# GUIDANCE NOTE ON INTERNAL AUDIT OF PHARMACEUTICAL INDUSTRY


THE INSTITUTE OF COST ACCOUNTANTS OF INDIA

(Statutory body under an Act of Parliament)

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## MISSION STATEMENT

"The CMA Professionals would ethically drive enterprises globally by creating value to stakeholders in the socio-economic context through competencies drawn from the integration of strategy, management and accounting."

## VISION STATEMENT

"The Institute of Cost Accountants of India would be the preferred source of resources and professionals for the financial leadership of enterprises globally."

# ABOUT THE INSTITUTE

The Institute of Cost Accountants of India is a Statutory body set up under an Act of Parliament in the year 1959. The Institute as a part of its obligation, regulates the profession of Cost and Management Accountancy, enrols students for its courses, provides coaching facilities to the students, organises professional development programmes for the members and undertakes research programmes in the field of Cost and Management Accountancy. The Institute pursues the vision of cost competitiveness, cost management, efficient use of resources and structured approach to cost accounting as the key drivers of the profession. In today's world, the profession of conventional accounting and auditing has taken a back seat and cost and management accountants are increasingly contributing towards the management of scarce resources and apply strategic decisions. This has opened up further scope and tremendous opportunities for cost accountants in India and abroad.

After an amendment passed by the Parliament of India, the Institute is now renamed as "The Institute of Cost Accountants of India" from "The Institute of Cost and Works Accountants of India". This step is aimed towards synergising with the global management accounting bodies, sharing the best practices which will be useful to large number of trans-national Indian companies operating from India and abroad to remain competitive. With the current emphasis on management of resources, the specialized knowledge of evaluating operating efficiency and strategic management the professionals are known as "Cost and Management Accountants (CMAs)". The Institute is the 2nd largest Cost & Management Accounting body in the world and the largest in Asia, having approximately 5,00,000 students and 85,000 members all over the globe. The Institution headquartered at Kolkata operates through four Regional Councils at Kolkata, Delhi, Mumbai and Chennai and 108 Chapters situated at important cities in the country as well as 11 Overseas Centres. It is under the administrative control of Ministry of Corporate Affairs, Government of India, New Delhi.

## Internal Auditing and Assurance Standards Board (IAASB)

The Institute & eminent resource persons from our profession have felt the need for the constitution of board for Internal Audit. The Present Council for the first time has nurtured the Board to formulate and issue standards, guidelines and advisory for the Internal Audit Function. The Cost Accountants have been recognized by the Companies Act, 2013 and other regulatory bodies for appointment as Internal Auditors.

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12, Sudder Street, Kolkata - 700 016

## Contact Details

**CMA P. Raju Iyer**
**Vice President & Chairman**
The Internal Auditing and Assurance Standards Board
E-mail: vicepresident@icmai.in

**CMA Kushal Sengupta**
**Addl. Director**
**&**
**Secretary**
Internal Auditing and Assurance Standards Board
E-mail: iaasb@icmai.in

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## FOREWORD OF PRESIDENT

It is our great pleasure to announce the formation of the **Internal Auditing & Assurance Standard Board (IAASB)** by the **Council of the Institute for the block year 2019-2023,** taking into consideration the Statutory Provision of the Companies Act, 2013 wherein the Cost Accountants along with other professionals have been considered for taking up the assignment of Internal Audit. As per **Section 138 (1) of the Companies Act, 2013,** such class or classes of companies, as may be prescribed, shall be **required to appoint an internal auditor**, who shall either be a Chartered Accountant or **a Cost Accountant**, or such other professional as may be decided by the Board, to conduct internal audit of the functions and activities of the company. Keeping this in mind and in line with the regulatory recognition of practicing Cost Accountants under section 138 (1) of Companies Act 2013 to be appointed as Internal Auditors, the present Council for the first time as a hall mark in the history of the Institute, has constituted the Board to formulate and issue standards, guidance notes, guidelines and advisory for the Internal Audit activities.

This Guidance Note focuses on **Internal Audit in the Pharmaceutical Industry**. It also provides an insight into the general framework of Internal Audit mechanism vis-à-vis sector specific issues which are prevalent in Cement Industry.

On behalf of the Institute, I do acknowledge the sincere and persistent effort of **CMA Sukrut Mehta**, Member of the Institute who has been entrusted for preparation of this Guidance Note as an author and also extending sincere gratitude to **CMA B.B.Goyal**, Co-opted Member of IAASB for his enormous support and guidance as reviewer nominated by IAASB.

I am thankful to CMA P.Raju Iyer, Vice-President of the Institute and Chairman of the Internal Audit Assurance & Standards Board (IAASB) for their relentless support without which, the formation and smooth functioning of the Board would have proved to be difficult.

I am quite sure that the readers of Guidance Note will find it very useful in their professional life and will be benefitted to enrich their knowledge in the field of Internal Audit.

**CMA Biswarup Basu**

President

Date: Kolkata, 30th July, 2021.

## FOREWORD OF VICE- PRESIDENT

It gives me immense pleasure to take this opportunity to present the Guidance Notes on **Internal Audit on Pharmaceutical Industry** prepared by "The Internal Auditing and Assurance Standards Board (IAASB)" on behalf of the **Council of the Institute for the block year 2019-2023. I do also extend my personal gratitude to the Council for formation of Internal Auditing & Assurance Standard Board (IAASB),** taking into consideration the Statutory Provision of the Companies Act, 2013 wherein the Cost Accountants along with other professionals have been considered for taking up the assignment of Internal Audit.

