconciliation of Loans and advances	Inadequate recovery	Timely recovery of loans and advances to employees	Reconciliation of loans and advances as per Payroll software and Books is conducted quarterly and differences are identified/adjusted.
10	Payroll Processing	Inaccurate/incomplete attendance records impacting payroll processing	To ensure an adequate and correct database of attendance for payroll processing.	All employees are mapped through the biometric system and the employees' attendance is captured in the Biometric system based on the entry-exit punching in the office/factory. Attendance is regularized by the employee prior to payroll processing based on the approval of the respective employee reporting Manager.
11	Payroll Processin	Absenteeism without approved leave is not	To ensure the deduction of unapproved/un	Daily attendance is reconciled with approved leave

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	g	deducted	paid leave	records and ensures the deduction of unapproved/unpaid leave from the monthly payroll.
12	Payroll Processing	Absence of maker checker leading to fraud / incorrect payment.	To ensure correct payments	Ensure following checks by Payroll before processing payroll for payments: • Reconciliation of attendance and deduction of unpaid leave • Comparison salary of current month and the previous month • Headcount of the current month and previous month • Contribution to Provident Fund (PF), EDLI, ESIC, Superannuation, etc. • Deduction for Professional Tax / TDS.
13	Payroll Processing	Incorrect salary payments	To restrict unauthorized access	Payroll details are password protected before sending to Accounts

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				Department and the bank for payments.
14	Payroll Processing	The payroll system does not reconcile with General Ledger (GL)	To restrict unauthorized payments	Payroll entries are posted in the system only after Administrative Director and Director-Operation approve Monthly Payroll sheets. HOD verifies accounting entries-Accounts before posting. Reconciliation of payroll processed in the current month vis-a-vis the previous month, gross payroll vis-à-vis the payroll as per Excel sheet with HR is conducted, including headcount. All discrepancies are investigated.
15	Payroll Processing	Excess leave encashment	To avoid excess payment	The Accounts department verifies the calculation of leave encashment before disbursal.

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
16	Payroll Processing	Excess payment of Reward/ incentive and other reimbursements	To ensure correct payment	Reward /incentives and reimbursement are paid to employees as per Appointment Letter/policy prepared by HR and verified by Payroll before disbursal.
17	Provision for Retirement benefits	Incorrect retiral provisions / Non-payment of contribution leading to disallowance of expenditure.	Accounting and contributions for retiral benefits as per Actuarial Valuation.	Provision for Gratuity / Leave Encashment and contribution to LIC for Gratuity / Leave Encashment is made based on Actuarial Valuation Reports every year.
18	Bonus / Ex-Gratia	Excess payment of Bonuses and other variable components and allowances may result in excess manpower cost	To ensure payment of Bonus as per Statutory provisions.	Bonus / ex-gratia is calculated per the limits approved by the management and verified by Payroll before disbursal.
19	Tax Deduction at Source and Proof of Investment	Non-compliance with the statutory requirements	Compliance with Income Tax is ensured	The monthly tax is deducted based on the calculation provided by Accounts and the declaration of investment by the Employee. Non-receipt of proof of

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				investment before the cut-off date is adjusted in tax before year-end.
20	Reconciliation of Salary Payments, Loans and advances	Incorrect/excess payment of salary. Non-recovery of loans	To identify inaccurate payments and take corrective actions	Reconciliation of Salary payable accounts with salary paid is done monthly and approved by General Manager. Inaccurate payments are identified and adjusted in the next month's salary.
21	Final Settlement of Dues	Possible financial loss to the Company	Adherence to HR Policy for Full and Final Settlement cases	The final settlement checklist (including guarantee/Assurances) is approved by all the concerned departments (i.e., sign-off from IT, Accounts, HR, Concerned Director, etc.) to ensure that there are no outstanding dues against the employee. The final settlement amount is verified before disbursal.
22	Final Settlemen	High attrition / low employee	To identify reasons for	Exit interviews of the resigned

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	t of Dues	morale/Actions to control attrition not implemented	separations and to take corrective actions	employees are conducted and reasons are analyzed. Reasons for resignations through exit interviews are recorded for review by the concerned superior.
23	Final Settlemen t of Dues	Excess costs	Recovery on account of non-serving of notice pay	The notice pay period deductions are made per the company's policy and waivers are approved.
24	Final Settlemen t of Dues	Possible financial loss to the Company	Timely settlement of full and final cases	Pending Full and final settlement is periodically reviewed and provision is created for pending Full and final settlement.
25	Final Settlemen t of Dues	Excess /Short payment of retiral benefits leading to non-compliance.	Correct payment of retiral benefits to employees	The amounts payable towards Gratuity / Leave Encashment are computed based on the period served and paid within the period prescribed by the Act after validation by the Accounts

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				department.
26	Final Settlement of Dues	Non-recovery of gratuity from trust leads to losses	Correct accounting of retiral benefits	Gratuity/Leave encashment paid is recovered from the LIC within the timelines. The amount recoverable from the Trust is shown as an asset.
27	Payment to Contractors	Absence of Contract leading to a dispute with the Contractors	To ensure adequate terms for contractors	The labour contract is entered with adequate terms and conditions and vetted by the Legal department.
28	Payment to Contractors	Excess payment	To validate payment to contract employees	In the case of the Labour Supply Contract, the Attendance of each worker is maintained by the User department and reconciled by the HR department with the Gate attendance before processing payment.
29	Payment to Contractors	Payment towards services not availed	To ensure accurate payment to manpower agencies	The invoice is passed only after approval by the respective User Department, Personnel /

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				Accounts Department and compliance towards statutory dues.
30	HR and Payroll MIS	Non-availability of accurate information and delay in information to management	To ensure correct reporting to management.	A standard format of periodic MIS with specific deadlines is defined. HR and payroll activities such as status on budget, open requisitions, recruitments/resignations during the month, TATs, discrepancies in salary computations highlighted by the employees and their status of being resolved, No. Of training conducted, etc., is prepared monthly and submitted to the Management.

Employee Expense Reimbursement

When employees pay for business travel expenses or other work-related expenditures out of their pocket, the employer must pay that back to the employee. This process is known as expense reimbursement.

For instance, when employees go on a business trip, they incur expenses like flight and hotel bookings, meal consumption and daily commute. They

pay for these expenditures out of their pocket, which you must reimburse later.

Here's an overview of how employee reimbursement expenses work in the pharmaceutical industry:

Expense Policy: Pharmaceutical companies typically establish an expense policy that outlines the types of expenses eligible for reimbursement and guidelines for submitting and approving expense claims. The policy ensures consistency and compliance with company guidelines and relevant legal and regulatory requirements.

Eligible Expenses: The expense policy specifies which expenses are eligible for reimbursement. This may include travel expenses for business trips, such as airfare, hotel accommodation, meals, ground transportation and any other necessary expenses incurred. Other eligible expenses may include client entertainment, conference or seminar fees, or office supply purchases made on behalf of the company.

Expense Reporting: Employees must submit expense reports documenting their eligible expenses. The reports typically include details such as date, description, amount and supporting documentation such as receipts, invoices, or tickets. Many companies use digital expense management systems to streamline reporting and ensure accurate record-keeping.

Approval Process: Supervisors or designated approvers review and approve expense reports within the company. Approvers ensure that expenses comply with the company's policy and that supporting documentation is provided. They may also verify the reasonableness and necessity of the expenses.

Reimbursement: Once an expense report is approved, the reimbursement process begins. The employee is reimbursed for the approved expenses, typically through payroll or direct deposit. Reimbursements may be processed regularly, such as monthly or bi-weekly.

Expense Auditing: Pharmaceutical companies often conduct expense audits to ensure compliance and prevent fraud. Auditing helps identify any discrepancies or potential misuse of funds. Auditors review a sample of expense reports to validate the accuracy of claims, verify supporting documentation and ensure adherence to the company's policies and procedures.

Tax Considerations: As hotel accommodation and other travel expenses are a part reimbursement or out-station allowances, If bills are not in the name of the company the company cannot claim input credit for GST even though these expenses are incurred by the company.

Employee reimbursement expenses may have tax implications. In some jurisdictions, certain expenses may be considered taxable income for the employee, while others may be tax-deductible for the employer. Pharmaceutical companies often work with tax advisors to ensure compliance with relevant tax laws and regulations.

Pharmaceutical companies must have clear policies and procedures regarding employee reimbursement expenses to promote transparency, accountability and effective cost management. By properly managing and reimbursing these expenses, companies can support their employees in carrying out their job responsibilities while maintaining financial controls and adherence to regulatory requirements.

Employee Reimbursement Audit Checklist

1. **Determine the Frequency of Audit & Analysis Patterns:** Chart out the expenses claimed by the employees and spread it across months/quarter/year as you may prefer for your trend analysis. Once you have observed increasing trend, pick up samples from those expense claims. It is advisable to review all the expenses and employee claims rather than picking few samples from each employee.

2. **Review he Expenses against Policy:** Ensure that the expenses claimed are in line with the policies & procedures created by the Organisation. Ensure that the policies are updated and are not conflicting or have any gaps that can be used by the employees.

3. **Ensure that the Expenses are for the Employee:** Make sure that the expense claimed is for the employee and does not include personal expenses. In many cases, personal expenses are clubbed with the business expenses and made to look like a business expense that is inside the rule book of the organisation.

4. **Ensure that the Invoices are Original & are in time:** Make sure that the expense claimed has been supported with sufficient & appropriate evidence. Ensure that the invoices are original. Ensure that the

reimbursements are claimed in time as per policy. Always look at the documents with suspicion.

5. IT Controls to match with Policy: Make sure that the IT controls set in the system are in line with the conditions placed in the policy. There is maker-checker designed in the system and the controls are placed for the upper limits for spends, duplicate checks as necessary.

6. Look for Red Flags: Typical red flags to look out for when matching receipts to reports include: the reported purchase does not match the receipt; the requested reimbursement is higher than the amount listed on the receipt; falsifying invoices or receipts and attempting to claim reimbursement for the same purchase multiple times.