The present Council has felt it necessary to constitute this Board to provide an opportunity to the members of the Institute to further their skills and knowledge in the field of Internal Audit by way of imparting specific training and providing guidance notes and standards for serving the industry in both the Manufacturing as well as the Service Sector.

I am of the considered view that this Guidance Note would go a long way in strengthening and updating the professional expertise of Cost Accounting Professionals and all other stakeholders in the field of Internal Audit in delivering a far greater role and responsibilities in the years to come.

On behalf of the Institute, I sincerely thanked **CMA Sukrut Mehta**, member of the Institute who has been entrusted for preparation of this Guidance Note as an author and also extending my sincere gratitude to **CMA B.B.Goyal**, Co-opted Member of IAASB for his enormous support and guidance as reviewer for imparting their expert knowledge in the field of Internal Audit for finalization of this guidance note.

I am happy to be associated with board as a member and would like to extend my sincere thanks to the President of the Institute, Council Members and the members of the Internal Audit Assurance & Standards Board (IAASB) for their relentless support & effort without which, the Board would not be able to achieve its desired goals and objectives.

I wish all the success of the Board in its future endeavor.

**CMA P.Raju Iyer**

Vice President

Place & Date: Chennai, 30th July, 2021.

THE INSTITUTE OF COST ACCOUNTANTS OF INDIA

# FOREWORD OF THE CHAIRMAN

The Council of the Institute, under the able guidance and leadership of CMA Balwinder Singh, Past President had constituted the **Internal Audit Standards Board (IAASB)** in the year 2019. This was a historic decision to **promote the role of Cost & Management Accountants in the domain area of internal audit**. The objectives and functions of the Board include development & issue of standards, guidance notes, implementation guides, technical guides, practice manuals, information papers and case studies etc. and to undertake their revision, where ever necessary.

The requirement of IAASB was the need of the hour considering the inclusion of "Cost Accountants" in the scope of Internal Audit as per provisions of Companies Act, 2013 and other legislations in force.

As the business activities and operations are undergoing continuous changes, auditing today, is not confined only to verification of documents and financial transactions but may also be suitably aligned with the developments in Artificial Intelligence and data mining. To assess the organization's performance, and to ensure the overall quality, credibility, consistency and comparability of the work performed by the Internal Auditors, it is necessary to follow the prescribed standards, policies, rules, and regulations covering various sectors.

To support & enable the Cost Accountants to qualitatively perform internal audit assignments, the Board felt the need for the preparation and development of Guidance Notes on Internal Audit for General requirement as well as for specific Industry /Service Sectors.

Considering the same, the board took up the assignment of preparation of **Internal Audit Guidance Note on Pharmaceutical Industry** along with other Guidance Notes on Inter Audit which will be published very soon.

On behalf of the Institute as a Council Member and as a Chairman of IAASB, I sincerely thanked **CMA Sukrut Mehta**, Member of the Institute who has dedicated his professional knowledge and expertise in preparing this Guidance Note as an author and also extending my sincere gratitude **to CMA B.B.Goyal**, Co-opted Member of IAASB for his enormous support, guidance and expertise as reviewer for finalization of this guidance note. I do also acknowledge and appreciate the support, expertise and guidance of all the members of the board for preparation and finalization of this guidance note.

I am sure that our members would find this Guidance Note as a very useful document for enriching their knowledge in Cement Industry and in furtherance to establish a lucrative career in Internal Auditing to tap the fullest potential of Internal Auditing and Assurance services.

**CMA P.Raju Iyer**

Chairman of IAASB

Place & Date: Chennai, 30th July, 2021.

# C O N T E N T S

# INTERNAL AUDIT

1

**What is Internal Audit?**

The establishment of Internal Audit can be linked to the need of independent verification with a view of reducing book keeping errors, general misappropriations and fraud. With the booming growth of business size and structure it was felt that many businesses did not have appropriate controls in place to permit full achievement of their strategic objectives. The management of these businesses found it impossible to visually observe all of the operating areas in their respective areas of responsibility or to have sufficient personal contact with individuals who directly or indirectly reported to them. In seeking ways to deal with these new problems, management appointed special staff people to review and report on what was happening and to probe for the "why". These people came to be known as "internal auditors." Thus, Internal Audit is defined as:

"Internal Audit is continuous process of appraisal of an organization's operations, evaluation and monitoring of risk management reporting and control practices. It is an independent and objective oriented assurance and consultancy activity designed to add value and improve an organization's operations"

**Statutory Requirements**

While, Internal Audit continues to be driven by the ethics and direction of the company Board, it is no longer an option due to its statutory obligation. As per section 138 of the Companies Act 2013, it is now mandatory to have Internal Audit of (1) Such class or classes of companies as may be prescribed shall be required to appoint an internal auditor, who shall either be a chartered accountant or a cost accountant, or such other professional as may be decided by the Board to conduct internal audit of the functions and activities of the company. (2) The Central Government may, by rules, prescribe the manner and the intervals in which the internal audit shall be conducted and reported to the Board.

In this context, rule 13 of Companies (Accounts) Rules 2014, clearly defines the companies which are mandated to have Internal Auditors. Further, for the purpose of this rule, the internal auditor may or may not be an employee of the company, but does include the term "Chartered Accountant" or "Cost Accountant", which shall mean a "Chartered Accountant" or a "Cost Accountant" whether engaged in practice or not.

**Scope & Objectives of Internal Audit**

The internal audit function varied greatly with respect to the number of people assigned to perform it, the scope, and the nature of the work being done. In some organizations, internal auditors were used to check on routine financial and operational activities with a heavy emphasis on compliance, security, and detection of fraud. In others, internal auditors were given higher levels of status and were asked to analyze and appraise more substantive financial and operational activities.

Gradually, internal auditors also began to exhibit "industry specialization" in terms of their domain knowledge of specific industries such as health care, oil, gas, and energy, defense, financial services, transportation, wholesale and retail, technology, media and entertainment, telecommunications, government and nonprofits, education, etc.

The business environment has experienced rapid and revolutionary change with far reaching consequences for organizations worldwide. Management responses to fierce global competition

have included improved quality and risk management initiatives, reengineered structures and processes, and greater accountability — all needing more timely, reliable, and relevant information for decision-making. Organizations are also scrambling to put in place more effective governance structures and processes. In such a climate, it is no surprise that the internal audit function is viewed as a qualified group of professionals to help with such experimentation with improved governance as well as support key governance processes: for monitoring the controls over, and for evaluating the operational effectiveness of, these management strategies and initiatives.

However, to take advantage of this tremendous surge in the demand for their services, not only do internal auditors need a considerably enhanced repertoire of skills, attributes, and competencies but they also need to commensurately showcase industry specialization and exposure to varied operating specialties with the industry. With the recent advents of increase in scope and acceptability Cost Audit and Compliance Report, CMAs are in perfect position to demonstrate the requisite skills and competencies necessary for undertaking successful Internal Audit function.

Internal Auditing is an independent appraisal function established within an organization to examine and evaluate the company's activities and effectiveness of its controls. The primary objective of internal auditing is to assist members of the company to effectively discharge their individual and collective responsibilities. Thus, Internal Audit provides analyses, appraisals, recommendations, counsel and information concerning the activities reviewed. The internal auditor has a dual role in providing consulting advice and help to the business and also providing objective assurances across the organization. In a nut shell, help is given to managers on request, or as spin-off from a previous audit, and there will be clear criteria to approving all requests for help. The internal audit function can help with the following:

- Facilitate Cost and operational appraisal report
- Developing risk management arrangements.
- Internal control awareness training.
- Facilitating risk workshops.
- Establishing control reporting structures.
- Implementing compliance checks and supporting management's compliance teams.
- Understanding the new governance agenda.
- Developing good audit committee resources.
- Reviewing and updating procedures.
- Developing control frameworks.
- Assessing the level of control awareness among staff.
- And a whole assortment of other related projects.

The Government of India has always considered Pharmaceuticals as a strategically important industry due to its wide-reaching socio-economic impact. To ensure accuracy of data and cost, Government of India for the first time promulgated "Cost Accounting Records (Bulk Drugs) Rules, 1976" and "Cost Accounting Records (Formulations) Rules, 1989" under sec. 209 (1)d of the Companies Act, 1956. In year 2011, both these rules were consolidated into "Cost Accounting Records (Pharmaceutical Industry) Rules, 2011. Under these rules, all the Companies engaged in manufacturing and marketing of Bulk Drugs or Formulations or both, were required to maintain cost records as specified under Cost Accounting Standards (CAS) and Generally Accepted Cost Accounting Principles (GACAP). Later, with the implementation of the Companies (Cost Audit and Records) Rules 2014, the inclusion of Pharmaceuticals for Cost Records maintenance and Audit has continued.

The objective of this Guidance Note on Internal Audit of Pharmaceutical Industry is to focus more on understanding the products covered, industry scenario, techno-commercial aspects of the industry, its manufacturing process, specific performance parameters, internal processes etc. to guide Internal Auditor of the Pharmaceutical industry to conduct internal audit effectively.

# INTRRODUCTION TO PHARMACEUTICAL INDUSTRY

2

**About the Sector**

The Indian pharmaceutical industry has for long been India's torch bearer in science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds; almost every type of medicine is now made in the Indian pharmaceutical industry. This Industry driven by knowledge, skills low production costs and international quality products has witnessed a robust growth from production turnover of about INR 5,000 crores in the year 1990, to over INR 1 lakh crores in 2009-10, and Rs. 2, 04, 627.15 Crores in 2015-16, comprising of domestic market of INR 98, 414.4 Crores and export of INR Rs. 110, 5, 342.20 Crores (Data source – CMIE – Economic Outlook). This was a landmark year for the Indian Pharmaceutical Industry as its exports outperformed domestic sales for the first time. Indian pharmaceutical industry has the largest number of U.S. Food and Drug Administration (USFDA) approved manufacturing facilities (262) outside USA. 253 plants are European Directorate for the Quality of Medicines (EDQM) approved and 1300 World Health Organization (WHO) Good Manufacturing Practices (GMP) compliant plants. Top exporting destinations are North Americas (27%); European Union (18%); Africa (18%); Middle East (7%); ASEAN (6%); Latin America (6%); and CIS (6%). India is also called the 'pharmacy of the world' and renowned for very high-quality drugs at very cost competitive prices.