Key Controls in Employee Expenses Reimbursement Cycle

The following table gives a brief description of various activities, control objectives and key controls in employee expense reimbursement cycle:

Sr. No.	Activity	Risk	Control objective	Key Controls
1	Expense Claims	Inaccurate or fraudulent expense claims	Ensure accuracy and validity of expense claims	• Expense policy and guidelines • Pre-approval process • Documentation and receipt requirements • Expense review and verification
2	Tax Compliance	Non-compliance with tax and regulatory requirements	Ensure compliance with tax and regulatory obligations	• Tax compliance education and training • Tax documentation and reporting • Expense coding and

Sr. No.	Activity	Risk	Control objective	Key Controls
				classification • Periodic tax compliance review
3	Expense Reimbursement Process	Inadequate control over the expense reimbursement process	Ensure effective control and management of the process	• Segregation of duties • Expense approval hierarchy • Implement an automated expense management system with controls for approval workflows, verification and auditing. • Regular monitoring and reporting
4	Supporting Documentation	Lack of supporting documentation for expense claims	Ensure proper documentation for expense claims	• Document retention policy • Expense report submission deadline • Expense report review
5	Travel Expenses	Insufficient controls over mileage and	Ensure accuracy and appropriate	• Mileage tracking and verification

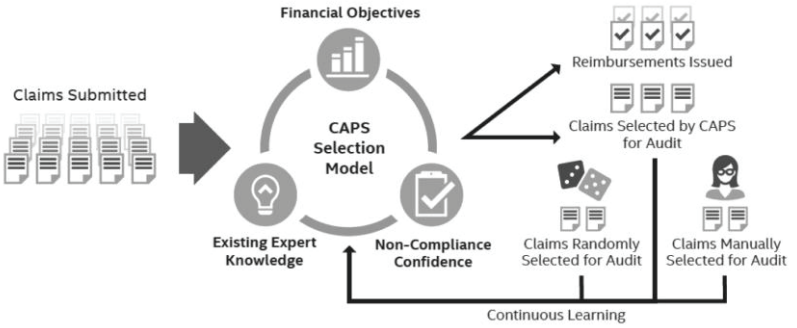
Sr. No.	Activity	Risk	Control objective	Key Controls
		travel expenses	approval for mileage and travel expenses	• Travel authorization process • Review of travel expenses against the policy
6	Delayed Processing	Delayed processing of expense reimbursements	Ensure timely processing of expense reimbursements	• Clear reimbursement timeline • Escalation process for delayed reimbursements • Automated expense reimbursement system

Case Study: Automation – Intel

PROBLEM
• The Intel Inside® program is one of the world's largest co-operative marketing efforts with hundreds of members licensed

to use the Intel® brand on their devices.

- IIP members can qualify for reimbursement of specific marketing activities if they submit a claim that complies with program requirements.
- As part of the business process, Intel's Global Audit Team (GAT) selects samples from the incoming claims and audits them for compliance.
- Ideally, every claim would be audited for compliance, but due to resource constraints and the thousands of claims submitted each month, the audit team is only able to randomly or manually select claims for auditing based on human ability to recognize non-compliance.
- This process increased the possibility of non-compliant claims slipping through, which could result in a loss of marketing value.



SOLUTION

- Intel IT's Advanced Analytics team developed the Compliance Analysis and Prediction Service (CAPS), designed to support the decision process for which IIP claims are selected for audit.
- Its goals included increasing the recovered dollars from non-compliant claims, continuously improving the algorithm through machine learning and gaining user trust in AI.
- CAPS identifies patterns through data manipulation and predicts non-compliant IIP claims.

- Effectiveness is tracked based on a percentage of the total non-compliant claims, the percent of dollars reviewed and the percent of claims accurately predicted for audit. CAPS provides the GAT with actionable information in real time.
- One of the most powerful features of CAPS is the ability to automatically tune its models through self-learning, improving its success rate over time. It learns from past claims submissions, creating a new predictive model based on updated data each month.

IMPACT

The claims selected by CAPS accounted for 97 percent of total dollars recovered from non-compliant claims — an average of USD 20 million in marketing value per year that may have been lost due to non-compliance.

Expense Cycle

The expense cycle in the pharmaceutical industry refers to the process of managing expenses incurred by pharmaceutical companies. The expense cycle in the pharmaceutical industry encompasses various other aspects related to operational expenses, research and development, marketing, sales and administrative costs.

The expense cycle includes the following steps:

1. **Budgeting:** Pharmaceutical companies create a budget for their expenses based on their projected revenue and expenses.

2. **Expense management:** Pharmaceutical companies manage their expenses by tracking them and ensuring they are within budget.

3. **Approval process:** Pharmaceutical companies have an approval process for expenses that exceed a certain amount.

4. **Payment processing:** Pharmaceutical companies process payments for their expenses.

5. **Reporting and analysis:** Pharmaceutical companies analyse their expenses to identify areas where they can reduce costs.

The expense cycle is important for pharmaceutical companies because it helps them manage their expenses effectively and efficiently.

In the pharmaceutical industry, various expenses are incurred while conducting business operations. Some common types of expenses, other than expenses covered separately in this book, in the pharmaceutical industry include:

- Fuel Expense
- Contract Labour and Security Expenses
- Maintenance, Testing and Other Expenses
- Marketing and Promotional Expenses
- Transport
- Insurance
- Sample (Advertisement) Expenses
- Rent & Insurance Expenses
- Administrative and General Expenses
- Repairs & maintenance
- Mediclaim Expenses
- Bank Charges
- Legal and Professional Expenses
- Corporate Social Responsibility
- Donations
- Directors' Sitting fees
- Commission
- Formulation Development Expense
- Advertising, publicity and medical awareness
- Field Employee Expense Reimbursement

Risks in Expenses Cycle

The common risks associated with expenses are:

- Expenses are not as per the budget
- Expenses are not incurred.

- Expenses not related to the organisation's business or objectives.
- Incorrect or insufficient supporting invoices/documents.
- Unauthorized expenses/payments.
- Expenses not charged to the appropriate accounting period.

Common control objective while auditing these expenses:

- All payments are duly authorized and made to the correct vendor.
- All accounts payable amounts are accurately calculated and recorded.
- Budgets are duly prepared and signed; no major variance is observed.
- Respective expense policy is in place and followed.
- Obtain the details of the provision entries passed at the month's end and verify the accuracy.
- Verify if the three-way match is performed to ensure the accuracy of payments.

Fixed Asset

Fixed assets in an organization represent the long-term tangible assets that are used:

- to produce and deliver its products or services and
- to manage its operations.

They are assets held to provide or produce goods or services and are not meant for sale in the normal course of business. *Therefore, an asset can be classified as a fixed asset or otherwise, depending upon the use to which it is put or intended to be put.*

Internal Controls over Fixed Assets

Fixed-asset transactions typically represent the acquisition and disposal of assets and allocating related costs to reporting periods through depreciation expense. The internal controls over the acquisition of fixed assets include the following:

- Issuance and approval of a purchase order
- Receipt of assets and preparation of a receiving report

- Receipt of an invoice from a vendor
- Reconciliation of the vendor invoice to the related receiving report and purchase order
- Authorization of the payment for the vendor invoice
- Issuance of payment for the vendor invoice
- Posting of the entry in the equipment sub-ledger
- Posting of the equipment sub-ledger activity to the related general ledger control accounts
- Reconciliation of the general ledger control accounts

Key Controls over Fixed Assets

The following table gives a brief description of various activities, control objectives and key controls in fixed asset process:

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
1	Budget monitoring	Unapproved budgeted expenditure	To restrict excessive expenses and ensure approval for unbudgeted expenses	The annual budget for capital expenditure is defined incorporating the nature of expense, justification and basis of budgeted cost and approved as per DOA (Delegation of Authority).
2	Purchase requisition	Unauthorized PR leading to the inappropriate purchase of the asset	To ensure correct and accurate purchase	Material requisition is raised with an adequate asset description and approved by the appropriate authority. The right to modify MR is restricted to the original approver only.

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
3	Quotation analysis	Absence of quotation leading to excess cost	To ensure adequate selection of vendor	Request for Quotations are sent to at least three vendors and Comparative Quotation Analysis (CQA) at landed cost is documented to shortlist the vendors (wherever applicable). A justification note is attached in case the vendor selected is other than the lowest cost.
4	Capitalization of Fixed Assets	Additions are recorded for fixed assets that do not exist when the entity does not have legal title to the fixed assets and at the incorrect amount.	Timely/accurate capitalization of assets	Asset capitalization is ensured only based on detailed Asset capitalization notes from the respective user department detailing all costs to be capitalized, supporting documents such as trial test run report acknowledged by the Quality Assurance, equipment Installation/commissioning report acknowledged by Quality Assurance, etc.
5	Acquisition of Fixed	Finance leases for	Selection of the correct	Manager Audit and Accounts review new

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	Assets	fixed assets are incorrectly accounted for as operating leases and vice versa.	lease type	lease contracts and lease modifications to determine whether they meet the criteria for finance or operating lease treatment. The senior Accountant reviews the journal entry and supporting documentation before posting.
6	Maintaining Asset Master	Inaccurate or incomplete recording of fixed assets in the register	Ensure the accuracy and completeness of the fixed asset register	Conduct regular physical inventory checks to verify the existence and condition of assets and reconcile them with the recorded information
7	Physical verification of Fixed asset	Acquisitions of fixed assets are not recorded; fixed Assets recorded, however, do not exist.	To reconcile physical assets with assets as per FAR to identify unaccounted assets	Periodic counts of fixed assets. Physical Assets are matched with the fixed assets register, verified for existence and ownership and supporting documentation that the company holds legal title. Coverage of all assets within a period of three years is ensured. Written confirmations are

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				obtained for FA outside company premises from the respective operational owner of the assets at least once a year. Differences, if any, in reconciliations are analyzed.
8	Tagging of asset	Non-tagging could lead to difficulty in the traceability and reconciliation of assets.	Easy Identification of physical assets with FAR	Asset codes are timely communicated to users and tagging is ensured on assets.
9	Revenue expenses	Assets accounted as revenue expenditures	Capitalization of spare parts instead of treating them as revenue	Periodic scrutiny of spare parts purchased is conducted and major spares for Machines are capitalized and not treated as revenue.
10	Transfer of asset	Unapproved movement of the asset	To ensure adequate approvals before the movement of assets	The asset is moved from one location to another based on the Transfer note approved by the appropriate authority.
11	Depreciation on Fixed	Depreciation expense is: • Calculated	Correct calculation and accounting of	Depreciation rates and assets' depreciable life is considered per

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	Assets	using an inappropriate rate or using an inappropriate methodology, • Recorded at the incorrect amount	depreciation	schedule II and the Manager Audit and Accounts review the methodology of depreciation computation before posting depreciation in the accounting system.
12	Impairment of Assets	Incorrect asset valuation and noncompliance with Accounting Standards	Adherence to Accounting Standards for the Impairment of Assets is ensured	The accounts department and respective user departments meet to assess internal or external factors that may be indicators of impairment of assets. The impairment report and assumptions considered for computation are documented and approved by management. Authorized person records entries.
13	Disposal of Assets	Blockage of funds and unused assets	To identify idle/obsolete assets	Idle/obsolete assets/assets to be retired/ disposed of are identified half-yearly and the Accounts department receives a list of such assets along with

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				reasons.
14	Disposal of Assets	The sale, disposal, or theft of fixed assets, including assets held for sale, has not been recorded.	Correct accounting of profit/loss on sale/disposal of assets	Journal entry w.r.t disposal of fixed assets, availability of approved Purchase order of the customer, approved Order registration form and Invoice of customer etc. and computation of loss/profit on loss is verified before posting in ERP.
15	Disclosure	Non-compliance with Accounting Standards	Compliance with Accounting Standards	Disclosures with respect to Fixed assets are made in the Financial Statements w.r.t. IND AS for owned/leased/hire-purchase, constructed assets, valuation, revaluation, impairment, sale/disposal, depreciation, capital commitments etc., approved by management.
16	Self-generated assets	Incorrect accounting of self-generated assets	Appropriate accounting treatment for self-generated assets	Capitalization Policy, Compliance with Accounting Standards, Cost Tracking and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				Allocation, Project Authorization and Documentation
17	ROI (Return on Investment)	Wasteful capital expenditures	To ensure Return on Investment before procurement of asset	Cost and Benefit analysis is carried out to provide justifications for procuring assets.