Today, the Indian pharmaceutical industry is the world's third largest of drugs by volume1. The Industry's journey to annual revenues of about USD 38 billion2 can be attributed to world-class capabilities in formulation development, the entrepreneurial ability of the firms and the vision of the industry to establish India's footprint in large international markets such as the United States. Yet, the Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The Pharmaceutical and Chemical industry in India has severe price competition and government price control. The Pharmaceutical industry in India caters to the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals, and Injectible. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units).

Pharmaceutical industry is a typical sector and medium to large scale units' market anything between 200 to 800 products. If the company is very active in the export market, then the number of products (SKUs) may sky rocket to couple of thousands, because, the product required to be sold in those foreign countries have to comply with the requirement of FDA/MHRA authority of those respective countries. Further, there are different norms for Packing Materials in different countries and the Packing Materials have to be printed in different languages for different countries. This will multiply the number of products. If one considers 15 to 17 input materials for each formulation, the Companies may be handling phenomenal number of inputs.

These features necessitate much detailed exercise on material management front. It also calls for standardization of Packing Materials to reduce the variety and thereby reduce the necessity of holding very wide range of Packing Materials. Internal Audit needs to look at this rationalization of

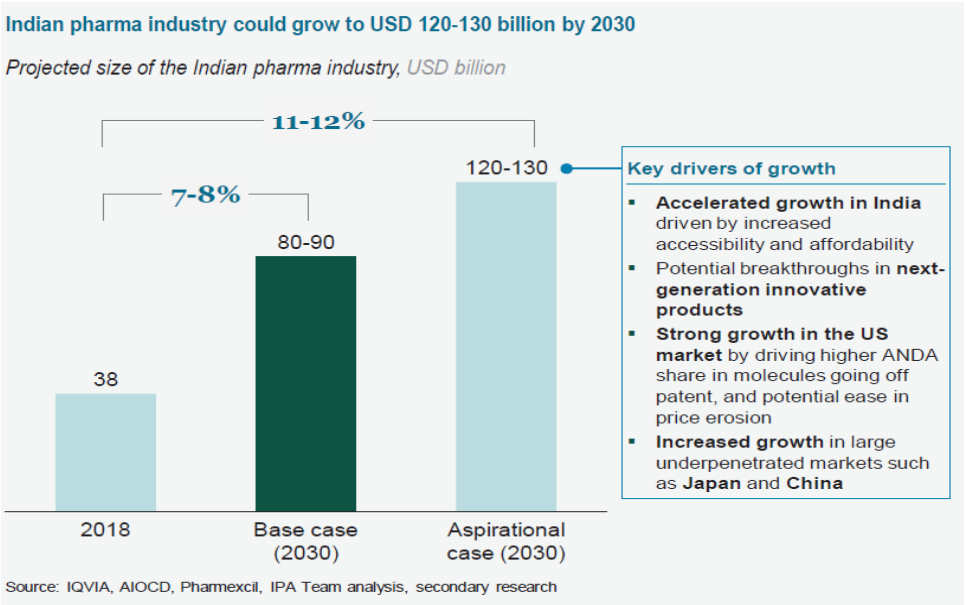
specification where ever it is feasible. For example - in case of Foil and Blister, the back of foil or strip is plain and if its size is rationalized, then the inventory of such foil can be controlled.

In case of Bulk Drug/Active Pharmaceutical Ingredient (API), it is necessary to consider purity and consistency and on detailed analysis it may appear that a particular supplier may turn out to be cheapest considering all the cost, especially for the input which requires cold chain (controlled temperature all throughout the transit from the manufacturer to the consumer).

Over the past decade, pharmaceutical companies have entered a difficult period where shareholders, the market, and regulators have created significant pressures for change within the industry. The core issues for most of drug companies are declining productivity of in-house R & D, patent expiration of number of block buster drugs, increasing legal and regulatory concern, and pricing issue. As a result, larger pharmaceutical companies are shifting to new business model with greater outsourcing of discovery services, clinical research and manufacturing. Owing to a wide-ranging product mix consisting of high-end research services, biologics, and complex technology services, all offered at a low cost, contract manufacture and research services (CRAMS) industry has witnessed tremendous growth in the Indian subcontinent.

Estimates suggest that the industry directly and indirectly provides employment to over 2.7 million people, in high-skill areas like R&D and manufacturing3. The industry generates over USD 11 billion of trade surplus every year and is amongst the top five sectors contributing to the reduction of India's trade deficit4. The Indian pharmaceutical industry has attracted more than USD 2 billion in FDI inflows over the last three years, making it one of the top eight sectors attracting FDI5. This FDI inflow has only gained momentum in 2020 with Private Equity (PE)/Venture Capital (VC) investments in pharmaceutical companies having grown by more than 3.5 times in 2020 and for the first time crossed $1 billion to touch $1.69 billion during January to September 2020. Some of the major deals reported in 2020 include Carlyle's $490 million investment in Piramal Pharma, KKR's $414 million investment in JB Chemicals, Carlyle's $210 million investment in SeQuent Scientific, ChrysCapital's $132 million investment in Intas Pharmaceuticals, Advent International's $128 million in RA Chem Pharma, among others6.

The Indian pharmaceutical industry has established a strong presence in the global generics market by delivering high-quality drugs at scale. The industry has made innovations in processes and formulations and developed itself as a reliable, high quality and cost-effective global drug supplier7. By making essential drugs affordable and accessible, the industry has captured a leading share in developed economies such as the United States (1 of every 3 pills8) and the United Kingdom (25 percent of medicines consumed9). Thus, even at current rates of seven to eight percent CAGR, the industry's annual revenues can grow to about USD 80 to 90 billion by 2030. However, it could also set bold aspirations of eleven to twelve percent CAGR, and grow to annual revenues of about ~USD 65 billion by 2024 and about ~USD 120 to 130 billion by 2030. This would require multiple growth cylinders to fire simultaneously, as depicted in the Exhibit below.




India is also amongst the preferred destinations for outsourcing of research as well as manufacturing activities. New age CRAMS providers are able to cater to not just the pharmaceutical clients, but also biotech, agrochemicals, nutrition, animal health, consumer goods and others. This has opened up wider growth opportunities for the sector. At present, there is very less innovator manufacturing happening out of India as contract manufacturing. However, with the right scale, capacities, systems and infrastructure, integrated service providers are well placed to capture a larger share of the innovator manufacturing opportunities.

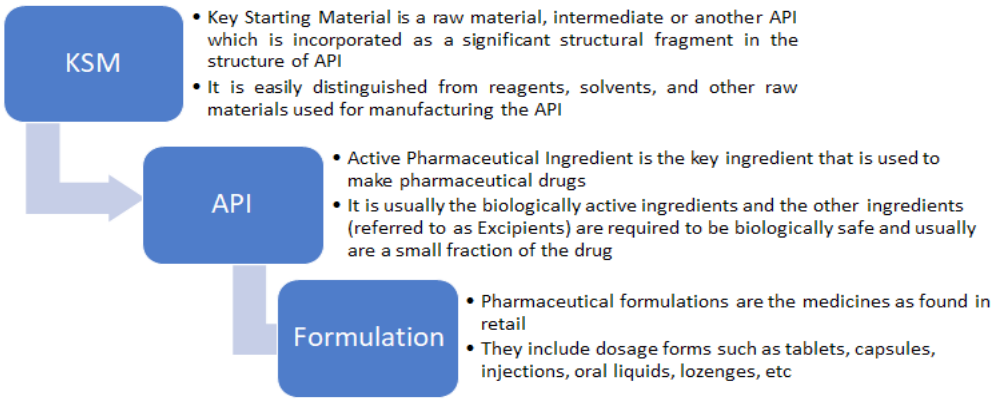
Current global financial conditions and the threat of a broad recession accelerated the timetable for implementing transformational changes in global organizations, as the industry confronts lower corporate stock prices and an increasingly cost-averse customer. Leaders of the largest global pharmaceutical companies recognize the need for transformational change in their organizations, but will need to move swiftly to digitization technologies and ensure sustained growth.

Even if the Indian stock market may be dreading a possible recession but Indian pharmaceutical companies seem unfazed by slowdown fears. Riding on better sales in the domestic and export markets, Indian pharmaceutical industry is expected to continue with its good performance. Today Indian Pharmaceutical Industry can look forward to the years to come, with great expectations. There are opportunities in expanding the range of generic products as more molecule come off patent, outsourcing, and above all, in focusing into drug discovery as more profits come from traditional plays. At the same time, the Indian Pharmaceutical Industry would have to contend with several challenges particularly the

- Effects of new product patent
- Drug price control
- Regulatory reforms
- Infrastructure development
- Quality management and
- Conformance to global standards.

Further, the certain pharmaceutical companies such as Cipla, Ranbaxy, Dr Reddy's Labs and Lupin are actively supplying quality drugs to the government's ambitious 'Jan Aushadhi' project. In an attempt to commercialize the project, the Government has roped in the private sector to bulk-procure generic drugs from them. There are currently over 5,000 Jan Aushadhi stores across the country.

**Product Categories**




**Types of Products under the Pharmaceutical Industry**

The above figure clearly lists the types of products in the pharmaceutical industry. If, however to categorize drugs, there are three main drug categories namely patented medicines, generic medicines, and OTC medicines.

- **Patented Medicines:**

  Patented drugs are usually launched after years of research and a lengthy approval process. These compositions, novel drugs, drug delivery systems, or process of manufacturing/ synthesizing/fermenting are protected under Intellectual Property Rights and usually command a significant premium due to their added pharmacokinetic or pharmacodynamic contribution to the treatment. This premium is permitted so that the company is compensated for its Research and Developmental activities.

- **Generic Medicines:**

  Generic drugs are usually allowed after the expiry of the Patents on a drug as the absence of patent protection of drugs, motivate other companies to enter into the market because generic companies do not bear the high cost of research and development. One of the major drawbacks of the generic medicines is that the patients and doctors may not know of their existence and thus, companies have started to launch 'branded generics'. Branded generic drugs are medicines that are sold under a brand name but are no longer covered under a patent.

- **OTC Medicines:**

  Schedule H is a class of drugs which cannot be purchased without a doctor's prescription. However, not all formulations are covered under the Schedule H, as they are deemed to be safe for self-medication in moderation. Thus, these formulations do not need a doctor's

prescription for purchase and are approved for Over-The-Counter (OTC) purchases. Usually, OTC drugs have a low chance of misuse or abuse, their benefits outweigh their risks, they are appropriately labelled, and patients can administer them safely without the assistance of any medically trained personnel.