Financial Reporting Process

Financial reporting provides financial information about businesses useful to investors and other users in making decisions. Financial reporting uses financial statements and reports to disclose financial data that indicate the economic health of a company over a specific period. The information is vital for management to make decisions about the company's future and provides information to capital providers like creditors and investors about the profitability and financial stability of the company.

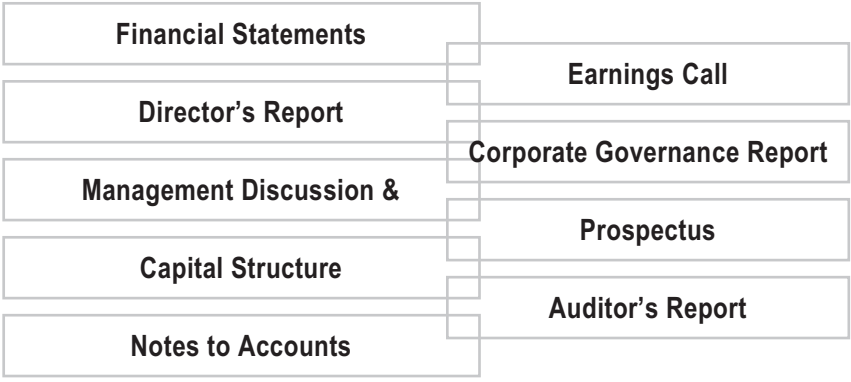
The financial reporting process in India is governed by various regulations and standards that ensure accurate and reliable financial information. The key regulations and standards that impact the financial reporting process in India include the Companies Act, 2013, the Accounting Standards issued by the Institute of Chartered Accountants of India (ICAI) and the Securities and Exchange Board of India (SEBI) regulations for listed companies.

The financial reporting process in India typically involves the following steps:

- Determine the applicable financial reporting framework based on the regulatory requirements.
- Select appropriate accounting policies that comply with the applicable financial reporting framework.
- Gather relevant financial data from various sources,
- Preparation of Financial Statements
- Ensure compliance with the Accounting Standards issued by the ICAI.

- Conduct an audit of the financial statements by an independent external auditor.
- Comply with the disclosure requirements of various regulatory bodies.
- Communicate the financial statements and related information to stakeholders, including shareholders, investors, lenders and regulatory authorities.
- Establish internal controls and monitoring mechanisms to ensure the accuracy, reliability and integrity of financial reporting.

What constitutes Financial Reporting?



Key Controls in Financial Reporting Process

The following table gives a brief description of various activities, control objectives and key controls in financial reporting process:

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
1	Creation of the accounts	Unauthorized or fraudulent accounts to be created, mapping and consequent errors in grouping, reporting and	Only authorized individuals are granted access to systems and resources and proper controls are in place to prevent unauthorized or	User Access Controls, Segregation of Duties, a clear process for authorizing and approving new account creations,

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
		disclosures	fraudulent account creation.	Maintaining accurate documentation and records of account creation requests, approvals and related activities. Conduct periodic reviews and audits of account creation to identify anomalies, unauthorized accounts, or deviations from established processes.
2	Updation of the chart of accounts	Unauthorized changes in account mappings/ codes	Prevent unauthorized modifications to account mappings or codes that could misrepresent financial information, incorrect reporting, or potentially fraudulent activities.	Access for changes in account mappings should be restricted to authorized employees only.
3	Posting of	Errors in the	Minimize the risk	All vouchers

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
	data	entry made in the ledgers due to lack of review	of inaccuracies, misstatements, or omissions in financial records by implementing controls that promote thorough review and verification of ledger entries.	posted in the system should have adequate supporting attached. In case of purchases made or services obtained from any vendor, a purchase or service order is prepared in the system against which invoices are posted.
4	Posting of data	Access to an accounting ledger, general ledger and passing journal entries may not be restricted	Only authorized individuals can initiate entries with appropriate approval and supporting's	The access to park the entries should be given to Executives authorized users only. The organization should have internally assigned roles and responsibilities for scope areas.
5	Posting of data	Inadequate account closure procedure and the possibility of income/expenses may not be	Transactions in the ledger can only be posted in the current period	The system should have control whereby entries can only be made for the open period.

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
		booked in the current year		
6	Posting of data	Inaccurate and Unapproved journal entries	All JV posted in the system have park and post concepts. The JV is posted with adequate supporting papers	JVs are posted by authorized users only basis on supporting available. If support is unavailable, a higher authority's approval should be taken before posting an entry in the system.
7	Recording of standard and recurring entries	Incorrect Opening balances	Ensure the accuracy and integrity of financial statements by preventing errors or misstatements in the initial balances recorded at the beginning of an accounting period or system	Implement controls to ensure accurate data migration if opening balances are transferred from a previous system or data source. This includes validation checks, data cleansing and reconciliation with the source data to identify and rectify any inconsistencies or errors.

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
8	Recording of standard and recurring entries	Incorrect or inadequate provisions in the books will lead to incorrect financial statements Assertion of valuation and allocation because some expenses accrued in the current period are excluded.	Provisions are created in the books based upon the judgment of approximate expenses, which are recorded in a sheet for tracking. Reversal of provision is done as per Company policy.	Establish clear policies and procedures for determining and recording provisions per applicable accounting standards Implement robust systems and processes for accurately tracking expenses incurred during the current period. This includes maintaining detailed records of expenses and ensuring timely and accurate recording of transactions.
9	Review of data collected	Unauthorized or incorrect changes to ledgers	Prevent unauthorized modifications, errors, or fraudulent activities that can lead to inaccurate financial records and	Implement a formal process for authorizing and approving ledger changes. Maintain version control and an audit trail of ledger changes,

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
			misrepresentation of financial information.	recording the date, time and individuals responsible for making the changes. This allows for traceability and accountability, making identifying and addressing unauthorized or incorrect modifications easier.
10	Closing of books of accounts	Data being entered after the reports are generated from the system	Ensure the timeliness and accuracy of financial reporting by preventing the inclusion of data entered after the reports have been generated.	Establish a clear cut-off time or date for report generation to prevent the inclusion of subsequent data. Implement controls to lock down the data used for report generation once the cut-off time or date is reached.
11	Preparation of schedules	Failure to analyse current and prior period actuals may fail	MIS are prepared and discussed for variances so that problems or	Develop a structured framework for analysing the

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
		to detect problems or trends that could adversely affect operational performance or financial misstatements.	trends affecting operational performance or financial misstatements are detected and addressed in a timely manner through the proper analysis of actual data.	current and prior period actuals. This framework should include key performance indicators, financial ratios, trend analysis and benchmarks to identify deviations, patterns and potential issues. To identify significant variances, compare performance against budgets, forecasts and targets. Perform root cause analysis to determine the underlying factors contributing to identified problems or trends.
12	Formulation of accounting closure	Inadequate account closure procedure	Ensure the proper and timely closure of accounts when	Establish a clear account closure policy that outlines the

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
	procedures		required, minimizing the risk of unauthorized access, misuse of resources and potential financial and operational consequences.	criteria and process for closing accounts. This policy should define the circumstances under which accounts should be closed, specify the responsible parties and provide guidance on the necessary steps. The Company should also have a quarterly and annual financial closure checklist.
13	Evaluation of the disclosures against regulatory publications	Non-compliance with reporting requirements	Ensure that all required disclosures are made accurately, completely and in a timely manner, reducing the risk of regulatory penalties, legal liabilities and reputational harm.	Develop a framework for identifying, assessing and categorizing the required disclosures. This framework should include a comprehensive inventory of disclosure

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
				items, their associated timelines, responsible individuals and approval processes. Implement a rigorous review and approval process for disclosures.
14	Evaluation of the disclosures against regulatory publications	Schedule III requirements may not comply. All subsequent events not addressed, Accounting policies are not followed at the time of preparation of financial statements.	Financial statements should be prepared per applicable accounting standards, including the specific requirements of Schedule III and all subsequent events and accounting policies should be properly addressed and followed.	Conduct a comprehensive review of the financial statements to ensure compliance with the specific requirements outlined in Schedule III of the applicable accounting standards. This includes verifying the proper presentation and disclosure of information as per the prescribed formats and

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
				guidelines.
15	Contingent Liability	Accounting commitments and contingencies are not complete, in existence and are not properly reflected in the financial statements.	All commitments and contingencies are properly identified, evaluated and accurately reflected in the financial statements per applicable accounting standards and disclosure requirements.	Thorough assessments of contractual obligations, legal claims, pending lawsuits, guarantees, warranties and other potential liabilities. Establish procedures to evaluate and measure the financial impact of commitments and contingencies based on the applicable accounting standards and disclosure requirements.
16	Prepaid expense	The amounts shown as prepaid expenses may not have occurred or exist as of the balance sheet date.	Prepaid expenses reflected in the financial statements represent actual expenses that have occurred and exist as of	A review is done for the prepaid expense appearing in the balance sheet and adjustments for actual expenses are made against

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
			the balance sheet date.	the prepaid expense recorded
17	Employee benefits	Disclosures requirements as laid down by AS 15 may not have been met.	Ensure Gratuity provision calculations are done accurately during annual book closure. The accounts and Finance Head should review notes to accounts for adequate disclosure.	An external consultant is hired to ensure compliance for AS-15, period-end accruals for gratuity and leave encashment. Period-end accruals are calculated based on assumptions and details submitted at each quarter's end. Based on the actuarial report received, provisions for gratuity are created in books by the accounts department.
18	Related party transactions	As laid down by AS-18 for related party transactions, disclosure requirements may not have	Ensure accurate and comprehensive disclosure of all transactions, relationships and balances	Accounts and legal departments should maintain a list of all related parties of the company.

Sr. No.	Activity	Risk	Control Objective	Key Control Measures
		been met.	involving related parties in the financial statements.	Disclosure of interest from directors should be obtained at the beginning of the year. Any related party transactions are shared with the board of directors in meetings and disclosed in financial statements.

Entity-Level Controls (ELC)

Entity Level Control (ELC) is a crucial component of internal control systems within the pharmaceutical industry. It refers to the controls implemented at the organisational or entity level to ensure the effectiveness and integrity of the overall control environment. ELC encompasses the policies, procedures and practices that govern the entire organisation and support the achievement of its objectives, particularly related to governance, financial reporting and regulatory compliance.