Classification of Drugs is undertaken considering their chemical characteristics, structure, and its ability to treat specific ailments. While there are numerous therapeutic, and sub-therapeutic categories, the mostly commonly used categories are as under:

- **Anti-Infectives:** These are drugs which attack anti-infectious agents or prohibit them from spreading. Anti-infectives include antibacterial, antifungal, antiviral and antiproatozoans.
- **Gastro Intestinal:** These include drugs for treatment of nausea, diarrhea, or ulcers. Sub-therapeutics in this category include Anticholinergics, Antidiarrheals, Antiemetics, Antiulcer Medications.
- **Antibiotics:** These are general use medicines which target a variety of bacterial infections. Antibiotics inhibit the growth of bacteria by interfering with the production of certain biochemical, which aids in quick elimination of infections.
- **Analgesics:** These are also called as 'Pain Killers' and help patients achieve analgesia relief from the pain by targeting the peripheral or central nervous systems. The sub-therapeutic categories include Non-opioid analgesics, antipyretics and no steroidal anti -inflammatory medicines, Opioids, Medicines to treat Gout, and Disease modifying agents used in rheumatoid disorders.
- **Anesthetics Agents:** These medicines are usually administered by trained medical staff and include General Anesthetics, Local Anesthetics, Preoperative medication and sedation for short term procedures.
- **Others:** Other therapeutic categories include Anticonvulsants/Antiepileptics, Antimigraine, Antineoplastic/ immunosuppressives, Blood products and Plasma substitutes, Cardiovascular drugs, Diuretics, Vaccines, Muscle relaxants and cholinesterase inhibitors, Ophthalmological Medicines, and Vitamins and Minerals.

**Government Policies, Rules, and Schemes**

There are various Government Policies and Rules applicable to the pharmaceutical sector. It is one of the selected few regulated industries. There are many problems faced by the organizations within this industry in accessing requisite information in order to comply with the regulatory requirements domestically and in the regulated foreign markets. The important Indian and International guidelines and regulations to be followed are as under:

**1)** **CDSCO:** The Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India. To regulate all filings and licensing requirements, CDSCO has launched the SUGAM portal which is further explained later.

2) **DPCO, 1995:** While the Drugs (Price Control) Order 1995 has been replaced by DPCO 2013, overcharging and non-compliance notices under the Act continue to haunt major pharmaceutical manufacturers with the Government of India claiming an overcharge of over Rs. 5,000 Crores from the Industry. The provisions of this important Act are further discussed below.

3) **DPCO, 2013:** DPCO 2013 was launched in May 2013 and has since been the price control mechanism for all retail sales of medicines in India. DPCO 2013, its compliance regulations, issues, and process for verification have been detailed below.

4) **D&C Act, 1940:** The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India. It helps protect against manufacture and sale of misbranded, adulterated and spurious drugs.

5) **GCP Guidelines:** The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guidelines for research in human subjects. These Good Clinical Practices or GCP guidelines are essentially based on Declaration of Helsinki, WHO guidelines, and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) requirements.

6) **The Pharmacy Act, 1948:** Baring sale of drugs through institutional sales, the sale of all drugs is directed through retail pharmacy outlets. The Pharmacy Act, 1948 is meant to regulate the profession of Pharmacy in India.

7) **DMROAA, 1954:** The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities.

8) **NDPSA, 1985:** The Narcotic Drugs and Psychotropic Substances Act, 1985 is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

9) **WHO:** WHO guidelines on medicines policy, intellectual property rights, financing & supply management, quality & safety, selection & rational use of medicines, technical co-operation and traditional medicines.

10) **ICH:** International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) guidelines defining quality, safety, efficacy & related aspects for developing and registering new medicinal products in Europe, Japan and the United States.

11) **OECD:** Organization for Economic Collaboration and Development including 30 member countries covers economic and social issues in areas of health care.

12) **EMEA:** European Medicines Agency (EMEA), a decentralized body of the European Union headquartered in London, prescribes guidelines for inspections and general reporting and all aspects of human & veterinary medicines in the European Union.

13) **US FDA:** All Regulations, guidelines, notifications, news and communications from United States of America Food and Drug Administration. Any export sale to USA must comply with US FDA requirements.

14) **TGA:** Specifications regulating medicines, medical devices, blood, tissues & chemicals, issued by Therapeutic Goods Administration, the Australian regulatory body.

15) **MHRA:** News, warnings, information and publications of Medicines and Healthcare products Regulatory Agency (MHRA), responsible for ensuring efficacy and safety of medicines and medical devices in the UK.

In addition to these industry/product specific regulations, the common rules pertaining to The Goods and Services Tax and other business-related rules and policies must also be complied with.

16) **Goods and Service Tax:** The GST subsumed all indirect taxes upon its implementation has led to one complex yet uniform code for taxation across India. Recent estimates show that by mere rationalization of supply chain costs across states, 2% of pharmaceutical distribution costs have been saved. However, the following illustration showcases the one time increase in prices of essential medicines due to implementation of GST.

| Particulars | INR |
|---|---|
| Current MRP | 100 |
| VAT | 5 |
| Excise (5%) @ 65% ABT | 3.25 |
| MRP Less Taxes /CP | 91.75 |
| Less: MTR | 18.35 |
| PTR | 73.4 |
| GST @ 12% (Expected) | 12.51 |
| New MRP (Expected) | 104.26 |
| Cost Impact | 4.26 |

If the MRP of a formulation was Rs. 100 in June 2017, then 'MRP less taxes' can be calculated at Rs. 91.75. It was decided to keep the MRP less taxes as consistent and thereby companies could charge GST over Rs.91.75. This led to the new MRP post implementation of GST to rise to Rs. 104.26. Thus, the final consumer ended up paying an additional Rs. 4.26 for the formulation.

It may be noted that such a price increase was only permitted for scheduled formulations and no price increase was allowed for non-scheduled formulations on account of implementation of GST. The distinction between scheduled and non-scheduled formulations is explained later.

17) **Income Tax:** If a company has its manufacturing facilities located in hilly states, and another facility located in other states, it is necessary to take upmost care in determining the profits of unit in hilly state which is exempted from income tax hence, the unit in hilly state should be treated as independent unit and its profit or loss should be worked out.

18) **Transfer Pricing International:** There are several multinational foreign companies which have pharmaceutical manufacturing activities in India and abroad. The cost of pharmaceuticals is the lowest in India, by an estimate it is 5% of prevailing retail prices in USA and 7% of prevailing retail prices of Europe. On the other hand, several Indian pharmaceutical companies also have their setup in various countries across the globe and they frequently deal with their Indian arms. The tax authorities in both the countries are concerned about the tax on profit made by such related parties and therefore, it is necessary to work out distribution of profits between the Indian arms and foreign on one of the following basis:

a. Comparable uncontrolled price method
b. Transactional net margin method
c. Profit split method
d. Cost plus method
e. Resale price method

f. Such other method as may be prescribed by the Board

19) **Transfer Pricing Domestic:** With effect from 1st April, 2012, the transfer pricing rules have been notified for related party transactions even within India. The compliance of the same also needs to be addressed by the internal audit function.

20) **Uniform Code for Pharmaceutical Marketing Practices (UCPMP)**

The Uniform Code for Pharmaceutical Marketing Practices (UCPMP) is introduced to regulate marketing practices of pharmaceutical industry. This order imposes requirements of prior permission from Drugs Controller General of India for domestic promotion of medicines. Any promotional activities must be accurate, fair, objective, verifiable and not be misleading. The order lays down standards for rival product comparison and mandates that promotion will not involve exchange of gifts in any form. Finally, while the order is a voluntary code with a condition that non- compliance will result in conversion to statutory code. Accordingly, every pharmaceutical company has been ordered to submit its list of activities to ensure compliance with the UCPMP to the Department of Pharmaceuticals on a quarterly basis.

The Internal Audit function should audit the procedures and compliances as mandated by law to ensure smooth working of the company. In addition to various rules and policies, the Government of India has also notified various schemes for promotion of Pharmaceuticals and Medical Devices in the country. These include:

- **Production Linked Incentive Schemes:** this scheme is aimed to attain self-reliance and reduce import dependence in critical KSMs/DIs/APIs. Under the Scheme, financial incentives shall be given based on threshold investment and domestic sales made by selected applicant for the eligible products.
- **Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:** This Scheme aims to provide financial incentive to boost domestic manufacturing and attract large investments in the Medical Device segments such as cancer care devices, radiology and imaging devices, anesthetics devices, implants etc.
- **Promotion of Bulk Drug Parks: This scheme was introduced with three key objectives:**
    - o To promote setting up of bulk drug parks in the country for providing easy access to world class Common Infrastructure Facilities (CIF) to bulk drug units located in the park in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry
    - o To help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system.
    - o To exploit the benefits arising due to optimization of resources and economies of scale
- **Promotion of Medical Devices Parks:** This scheme was introduced with the following objectives:
    - o Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader.
    - o Easy access to standard testing and infrastructure facilities through creation of

world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market.

- o Exploit the benefits arising due to optimization of resources and economies of scale

- **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP):** This scheme is aimed to make available quality medicines consumables and surgical items at affordable prices for all and thereby reduce out of pocket expenditure of consumers/patients, to popularize generic medicines among the masses and dispel the prevalent notion that low priced generic medicines are of inferior quality or are less effective and finally, to generate employment by engaging individual entrepreneurs in the opening of PMBJP Kendras. While, this scheme aims at general public and not corporates, many companies have benefitted by supplying quality generics to the PMBJP.
- **Scheme for Development of Pharmaceuticals Industry:** This scheme aims to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry with the following sub-schemes:
  - o Assistance to Bulk Drug Industry for Common Facility Centre;
  - o Assistance to Medical Device Industry for Common Facility Centre;
  - o Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS);
  - o Assistance for Cluster Development; and
  - o Pharmaceutical Promotion Development Scheme (PPDS)

Further details regarding all these schemes are available at

https://pharmaceuticals.gov.in/schemes and

https://www.investindia.gov.in/schemes-for-medical-devices-manufacturing

**Legal and Regulatory Framework**

Indian Pharmaceutical Companies fall within the purview of The Companies Act, The Drug and Cosmetic Act, Drug (Price Control) Order, 2013. The regulatory framework includes the authorities like Drug Controller General of India (DCGI); National Pharmaceutical Pricing Authority (NPPA), Ministry of Chemical and Fertilizer and Department of Pharmaceuticals, Government of India. All these authorities extensively use cost data for protecting interest patients and genuine growth of the industry. Among the various rules and regulations mentioned earlier, the Drugs and Commodities Act, 1940 and the Drugs (Price Control) Order, 1995 are the most relevant and unique in nature.