The following table gives a brief description of various activities, control objectives and key controls in entity-level control systems:

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
1	Board of Directors	Risk: Poor governance due to inadequate or wrong	Establish procedures to ensure adequate and proper	The Corporate Board of Directors is available as required by the statute and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		composition of BoD.	composition of the Board of Directors	compliances to its composition are taken care of. The compliance department brings to the notice of Management in case of any change to any law which impacts the appointment, re-election, or removal of any director.
2	Board performance	The efficacy of the Board of Directors is not reviewed periodically	To ensure the performance of the Board of directors is as per mandate and expectations	The Board of Directors is evaluated annually on the quality and efficiency of the proceedings of the Board of Directors and its delegated bodies; the diversity in the composition and skills of the Board of Directors.
3	Audit Committee	The responsibilities of the Audit Committee are not formally established	To establish the responsibilities of the Audit Committee	The responsibilities of the Audit Committee are established in an Audit Committee Charter.
4	Audit Committee	The reviews performed on the financial information are	To ensure financial findings are communicate	The Audit Committee holds periodic meetings to review the

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		not adequately communicated to the Audit Committee	d to the Audit Committee	periodic financial information; Internal Audit findings; related party transactions, etc.
5	Code of Conduct and Ethics	Professional misconduct	To ensure professional discipline by employees	The Code of Conduct is distributed to all new employees on hire and an acknowledgement form is signed by the employee and kept in the personnel file. Training on Ethics is provided.
6	Code of Conduct and Ethics	Misconduct of Manufacturers and Suppliers	To ensure professional discipline by suppliers	The Code of Conduct for Manufacturers and Suppliers defines minimum standards of ethical and responsible behaviour that the manufacturers and suppliers of the products must meet.
7	Code of Conduct and Ethics	Misconduct and lack of compliance with the Code of Conduct are not being	To ensure appropriate mechanisms to deal with ethical issues	The company has an Ethics Committee. The Ethics Committee oversees compliance with the

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		detected and followed-up		Code and oversees the Whistleblowing channel and compliance with its procedure.
8	Risk Management	Lack of Risk Management	To ensure enterprise-level risks are appropriately dealt with	Risk Management Policy is drafted. Upon approval of the policy, the risk identification process to be initiated.
9	Risk Management	Lack of Control against Fraud	To control the risk of fraud	Fraud Risk Assessment and management process to be in place.
10	Processes	Inadequate knowledge of the business processes resulting in inefficiencies, errors, losses, etc.	To streamline business processes	Business Process Manuals are defined as incorporating the tasks, responsibilities, etc. Process Manual is reviewed annually for inclusion/modification of processes based on feedback received from internal customers.
11	Policies	Non-standardization of practices	To standardize practices	Corporate Policies are defined and approved on key

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		followed across entities.		elements such as procurement, Credit and receivable management, Inventory management, Human resources, Investments, Capital expenditure, write-off and write-back, Forex, etc. A periodic review of policies for any revision is ensured. Communication of policies to all concerned employees ensured.
12	DOA (Delegation of Authority)	Unauthorized transactions	To ensure transactions are appropriately authorized	The company has an approved Delegation of Authority where the approvals are established for all types of key transactions. All elements of the DOA are deployed through the system.
13	Organizational Structure	Lack of clarity on reporting in the absence of an established structure	To establish an organizational structure	The organizational structure is designed to provide adequate lines of communication and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				a span of control. HR Head reviews the organizational structure annually and updates the changes in the structure, if any.
14	Job Description:	The responsibilities, hierarchy and authority are not adequately regulated	To establish responsibilities at various levels	The responsibilities, duties and skills required for each job are defined by HR Department and approved by the Human Resource Director.
15	Recruitment	Inappropriate candidate and non-capability of taking legal action in the absence of required documents	To recruit verified candidates	An outsource vendor/HR team conducts background checks. An offer letter and a copy of the code of conduct are shared with employees. The Payroll department maintains employee files.
16	Performance analysis	Nonidentification of Dissatisfaction amongst employees and improvement	To ensure appropriate appraisal	KRA of employees is linked to job responsibilities. Management discusses job performance with

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		areas to achieve company goals		each employee that reports to them along with HR. Job evaluation is performed for each employee basis defined parameters.
17	Training	Lack of improvement of employees due to no or irrelevant training	To lay training & development framework	The training calendar is prepared in advance and a specific amount is allocated to training in the budget (at the beginning of the year).
18	Succession planning	Loss of key personnel	To establish a succession plan	There is a Succession Plan established for the critical positions. Gap analysis is performed and employees are trained to take up critical positions.
19	Statutory Compliance	Penalties & losses due to non-compliance with the regulatory and statutory requirements	To establish a statutory compliances framework	There is a Statutory Compliance Framework for Indirect Tax, Direct Tax, Intellectual Property, Store Licences, Secretarial Compliance, Labour Law Compliance

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				and General Companies Act Compliance. In this document, it is defined the process owner, the description and the control for each of the areas.
20	Contracts	Lack of review of contracts	To establish a robust legal framework	The legal department has framed and approved a predefined contract template. The legal team approves the contract in case of a material deviation from the template. All the contracts are prepared in line with the template document. The legal head ensures that all the contracts are either per the defined template or approved by the legal department.
21	Legal Case managemen t	Non-reporting and non-documentation of significant events to an	To ensure control over litigations made by & against the	The Legal department maintains a litigation tracker/ summary of all the

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		appropriate authority	company	litigations against the company and its status. The report is updated quarterly and shared with the management as and when requested.
22	Budget Monitoring	Non-availability of visibility on the cash flow and fund flow and Excess expenditure	To control & monitor funds	Budget for revenue from operations, Capital expenditure, revenue expenditure, Manpower cost, etc., are prepared and approved as per the approved DOA. Revisions in Budgets are approved as per DOA. The need for revision of the budget is analysed periodically.
23	Budget Monitoring	Excess expenditure then the budgeted	To control & monitor expenses	Variances between budget and actual are monitored and analysed for corrective actions.
24	Risk Managemen t	Nonexistence of a Business Continuity Plan	To secure data	The business Continuity Plan / Disaster Recovery Plan has been properly defined for the Corporate.

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
25	Data Security and retrieval	Non-availability of data/documents when needed	To ensure compliance with the Companies Act 2013 provisions relating to managerial remuneration.	Data security and retention policy are defined. Adherence with Policies monitored. System backup is ensured periodically.
26	Compensation & Remuneration - CA, 2013	Noncompliance to provisions of the Companies Act 2013 relating to managerial remuneration	To ensure compliance with the Companies Act 2013 provisions relating to managerial remuneration.	The process is in place to ensure compliance with the Companies Act 2013 provisions. Appropriate disclosure is made in financial statements.

Governance

As per SIA 140, Governance activities, forming part of the framework, are designed to enhance the organisation's ability to, amongst others:

a. Provide strategy, leadership and direction;

b. Nurture a culture of values and ethics;

c. Sensitive to multiple stakeholder interests;

d. Promote collaborative decision making;

e. Provide structure and design to organisation resources and their deployment;

f. Prevent undue concentration of power with few;

g. Encourage risk-based prioritisation, consistency and efficiency in business processing;

h. Support resource development in the area of good governance;

i. Exercise judicious monitoring and oversight on business and individual performance; and

j. Ensure full and transparent communication and reporting.

All these initiatives, generally, form part of the Entity Level Controls (ELCs) which are essential to the overall internal audit agenda.

Responsibility of Internal Auditor Standard on Internal Audit (SIA) 140, Governance issued by ICAI states that :

The nature and extent of internal audit procedures to be conducted in the area of governance is dependent on the framework in place and the maturity of the processes.

1. Auditing the Governance Framework

Where there is a formal governance framework in place, the work to be performed by the Internal Auditor shall be directed to ensure that, amongst others:

a. The organisation has designed the framework consistent with best in-class and globally recognised frameworks;

b. The organisation has implemented various enabling mechanisms, such as:

i. Shared organisation vision, mission, objectives, goals and targets;

ii. Established a code of conduct or ethics and a whistle blower mechanism;

iii. Acts to identify and address the concerns and balance the needs of various stakeholders (internal and external), through open communication and discussion;

iv. Formed active and functioning governing bodies with defined agendas;

v. Shared organisation design and structure with clearly defined roles and responsibilities of each position;

vi. Delegated power and authority through a formal document, duly approved by the Board;

vii. Deployed risk-based systems and processes deploying, where possible, with technology as a foundation;

viii. Conducts regular training programs to develop staff awareness and competency in the area of good governance;

ix. Continuously tracks business performance against budgets and goals with adequate reviews and oversight mechanisms; and

x. Undertakes active communication and periodic reporting of governance matters to those charged with governance and other stakeholders.

The Internal Auditor will review the governance system and processes in place to evaluate whether they are operating in an effective and efficient manner and help to ensure full compliance. Any shortcoming shall result in recommendations for improvement and suggestions on how to make the governance framework more efficient and effective in line with stated objectives.

2. Auditing Governance Activities and Processes

Where no formal governance framework exists, the Internal Auditor shall design and conduct audit procedures with a view to highlight any exposures arising from weak or absent governance activities and processes, make recommendations to implement and strengthen those processes and thereby, improve governance.

3. Independent Assurance over Governance Framework

In situations where a written assurance report is being issued, the Internal Auditor shall consider the following (as a basis for his opinion):

a. The linkage of the governance framework with other frameworks, such as, Risk, Compliance, Fraud, or Information Technology frameworks which may exist.

b. The system of compliance certification on governance matters.

c. The process in place for self-assessment and certification from governance owners as part of a continuous system of compliance.

The Internal Auditor shall not assume any responsibility to manage or operate the Governance framework or to take governance related decisions. The focus of the audit procedures is on the process of governance and not the outcome of the process, such as, second guessing or questioning the

actions or decisions of the governing bodies. It is not responsibility of the Internal Auditor to execute or resolve governance related risks.

Compliance with Laws and regulations

While the primary objective of an internal audit is to strengthen the system and process of compliance, there may be instances where the Internal Auditor is asked to undertake compliance audit assignments with the primary objective of identifying any instances of non-compliances. In such situations and where no formal compliance framework is in place, the Internal Auditor may not be able to provide a written opinion in line with requirements of SIA 110 "Nature of Assurance". Never-the-less a Summary of Findings may be possible, listing any instances of non-compliance identified as a result of the internal audit procedures undertaken. These findings shall be reported along with the following:

a. the scope, listing all the specific laws and regulations tested;

b. audit procedures performed, sample selected and population covered;

c. summary of the work performed; and

d. limitations, if any, on the responsibilities assumed by the internal Auditor, such as, inherent limitations in sample selection, or that a court of law is the ultimate authority in establishing legal interpretation of non-compliance, etc.

Responsibility of Internal Auditor as per SIA 150 related to Regulatory Compliance are:

1. Auditing the Compliance Framework

Where there is a formal compliance framework in place, the work of the Internal Auditor shall be directed to ensure that, amongst others:

a. The organisation has designed the framework consistent with best-in-class and globally recognised frameworks;

b. The organisation has implemented various enabling mechanisms, such as:

   i. Issued compliance policies and implemented supporting procedures;

   ii. Set the right "tone at the top" with supporting messages/ activities;

iii. Designed compliance structure, appointed compliance officers and assigned each compliance to a specific "compliance owners";

iv. Identified all laws and regulations applicable to the entity (created a database of compliances), risk assessed each for importance and priority and embedded them into the relevant processes;

v. Regularly conduct training programs for compliance officers and owners, covering knowledge and competency for effective compliance;

vi. Implemented robust compliance systems, deploying technology (where possible), to monitor their progress and track their status, to document timely completion with relevant proofs and artefacts and to support timely escalations in case of slippages;

vii. Continuously tracks performance against compliance targets and goals with sufficient reviews and oversight mechanisms;

viii. Established timely communication and periodic reporting systems and protocols, including issuance of self-assessment and compliance certificates.

c. The compliance system and processes in place are operating in an effective and efficient manner and help to ensure full compliance.

2. Auditing Compliance Activities and Processes

Where no formal compliance framework exists, the Internal Auditor shall design and conduct audit procedures with a view to highlight any exposures arising from weak or absent compliance activities and processes, make recommendations to implement and strengthen those processes and thereby, improve compliance

3. Independent Assurance over Compliance Framework

In situations where a written assurance report is being issued, the Internal Auditor shall consider the following (as a basis for his opinion):

a. The linkage of the compliance framework with other frameworks like the Risk, Governance, Fraud, or Information Technology frameworks which may exist.

b. The linkage of the compliance framework with other frameworks like the Risk, Governance, Fraud, or Information Technology frameworks which may exist.

IT General Controls and Audit

- The Security, Integrity and Reliability of financial and business information depends on proper IT Access Controls, Change Management and Operational Controls.
- IT Systems are becoming more integrated with business processes and implementing controls over financial and business information are compelling organisations to increase their focus on IT Controls to maintain reliability of business processes.
- Some of the areas that need IT controls are:

Area	IT Control Check
User Access Management	User access provisioning, Excessive access, Generic User id and Privilege access, User access de-provisioning, User access review
Change Management	Direct Change Access, Change evaluation, Unauthorised Change, Direct changes in Production, Segregation of duties in Change Management
Outsourced Service Provider	Service Providers need to have adequate controls and safeguards when they host or process data belonging to their customers. Evaluate exceptions in the Service Audit Report (SAR), etc.

Scope of ITGC Audit

- Standard on Internal Audit (SIA) 520 deals with Internal Audit in an IT Environment, commonly referred to as ITGC Audit. Equivalent standards also referenced are the ISO-9000-1 on Quality Management and the ISO 270001 on IT Security.

As per SIA 520, "INTERNAL AUDITING IN AN INFORMATION TECHNOLOGY ENVIRONMENT",

1. Internal Auditor shall gain an understanding of the business operations and the corresponding IT Environment. This information shall assist the

auditor to perform an independent IT risk assessment and identify the nature of controls required to mitigate those risks, before commencing any IT audit activities.

2. Internal Auditor shall obtain a Diploma in Systems Audit (DISA) or equivalent qualification to develop relevant knowledge and skills to perform IT audits. Knowledge and experience about Enterprise Resource Planning (ERP) systems, Analytic tools, Core Banking Systems (CBS), operating system and databases, cloud and other emerging technologies, like Robotic process automation, block chain, Artificial Intelligence / Machine learning are important to perform an effective IT audit. These credentials may be acquired externally and made available for the audit.

3. An Internal Auditor shall identify the scope of the IT audit procedures to be executed based on the understanding of the overall ITE, objectives of the IT audit and results of the IT risk assessments performed. Key areas within the audit scope (such as business and IT processes, systems and applications, third party services, etc.), need to be clearly identified and documented.

4. Appropriate planning activities shall be performed by the Internal Auditor before commencing the field work. Key outputs of the planning phase are: A documented understanding of ITE, Risk Assessment, planned audit approach, project plan and resources in terms of skills and team members required.

5. As part of audit execution phase, Internal Auditor shall test the design, implementation and operating effectiveness of relevant IT controls and identify control gaps, operating deficiencies and violations of procedures and laws, if any.

Scope of IT General Control Audit

The scope of the ITGC Audit includes all, but not limited to, the following items:

Illustrative Audit Areas		
IT Governance & Strategy	System Reports Testing	Emerging Audit Tools and Technologies
IT General Controls	IT Operations Audit	Compliance & Regulatory

Testing		Requirement
Automated Business Controls	Cyber Security	Disaster Recovery & Business Continuity

Illustrative Control Parameters to be reviewed

IT Governance & Strategy	Audit of controls around IT Governing body, its structure, processes and practices for planning, budgeting and risk management
System change Control	Application changes are approved and tested, UAT testing and documentation, segregation of duty between development & production, Management Reviews
IT Security and Logical Access Control	Structured IT Security Policy, User Access Management & Reviews, User roles and privileges, Separation/ terminated cases handling, SoD violations, if any, IT Security
IT Backup & Recovery	Documented Backup & Recovery procedures, Testing of recovery, Disaster Recovery Sites, Business Continuity Planning
IT Physical & Environment Controls	Physical access controls, unauthorised access of data centres, monitoring of data centre, environment, Fire Control Systems, etc
IT Inventory	Inventory Management of IT Assets, hardware & software, documented procedures on maintenance of inventory, handling of obsolete assets, Support AMCs etc
IT Operations	Real time monitoring and alerting framework, Log maintenance, error handling, Legal & Regulatory compliance, use of licensed s/w, HR Policies
IT Interface and Job Monitoring	Monitoring and regulation of system interfaces, authorised users have access to changing of batch jobs
IT Service Agreements	Supplier Relationships, Vendor Agreements, MOUs, NDAs, SLA with Service Providers, Contracts and Licensing
IT Cyber Security	Level of cyber protection of servers, networks, work

Policy	stations, Data protection & Privacy, External threat monitoring and control

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
1	Policies, Standards and Procedures	a. Absence of IT controls at the Governance level would lead to loss of effective information management and security principles, policies and processes deployment in the organisation. b. The Board of Directors failed to review the IT Policies	a. Do corporate policies and standards that describe the need for IT controls exist b. Determine whether the board of directors have reviewed and approved IT policies	1. Identify the IT control environment of the organization, Whether Policy, Standards and Procedures exit in the Organisation. 2. Check for IT Security Policy document including Values, Philosophy, Management style, IT awareness, Organisation, Policies, Standards. 3. Check for evidence of performance and compliance metrics that demonstrate ongoing

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				support for IT Security framework. 4. Examine how Governance controls, IT Policies and Standards are mandated in the organisation - either by the entire board of directors or a board committee in conjunction with the organization's executive management.
2	IT Security Management	Lack of alignment between ISMS and Organisation Goals & Objectives will lead to non-fulfilment of business needs in an effective manner	a. Does the organisation have Information Security Management System (ISMS) b. IS Policy needs to be in line with Organisation's objectives, processes,	Alignment between ISMS and Organisational goals and objectives need to be checked with respect to: 1. Internal business objectives and requirements:

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			resources, etc)	2. Requirements specified in contracts and service level agreements (SLAs) of the Company 3. Compliance requirements defined in legislation and regulations
3	Regulations & Compliance	Non-Compliance to legislation of the country	What legislation exists that impacts on the need for IT controls and has the Management taken steps to ensure compliance with this legislation?	1. Check for industry specific laws and regulations that require protection of personal data that detail specific information security requirements; 2. Check for tele-communications regulations that specify information 3. Examine laws that

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				relate to relate to the admissibility of electronic evidence that organisations should be aware of regarding the collection of evidence during a security incident.
4	Technical Controls	2.11 Absence of standards and methodology adoption for Software Life Cycle Management will affect reliability and integrity of information assets. 2.12	2.13 Examine how IT management has defined standards and adopted a methodology governing the process of developing, acquiring, implementing and maintaining information systems and related technology. 2.14	Determine if IT management has adequate standards and procedures for: i. Systems development ii. Program change control iii. Data Centre operations iv. Data Base administration v. DASD management (Disk Subsystem) vi. Performanc

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				e monitoring vii. Capacity planning viii. Network administration ix. Information security x. Contingency planning/disaster recovery
5	Segregation of Duties	Lack of oversight or lack of segregation of duties rules within an organisation will increase the risk of fraud, as in the case when a single person performs every financial function.	Conflicting duties and areas of responsibility shall be segregated to reduce opportunities for unauthorized or unintentional modification or misuse of the organization's assets.	1. Is the allocation of responsibilities compatible with the need to apply division of duties? 2. Are IT responsibilities documented? 3. Are IT control responsibilities communicated to the whole organization? 4. Do individual role holders clearly understand their

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				responsibilities in relation to IT controls? 5. Does internal auditing employ sufficient IT audit specialists to address the IT control issues?
6	Information security roles and responsibilities	Inadequate mapping of roles with the organisational structure creates overlapping and confusing execution of activities	All information security responsibilities shall be defined and allocated.	Each function or department being assessed should be checked for availability of a well-defined Organization Structure and Roles & Responsibilities definition. Special checks should be performed to see whether there is any duplication of work pointing to improper segregation of

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				duties, especially in QA, Procurement, Finance, Supply Chain, etc. functions
2.15 7	Mobile Device Policy	Absence of a mobile device security policy can lead to security incidents and other potential costly problems that may lead to data breaches if employees aren't aware of the risks when using technologies improperly.	A policy and supporting security measures shall be adopted to manage the risks introduced by using mobile devices.	There is a need to check the following: 1. Acceptable use policy for mobile devices; 2. BYOD, CYOD (Buy/choose your own device), etc. policies and restrictions of use. 3. Mobile security policy related to user registrations, regular updates, etc.
8	Teleworking	Accessing Sensitive Data Through Unsafe Wi-Fi Networks, Using Personal	A robust policy addressing these risks would lead to safe working operations for all types of	A policy and supporting security measures shall be implemented to protect

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		Devices for Work, Ignoring Basic Physical Security Practices in Public Places, Email Scams, Cyberattacks on Remote-working Infrastructure, etc.	employees	information accessed, processed or stored at teleworking sites.
9	Policies and Procedures	Poor access control can expose the organization to unauthorized access of data and programs, fraud, or the shutdown of computer services.	a. An access control policy shall be established, documented and reviewed based on business and information security requirements. b. Users shall only be provided with access to the network and network services that they have been specifically authorized to use.	1. Verify that Access Control policy limits access to information systems and network systems to authorised personnel only 2. Verify that IT and facility personnel are aware of the applicable policies.
10	User Access	If user access	Ensure that	1. A formal

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	Management	privileges are not properly managed, there is a risk of unauthorized users gaining access to sensitive information and resources. This can lead to data breaches, theft, or misuse of confidential information.	terminated users are promptly removed. Obtain a current user account list for all systems and cross reference it with current payroll or human resource data. Any users not found in the payroll or human resource files.	user registration and de-registration process shall be implemented to enable assignment of access rights. 2. The allocation and use of privileged access rights shall be restricted and controlled. 3. Asset owners shall review users' access rights at regular intervals. 4. The access rights of all employees and external party users to information and information processing facilities shall be removed

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				upon termination of their employment, contract or agreement, or adjusted upon change.
11	User Responsibilities	Poor management or improper allocation of authentication information may result in unauthorised access to information systems and in loss of confidentiality.	Users shall be required to follow the organization's practices in the use of secret authentication information.	Secret authentication information is a gateway to access valuable assets. It typically includes passwords, encryption keys etc. so needs to be controlled through a formal management process and needs to be kept confidential to the user. This is usually tied into employment contracts and disciplinary

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				processes. Verify 1. Documentation of Management process, 2. Maintenance of confidentiality 3. Disciplinary processes
12	System and Application Access Control	Lack of System and Application Access Controls can result in risks like Software attacks, theft of intellectual property, identity theft, theft of equipment or information, sabotage, information extortion and many others.	1. Access to information and application system functions shall be restricted in accordance with the access control policy. 2. Where required by the access control policy, access to systems and applications shall be controlled by a secure log-on procedure. 3. The use of utility programs that might be capable of overriding	1. Determine the application and system level Login procedures - how failsafe they are, whether 2 factor authentications, etc. measures are employed 2. Determine the user base and roles assigned for admin and privileged access and how the user id/passwords for these types of access are

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			system and application controls shall be restricted and tightly controlled.	maintained and kept confidential. 3. Examine how granular are application and transaction level controls and how they are implemented and whether the process is reliable
13	Physical Security	Physical security represented by the security of personnel, hardware, programs, networks and data, if not protected from physical situations and events, can result in severe losses or harm to an enterprise, agency, or organization in terms of:	1. Secure areas shall be protected by appropriate entry controls to ensure that only authorized personnel are allowed access. 2. Physical security for offices, rooms and facilities shall be designed and applied. 3. Physical protection against natural disasters,	Examine whether following access procedures are in place: • Appropriate granting and discontinuanc e of authorizations ? • Observe and inquire about the physical security of the Computer Systems room. • Are alarm

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		1. Tailgating 2. Theft of documents 3. Unaccounted visitors 4. Stolen identification 5. Social engineering	malicious attack or accidents shall be designed and applied. 4. Access points such as delivery and loading areas and other points where unauthorized persons could enter the premises shall be controlled and, if possible, isolated from information processing facilities to avoid unauthorized access.	events logged and routinely reconciled to actual events? • List any network monitoring packages used along with the manufacturer and version. Obtain a list of the authorized users. Determine that any unauthorized network monitoring software is strictly prohibited and that access to authorized software is approved by IT management. • Assure that access authorization procedures are used for all persons

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				(employees, contract workers, security staff and visitors) requiring access to sensitive areas. (Are photo ID cards or electronic key cards required for entry?) • Are alarms installed at all potential entry and exit points of sensitive areas? • Determine that the physical components of the network are properly secured. This includes wiring closets, demarcation blocks, patch panels, cabling, terminals and LAN stations,

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				as well as the communications processors. • Is the LAN file server housing locked or otherwise secured to prevent removal of boards, chips and the computer system? • Determine if the plant utilizes a "Certificate of Understanding " for all employees with access to Personal Computers as required by Policy. This document should be distributed by the LAN Administrators at the plant to all personnel
14	Equipment	Lack of	1. Equipment	1. A clear

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	Security	controls for equipment security can lead to several risks associated with equipment malfunction, breach of contractual relations, industrial espionage, interruption of business processes and other threats that can damage an organisation's ability to perform and function.	shall be protected from power failures and other disruptions caused by failures in supporting utilities. 2. Power and telecommunications cabling carrying data or supporting information services shall be protected from interception, interference or damage. 3. Equipment shall be correctly maintained to ensure its continued availability and integrity. 4. Security shall be applied to off-site assets taking into account the different risks of	desk policy for papers and removable storage media and a clear screen policy for information processing facilities shall be adopted. 2. Review placement of water and drainage pipes to ensure they are routed away from operations areas. 3. Assess the potential for storage tanks to flood electronic equipment and the susceptibility to external flooding. 4. Review smoke detection and automatic fire extinguishing equipment to

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			working outside the organization's premises. 5. A clear desk policy for papers and removable storage media and a clear screen policy for information processing facilities shall be adopted.	ensure that it is functional and that it provides adequate protection. 5. Is there scheduled preventative maintenance on the components, either by the LAN administrator or by the vendor under a maintenance contract? 6. If a maintenance contract exists for routine cleaning, verify that the vendor has honoured the contract.
15	Operational procedures and responsibilities	Lack of SOPs (Standard Operating Procedures) would lead to inconsistency in operations	1. Operating procedures shall be documented and made available to all users who need	Verify that Standard Operating Procedures exist for each of the functions and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		of each of the above areas	them. 2. Changes to the organization, business processes, information processing facilities and systems that affect information security shall be controlled. 3. The use of resources shall be monitored, tuned and projections made of future capacity requirements to ensure the required system performance. 4. Developmen t, testing and operational environments shall be separated o reduce the risks of unauthorized access or changes to the	production, non-production departments and that people are aware of the documents and process steps. Also, verify that the SOPs are maintained under strict document and version control and that latest versions, duly authenticated are available for use.

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			operational environment.	
16	Protection from malware	Viruses and worms are malicious software programs (malware) aimed at destroying an organization's systems, data and network. Malware can be designed to steal sensitive information, including customer data, financial records, intellectual property and employee information. A data breach can have severe legal, financial and reputational consequences for the company.	Detection, prevention and recovery controls to protect against malware shall be implemented, combined with appropriate user awareness. Controls against Virus Protection 1. Determine the level of virus protection established on servers and workstations 2. The monitoring of infection being done by IS administration. 3. Virus Application should be updated on a monthly basis.	1. Check whether the organisation regularly conducts 3rd Party Vulnerability Assessment and Penetration Testing (VAPT) and takes remedial actions on the VAPT test report recommendations for reducing external threats 2. Check also how the system software and application software versions are kept updated 3. Check how 3rd Party Application Development

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				or outsourced application development work are checked for Security vulnerabilities before these are deployed in the production environments 4. Check the methods of Virus Protection software installation, tracking and resolution adopted in the organisation.
17	Backup/Recovery	Inadequate Backup & Recovery procedures in an organisation can result in major disruption of business operations in case of an unplanned	1. Whether the organisation has adequately documented backup and recovery procedures/ plans/schedules for critical sites. 2. If procedures exist, backup copies of	1. Verify: a. LAN is supported by an uninterruptible power supply (UPS). b. Has the UPS been tested in the last year (to test the batteries)?

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		event wherein the business will not be able to recover.	information, software and system images shall be taken and tested regularly in accordance with an agreed backup policy	c. Has the UPS been tested in the last year (to test the batteries)? 2. For disaster-recovery purposes, have LAN applications been prioritized and scheduled for recovery based on importance to the operation? You should also determine if the recovery sequence is proper so that key applications can be restored. 3. Are LAN files backed up at appropriate intervals to ensure the need to re-

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				enter data is minimized? 4. To ensure that the backups are good and can be used to recover the system have the System Administrator: Restore a file or files from the backup media. (Restore a file to a different location and then check the file) 5. Ensure that backup tapes are stored securely in a fire proof safe and not left in the open. 6. Determine the adequacy of the LAN facility insurance coverage.
18	Logging and monitoring	a. If the company fails	1. Event logs recording user	1. Verify the Security Event

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		to log the right data or configures logging improperly, critical events and security incidents may go undetected. This can lead to delayed response times or missed opportunities to prevent or mitigate attacks. b. Insiders with malicious intent may attempt to manipulate logs or evade monitoring systems, making it difficult to detect their actions until it's too late.	activities, exceptions, faults and information security events shall be produced, kept and regularly reviewed. 2. Logging facilities and log information shall be protected against tampering and unauthorized access. 3. System administrator and system operator activities shall be logged and the logs protected and regularly reviewed. 4. The clocks of all relevant information processing systems within an organization or security	Log Monitoring process followed in the organisation. 2. Conduct an electronic audit of the logs for indications that unauthorized security-related activities have been attempted or performed on a system or application that processes, transmits or stores confidential information. 3. Verify the security incidents on a sample basis, if any and check of documented root cause analysis and Corrective and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			domain shall be synchronised to a single reference time source.	Preventive actions taken to mitigate future risks 4. Check the process of Clock Synchronisation through the organisation's systems.
19	Control of operational software	Systems will become more vulnerable to ransomware attacks, malware and data breaches if automated procedures for software installation on operational systems are not implemented	Procedures shall be implemented to control the installation of software on operational systems.	1. Check for availability of Software Deployment tools in the organisation and the associated Group Policy for software deployment. Examples include Microsoft SCCM, AWS Code Deploy, Google Cloud Deployment Manager, or any other remote deployment tools. 2. Validate

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				the updates on the software tool and check whether latest versions are being used.
20	Technical vulnerability management	If vulnerabilities are not promptly patched or mitigated, attackers can exploit them to gain unauthorized access to systems, steal data, or disrupt operations.	1. Information about technical vulnerabilities of information systems being used shall be obtained in a timely fashion, the organization's exposure to such vulnerabilities evaluated and appropriate measures taken to address the associated risk. 2. Rules governing the installation of software by users shall be established and implemented.	1. Check whether the organisation regularly conducts 3rd Party Vulnerability Assessment and Penetration Testing (VAPT) and takes remedial actions on the VAPT test report recommendations for reducing external threats 2. Check whether the organisation restricts software installation through policies and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				use of tools like VMware Airwatch, or any other similar tool that allows IT to automate, control and secure administrative policies on laptops, tablets, or any other device connected to the organization's network,
21	Information systems audit considerations	a. The audit relies on accurate and complete data. If the data used for the audit is incorrect or incomplete, it can lead to incorrect assessments and recommendations. b. Weak access	Audit requirements and activities involving verification of operational systems shall be carefully planned and agreed to minimise disruptions to business processes.	1. Check for availability of formal Internal Audit Schedules within the organisation 2. Check validity of the scope of Internal Audit - whether the organisation periodically conducts ITGC and/or ISO 27001 audits

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		controls may result in unauthorized access to sensitive information, leading to data breaches or data manipulation during the audit.		3. Review Strengths, OFIs and non-conformities and whether appropriate actions have been initiated from the last audit
22	Network security management	Absence of Network Controls and Network Segregation could lead to risks of widespread cyberattacks and degrade network performance due to inability of restricting the number of users in specific zones.	1. Networks shall be managed and controlled to protect information in systems and applications. 2. Security mechanisms, service levels and management requirements of all network services shall be identified and included in network services agreements, whether these services are	1. Check whether the IT department of the organisation has implemented preventive measures like Network Segmentation & Network Zoning based on Zero Trust Architecture (ZTA) 2. Check the policy and deployment of Firewalls, whether the organisation makes use of

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			provided in-house or outsourced. 3. Groups of information services, users and information systems shall be segregated on networks.	latest Firewall technologies (For example, from Palo Alto Networks, etc.) 3. Check whether the company has made Documentation and Network Diagrams for all segments and locations making maintenance and traceability of malfunctioning devices easier. 4. Check whether the organisation has provided for redundancy in the network to avoid single point of failures. For example, use of Multi-Protocol Label

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				Switching (MPLS) and Internet Lease Lines (ILL) to provide redundancy to the Fibre based WAN services, etc.
23	Information transfer	a. During the transfer process, data may be lost due to technical issues, network interruptions, or human errors. Incomplete transfers can lead to the loss of critical information. b. If sensitive or confidential information is transferred insecurely, it could be intercepted by unauthorized individuals or malicious	1. Formal transfer policies, procedures and controls shall be in place to protect the transfer of information through the use of all types of communication facilities. 2. Agreements shall address the secure transfer of business information between the organization and external parties. 3. Information involved in electronic	Check for availability of Policies on: a. Information transfer policies and procedures b. Information & data flows and the classification system used c. Agreement on information transfer addressing the secure transfer of business information between the organisation and external parties. d. Electronic messaging

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		actors, leading to data breaches and privacy violations.	messaging shall be appropriately protected. 4. Requirements for confidentiality or non-disclosure agreements reflecting the organization's needs for the protection of information shall be identified, regularly reviewed and documented.	and protection of messages e. Confidentiality or non-disclosure agreements
24	Information security in supplier relationships	Absence of an adequate Supplier Policy may lead to financial, environmental, operational and legal risks.	1. Information security requirements for mitigating the risks associated with supplier's access to the organization's assets shall be agreed with the supplier and documented. 2. All relevant information security	1. Is vendor reliability considered before purchasing LAN hardware and software? 2. Is a service log maintained to document vendor support servicing? 3. Is a service log maintained to document

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			requirements shall be established and agreed with each supplier that may access, process, store, communicate, or provide IT infrastructure components for, the organization's information. 3. Agreements with suppliers shall include requirements to address the information security risks associated with information and communications technology services and product supply chain.	vendor support servicing?
25	Supplier service delivery management	Process disruptions, Intellectual property theft and Non-compliance	1. Organizations shall regularly monitor, review and audit supplier service delivery.	1. On a sample basis, select LAN hardware and software contracts. Are

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		with regulatory security standards.	2. Changes to the provision of services by suppliers, including maintaining and improving existing information security policies, procedures and controls, shall be managed, taking account of the criticality of business information, systems and processes involved and re-assessment of risks.	vendor support requirements clearly defined? Are product licensing restrictions clearly identified? 2. Obtain the service log and look for software or hardware that has been subject to numerous problems and vendor-assisted support. Can management and the users support or justify the activity? 3. From the sample of LAN hardware and software contracts, determine if the vendor is reliable. Such

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				information can be obtained from trade periodicals, financial reporting services (e.g. Standard & Poor's), trade associations and MIS management. 4. Obtain a copy of the negotiated service level agreement from the IS department noting specific performance requirements. Compare the agreement with the performance reports to ensure that it is meeting the agreement
26	Asset Responsibility	Improper IT Asset Management can drive up	1. Assets associated with information and information	1. Determine: Is there a complete inventory of

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		insurance costs, can lead to inability to identify potential savings, enhance performance and prevent data breaches as a result of outdated inventory information. Also, it will become difficult to remotely manage IT infrastructure.	processing facilities shall be identified and an inventory of these assets shall be drawn up and maintained. 2. Assets maintained in the inventory shall be owned. 3. All employees and external party users shall return all of the organizational assets in their possession upon termination of their employment, contract or agreement. 4. a. Is there a policy regarding disposal of obsolete or badly damaged asset b. Does the	the following: **Hardware:** Computers, File Servers, Printers, Modems, Switches, Routers, Hubs, etc. **Software:** all software for each PC is logged with licenses and serial numbers. 2. Check availability of Information Asset Register with records of all assets 3. Verify: a. Written procedures for keeping asset inventory. b. Do the inventory procedures identify who (title) is responsible for maintaining the inventory

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			policy require management approval of disposal of the equipment? c. Obtain a copy and determine if it has been reviewed and approved by management	report? c. Do the inventory procedures require regular updating of the inventory report? 4. Is unused equipment properly and securely stored? 5. Are copies of the software and hardware inventory reports stored at another secure location? 6. On a sample basis, match the inventory report to actual hardware devices (Inventory Record Accuracy Checks-IRA), is all of the hardware

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				present, properly identified/ tagged and located in the proper place?
27	Information Classification	Improper Information Asset Classification can impact Confidentiality, Integrity and Availability related to organisational operations, assets and individuals. Poor classification systems can lead to loss of information in areas like Health and Safety, Financial Loss, Company's Mission/Programs and Public Trust	1. Information shall be classified in terms of legal requirements, value, criticality and sensitivity to unauthorised disclosure or modification. 2. **Labelling of information**: An appropriate set of procedures for information labelling shall be developed and implemented in accordance with the information classification scheme adopted by the organization. 3. **Handling of assets:**	1. Check whether the organisation has adopted a formal Information Asset Classification method. The classification method may include: a. Identification of information assets (labelling), b. Classification of information assets; by confidentiality, integrity and availability ("CIA"); c. Determining controls identified and handling

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			Procedures for handling assets shall be developed and implemented in accordance with the information classification scheme adopted by the organization.	methods adopted based upon the classification. 2. Check availability of Information Asset Register with records of all assets
28	Media Handling	Management of Removable media in a systematic manner can avoid loss of sensitive information, which can lead to both reputational damage and financial loss. Error in physical media transfer could also lead to cyberattacks using the social engineering route	1. Procedures shall be implemented for the management of removable media in accordance with the classification scheme adopted by the organization. 2. Media shall be disposed of securely when no longer required, using formal procedures. 3. Media containing information	1. **Management of removable media:** Check documented procedures and records related to a. Authorization for the removal of media from the company and a record of these removals maintained in order to preserve the audit trail, b. Media storage: In compliance

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			shall be protected against unauthorized access, misuse or corruption during transportation.	with manufacturers' standards, all media should be kept in a secure and safe environment; c. Where confidentiality or integrity of data is important, whether cryptographic techniques for securing data on removable media is used, d. Whether Multiple copies of important data is stored in different media to further reduce the possibility of accidental data damage or loss; e. Process for Registration of removable media 2. **Disposal**

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				of Media: Check documented procedures and records related to: a. Whether Confidential media is disposed safely through, e.g. by incineration or shredding, or data erasure b. Procedures to identify the items that need safe disposal c. If opting for media collection and disposal services; care must be taken to select a suitable external party with adequate controls and experience; d. In order to maintain an audit trail, the

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				disposal of confidential items is being logged. e. Whether contents of reusable media that are to be removed from the organization should be made unrecoverable; 3. **Physical Media Transfer:** Check documented procedures and records related to: a. Reliable transport or the use of authorized couriers; b. Packaging to safeguard the content from any physical damage likely to occur during transit and to

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				protect the content against environmental factors such as exposure to heat, humidity, or electromagnetic fields which could reduce media recovering efficiency. c. Logs to be maintained with details of the media content, date/time of transfer to location and receipt at the destination.
29	Security requirements of information systems	Information Security Requirements, if not captured during the initial Analysis phase, could lead to the development unreliable software prone	Security requirements should be captured in Requirements Analysis phase and carried forward to design, development and	Check for the SDLC methodology adopted with specific inclusion of application security needs. Check how the documentation

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		to external threats and vulnerabilities.	implementation phases.	of security requirements have been carried out
30	Security in development and support processes	Any compromise in processes from design, development, testing, implementation and support would make the organisation vulnerable to external threats and lead to likely disruption of business operations.	1. Rules for the development of software and systems shall be established and applied to developments within the organization. 2. Changes to systems within the development lifecycle shall be controlled by the use of formal change control procedures. 3. Modifications to software packages shall be discouraged, limited to necessary changes and all changes shall be strictly controlled. 4. Principles for engineering	Check and validate the following: 1. Examine how the security requirements captured in the Analysis or Initial phases have been addressed in the design, development, testing and implementation processes. Special attention to be given on how the organisation has included preventive measures to block SQL Injection, Denial of Service threats, etc. from the

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			secure systems shall be established, documented, maintained and applied to any information system implementation efforts. 5. Organizations shall establish and appropriately protect secure development environments for system development and integration efforts that cover the entire system development lifecycle.	external environment 2. Check whether 3rd Party VAPT testing has been formally carried out on the developed system and remedial actions initiated and closed before Go Live 3. Assess the Change Management process to ascertain how changes have been carried out during development and post implementation phases ensuring security reliability. 4. Examine the procedures related to Infrastructure

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
				and operating system changes during the life cycle of the project implementation. Ensure that the organisation tracks and control the changes in a systematic manner for the complete infrastructure environment comprising of Dev, Test and Production servers.
31	Management of information security incidents and improvements	Failure to detect security incidents promptly can result in prolonged unauthorized access or data breaches, leading to greater damage and	1. Management responsibilities and procedures shall be established to ensure a quick, effective and orderly response to information security incidents.	1. Check for availability of procedures on management of Information Security Incidents, events and weaknesses with emphasis on: Responsibilitie

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		potential regulatory consequences.	2. Information security events shall be reported through appropriate management channels as quickly as possible. 3. Employees and contractors using the organization's information systems and services shall be required to note and report any observed or suspected information security weaknesses in systems or services. 4. Information security events shall be assessed and it shall be decided if they are to be classified as information	s & Procedures: • Planning and preparing incident response, • Monitoring, detecting, analysing and reporting information security events, • Logging incident management activities, • Handling forensic evidence, • Assessing and deciding on information security events and weaknesses, • Respondin g to a security incident, both internally and externally • Reporting Information Security Incidents

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			security incidents. 5. Information security incidents shall be responded to in accordance with the documented procedures.	• Reporting Information Security Weaknesses • Assessment of & Decision on Information Security Events • Response to Information Security Incidents • Learning from Information Security Incidents • Collection of Evidence 2. Check sample security incidents in the past and check compliance to the incident management processes
32	Information security continuity	Absence of a rigorous Disaster Recovery and Business	1. The organization shall determine its requirements for information	1. Check whether the Organisation has appointed a Top

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		Continuity Plan could result in a • Complete Loss of Data, which is critical to business operations • Business Interruption • Loss of Clients, • Damaged Reputation and/or • Business Failure.	security and the continuity of information security management in adverse situations, e.g. during a crisis or disaster. 2. The organization shall establish, document, implement and maintain processes, procedures and controls to ensure the required level of continuity for information security during an adverse situation. 3. The organization shall verify the established and implemented information security continuity controls at regular intervals	Management driven Disaster Recovery/BCP Task Force to implement the plan 2. Review how the organisation has implemented or is in the process of implementing DR/BCP with focus on • Project Planning • Country Risk/Analysis Review • Business Impact Analysis • Recovery Strategy (RTO, RPO guarantees) • Plan Development • Testing • Training • Business

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			in order to ensure that they are valid and effective during adverse situations. 4. Information processing facilities shall be implemented with redundancy sufficient to meet availability requirements.	Continuity Plan • Maintenance
33	Monitoring Processes, Performance Evaluation	Weak controls over monitoring processes can expose the organization to potential fraud or manipulation of performance data.	1. What processes exist to monitor compliance with all relevant legislation plus internal policies and standards? 2. Are there monitoring processes carried out by management outside of internal audit?	Examine the Performance Management and Monitoring process with special emphasis on metrics identification, measurement and reporting Also, review how actions have been initiated looking at metrics trends or targets not getting achieved

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
34	Management Review	Absence of Management Reviews would lead to progressive degradation of Security measures	Top management shall review the organization's information security management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness.	Validate how the Management Review process is carried out in the organisation - either directly by the Board of Directors or by appointment of an Audit Committee. Check for appropriate review records and action points.
35	Internal Audit	Absence of a formal Internal Audit function and not having adequate and competent staff in the internal audit activity are a risk that exposes the organization to inadequate evaluation of the	The organization shall conduct internal audits at planned intervals to provide information on whether the information security management system: 1. conforms to a. the	1. Check the Internal Audit policy, standard and procedure within the organisation 2. Check for evidence of Internal Audits conducted by the Organisation, the Audit schedules and

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
		effectiveness of risk management, control and governance processes.	organization's own requirements for its information security management system; and b. the requirements of this International Standard; 2. is effectively implemented and maintained.	the results of the Audit. 3. Check how the recommendations of the Internal Audit have been implemented examining a few sample cases.
36	Information & Communications	2.16 Absence of Management Reports involving metrics of Information Security System would not inspire confidence in the Board of Directors that the Security policies are working effectively	1. What metrics are provided to the board of directors, its committees and management in relation to IT security? 2. What additional reports are provided to the board of directors and to management on a regular basis? 3. Is management	1. Check the IT Security Management Reports that are prepared and circulated to the Board of Directors 2. Examine the content and records of the Board Review / Audit Committee review and the actions taken

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			always provided with reports when there are IT control failures? 4. Do the board of directors and its committees receive similar reports of IT control failures?	
37	Cryptographic Controls	Improper configuration of cryptographic controls, such as incorrect algorithm or key length selection, may weaken the overall security posture.	1. A policy on the use of cryptographic controls for protection of information shall be developed and implemented. 2. A policy on the use, protection and lifetime of cryptographic keys shall be developed and implemented through their whole lifecycle.	In case the Organisation's business environment requires, 1. Review the Cryptographic Control policy and procedures adopted in the organisation 2. Review that robust Key Management procedures are in place to protect sensitive information
38	Compliance with legal and	The organisation	1. All relevant legislative	Review and validate how

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
	contractual requirements	does not comply with legal and contractual requirements.	statutory, regulatory, contractual requirements and the organization's approach to meet these requirements shall be explicitly identified, documented and kept up to date for each information system and the organization. 2. Appropriate procedures shall be implemented to ensure compliance with legislative, regulatory and contractual requirements related to intellectual property rights and use of proprietary software products.	the organisation has identified and recorded its legal, regulatory and contractual obligations; the responsibilities for meeting such requirements and any necessary policies, procedures and other controls required for meeting the controls.

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			3. Cryptographic controls shall be used in compliance with all relevant agreements, legislation and regulations.	
39	Information security reviews	Managers fail to review the compliance of information processing and procedures within their area of responsibility with the appropriate security policies, standards and any other security requirements.	1. The organization's approach to managing information security and its implementation 2. Managers shall regularly review the compliance of information processing and procedures within their area of responsibility with the appropriate security policies, standards and any other security requirements. 3. Information systems shall be regularly	1. Check that Independent Reviews are being conducted periodically of the Information Security Policy with a focus to improve the organisation's approach to information security, including • The information security policy. • Topic-specific policies. • Related controls. 2. Check whether the persons who

Sr. No.	Sub Process	Risk	Control Objective	Key Control Measures
			reviewed for compliance with the organization's information security policies and standards.	have conducted the reviews have been independent, possess relevant operational competence and have no vested interests. 3. Check whether the organisation also conducts Ad-hoc reviews due to amendment of laws/ regulations, post security incidents, major changes to business, introduction of new products, organisational changes, etc.

Chapter 10

Third Party Service Providers

Managing Third Party Risks

10.1 In an increasingly interconnected pharmaceutical landscape, the strategic engagement of third-party entities offers both opportunities and intricate challenges. This chapter delves into the critical domain of third-party risks within the pharmaceutical sector, spotlighting manufacturing and data privacy concerns.

Manufacturing Risks and Controls

Quality Control and Assurance	
Risk	**Controls**
The reliance on external manufacturers exposes pharmaceutical companies to potential quality compromises, jeopardizing patient safety and corporate reputation.	Rigorous supplier vetting, routine manufacturing facility audits and clear quality agreements are essential to uphold quality standards.

Supply Chain Disruptions	
Risk	**Controls**
Third-party suppliers introduce vulnerability to supply chain disruptions, stemming from regulatory shifts, geopolitical factors and logistical issues.	Developing contingency plans, maintaining buffer stocks and fostering robust communication channels can mitigate supply chain risks.

Intellectual Property Protection	
Risk	**Controls**
Sharing proprietary manufacturing processes with third parties	Effective employment of non-disclosure agreements (NDAs),

heightens the risk of intellectual property infringement, leading to competitive setbacks.	restricted information access and legal safeguards safeguards proprietary interests.

Data Privacy Risks and Controls

Confidentiality Breaches	
Risk	**Controls**
Collaborative efforts with third parties expose sensitive patient data and confidential information to potential breaches, inviting legal and reputational repercussions.	Imposing stringent data sharing agreements, aligning with data protection regulations and implementing robust encryption bolster data security.

Data Integrity and Accuracy	
Risk	**Controls**
Data managed by third parties may lack proper validation, undermining regulatory submissions and clinical trial credibility.	Defining standardized data protocols, validation procedures and periodic data audits are indispensable to maintain data integrity.

Regulatory Non-Compliance	
Risk	**Controls**
Inadequate data privacy practices by third parties risk regulatory non-compliance, leading to regulatory sanctions and delays in approvals.	Comprehensive assessment of third parties' data management practices, audits and mechanisms for prompt addressing of non-compliance issues ensure adherence.

Examples:

Consider a pharmaceutical enterprise entrusting a pivotal drug's manufacturing to an external entity. Regular audits of the manufacturing facility aligned with Good Manufacturing Practices (GMP) uphold quality control and assurance.

In the realm of data privacy, envision a collaboration with a contract research organization (CRO) for clinical trials. A robust data sharing agreement encompassing data handling protocols, encryption standards and scheduled security audits ensures the security of patient data.

Navigating third-party risks in manufacturing and data privacy demands an integrated approach, incorporating proactive risk assessment, well-defined controls and constant vigilance. Striking this equilibrium fortifies the pharmaceutical sector's credibility, patient well-being and regulatory adherence.

As per SIA 530, "Third Party Service Provider", The Internal Auditor shall study and evaluate the scope of TPSP's services, governance and oversight process in place to outsource and manage risks of deploying TPSPs, especially, risks arising from direct access and control over critical information of the User Entity.

1. Third Party Governance and Oversight

Internal Auditor of User Entities outsourcing to TPSPs shall review scope of outsourcing as well as third party's governance and oversight process. Certain key elements of the third-party governance and oversight process is as follows:

a. Existence of a comprehensive database of all third-party arrangements and their respective business owners;

b. The criteria for categorisation of each arrangement is based on various factors, such as, tenure of the relationship, past performance, qualifications and credentials, risk assessment, cost/benefits, etc.;

c. Evaluation is conducted on the business criticality of the arrangement and the significance of the services provided to the User Entity, especially, its system of risk management and internal controls;

d. Objective manner of TPSPs', selection and appointment based on pre-defined criterion and based on merit;

e. The roles and responsibilities of the User Entity's officials charged with governance and oversight of these arrangements and the manner in which they discharge their responsibilities, especially regarding ethical dealings;

f. The roles and responsibilities of the User Entity's officials charged with governance and oversight of these arrangements and the manner in which they discharge their responsibilities, especially regarding ethical dealings;

g. Details of the Service Level Arrangements (SLAs) in place to ensure performance, quality, time, cost, etc. The manner in which SLAs are measured, verified and monitored for compliance;

h. Systems and controls through which all the information of the User Entity is collected, processed, stored, secured and continuously made available; and

i. Overview of the nature of governance and oversight mechanisms in place at the TPSP to protect the User Entity's information, including details of any TPAA reports to be provided by TPSP to the User Entity or allowing the User Entity with a right to audit and seek information as required from time to time.

2. Third Party Due Diligence

The User Entity management should undertake a due diligence of the governance, risks and control environment at the TPSP, especially, its ability to provide a highly reliable and secure IT system. Apart from conducting a back-ground check of the TPSP, an assessment should be made to evaluate their ability to conduct business with high-integrity and in a safe and secure manner and in compliances with all laws and regulations. Where management does not undertake such due diligence, the Internal Auditor shall make recommendations for such an exercise.

At times a TPAA report issued by an independent service auditor can provide assurance of the reliability of the IT systems in place, in this case the Internal Auditor should review the reliability of the TPAA report, with respect to the scope and audit procedures undertaken.

Post engagement of the TPSP, procedures should be undertaken to on-board TPSP staff and management to implement the systems and controls necessary to ensure a seamless service in line with expectations. For activities outsourced, a review of the controls should be undertaken for pre-transition and post transition.

3. Third Party Risk Assessments

An independent risk assessment of the third-party relationship shall be performed by the Internal Auditor, taking into account the nature of the service provided and its criticality to the overall business management and financial reporting. For example, a TPSP of the User Entity, such as, a call centre, may not be engaged in any financial transaction processing, it may still have access to the User Entity's customer database containing business critical information and hence explores with the risk of data-breach.

Similarly, where the arrangement includes provision of staff by the TPSP to the User Entity, a review of the risks involving contractual staff are in place (including risk mitigation steps, such as, background checks).

Aspect of Non-disclosure agreement for protecting the information may also be covered as part of the risk assessment. The Internal Auditor will review the controls at the TPSP and highlight any missing or weak controls over such vulnerabilities and any steps required to strengthen the controls. The contractual arrangements with the TPSP should permit the Internal Auditor to conduct such a risk assessment, including necessary internal audit procedures outlined in the scope of outsourced services at reasonable frequency.

4. Third Party Performance Monitoring

The Internal Auditor shall undertake a review of the steps taken by the management to periodically monitor the performance of the TPSP, in line with the SLAs and other legal stipulations. In addition, there shall be a regular assessment of any independent reviews undertaken at the TPSP by its auditor, issuing TPAA reports.

The Internal Auditor will gather sufficient and reliable evidence to confirm adequate mitigation of risks arising from the outsourcing of services to the TPSP. Monitoring by the management needs to be a continuous and an on-going exercise and the comprehensiveness of assessment would depend on the risk rating of the service organization.

5. Evaluation of Independent Third-party Audit and Assurance Report

The Independent TPAA report submitted by TPSP shall be evaluated considering the risks assessed with outsourcing and corresponding processes and controls. There are certain activities or processes which may

be retained by the User Entity and the auditor shall review the controls retained by the User Entity to form an overall opinion on controls.

The Internal Auditor shall ensure that a review of the TPAA report is undertaken in compliance with Standard on Internal Audit (SIA) 520, “Internal Auditing in an Information Technology Environment”.

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