As mentioned earlier, The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India. In addition to defining and protecting against Misbranded, adulterated and spurious drugs, the other important schedules are:

1) Schedule M of the D&C Act specifies the general and specific requirements for factory

premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.

2) Schedule T of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.

3) The clinical trials legislative requirements are guided by specifications of Schedule Y of the D&C Act.

The price control on medicines was first introduced in 1963 in the aftermath of the Chinese aggression with the promulgation of the Drugs (Display of Prices) Order, 1962 and amended in the years 1966, 1970(under the Essential Commodities Act, 1955), 1979, 1987 and 1995. For the purpose of Drugs (Price Control) Order, 1995 (DPCO), there were 74 Bulk drugs identified and brought price control regime with certain exceptions such as drugs produced by small scale units or through indigenous R&D were exempted. These policies were based on the principles of industry's growth, cost effective production, innovation and strengthening of capacity. All the erstwhile DPCOs followed "Cost Plus Pricing" wherein the Cost of Production was determined as under:

**"COP = RM + CC + PM + PC"**

COP – Cost of Production

RM – Raw Materials Costs

CC – Conversion Costs

PM – Packing Material Costs

PC – Packing Costs

**"CP = MRP = (COP + MAPE) + Taxes"**

CP – Ceiling Price

MRP – Maximum Retail Price

MAPE – Maximum Allowable Post Manufacturing Expense

To explain with an illustration,

| Particulars | Amount (Rs) |
|---|---|
| RM | 5 |
| CC | 1 |
| PM | 2 |
| PC | 1 |
| COP | 9 |
| MAPE @ 100% | 9 |
| MRP less Taxes | 18 |
| Taxes @5% | 0.9 |
| MRP = CP | 18.9 |

A brief of overview of the three erstwhile DPCOs is as under:

| Particulars | DPCO 1979 | DPCO 1987 | DPCO 1995 |
|---|---|---|---|
| Number of Drugs | 347 | 142 | 76 |
| MAPE - Category I | 40% | 75% | 100% |
| MAPE - Category II | 55% | 100% | N. A |
| MAPE - Category III A | 100% | N. A | N. A |
| MAPE - Category III B | 60% | N. A | N. A |

The Category of Drugs was defined based on the essentiality in India and was revised from time to time.

DPCO, 1995 lasted for 18 years thereby becoming the longest standing DPCO in Indian History. Even though, it is recommended by many that no DPCO should be significantly different from its predecessor and DPCOs should be revised or at least revisited from a policy perspective every 5 years. Both of these commendations were neglected and finally on 7th December, 2012 the Government of India notified the National Pharmaceutical Pricing Policy (NPPP), 2012.

NPPP, 2012 was the base on which policy makers drafted the prevailing DPCO, 2013. There was a revised drug policy and subsequent DPCO, 2002 introduced, between DPCO, 1995 and DPCO, 2013. However, DPCO, 2002 showcased an inability to include all essential and life-saving drugs of the time and received a supreme court order to not only revise the draft but also to revisit the principles on which the drug policy was based. Finally, The Drugs (Prices Control) Order, 2013 notified on 30th May, 2013 under the provisions of section 3 of the Essential Commodities Act, 1955.

As an Internal Auditor, it is necessary to ensure compliance with DPCO 2013 so that the company need not face the perils similar to DPCO 1995.

# SPECIAL TRANSACTIONS PECULIAR TO THE INDUSTRY


Pharmaceutical Industry has unique features of manufacturing and indirect marketing. The Formulation is marketed to a doctor or hospital and it is purchased by patient or their families through retail pharmacists.

**OUTSOURCING:**

This is an industry where outsourcing from other manufacturer is very common and a significant portion of industry is engaged in outsourcing either a part or the whole of the manufacturing, distribution, or marketing functions. The industry had more substantial manufacturing facilities to Hilly States of Himachal Pradesh, Jammu & Kashmir, Uttaranchal and Sikkim. It has its own issues which are dealt with in detail separately later in the guidance note.

These processes are so streamlined that procuring Formulations from another manufacturer is very common. However, it has its own issues from Internal Audit angle as substantial Raw Material and Packing Material are lying at support manufacturer's place and the yield is variable factor within limits. At times material are supplied directly to support manufacturer.

**PRINCIPAL TO PRINCIPAL (P2P):**

In case of Principal-to-Principal transaction the support manufacturer himself buys Raw Material and Packing Material from the approved sources. Under the circumstances, the scope of risk management increases manifold raising special issues dealt with at a subsequent chapter.

**Loan Licensing:**

Many companies directly or indirectly supervise the operations of support manufacturer in terms of input, sellable output, recovery from process, balance of raw and packing material at support manufactures location and dispatches from where generally there would be an agreement from support manufacturers that he will not procure any packing material directly nor will he produce anything with formula and process of the principal.

**Industry Specific Reports:**

However, there is eventuality that, an unscrupulous manufacturer may produce some quantity without the knowledge of the principal and sell in the market. This can happen in 2 ways:

1) Additional batches are produced by support manufactures and cleared under duplicate batch number. Such batches are cleared without payment of excise duty and VAT or now GST resulting in very high profit for the support manufacturer.

2) In second case, presuming that there is an agreement to give production of 95% of batch size and the manufacture delivers say, 93% and dispose-off remaining 2% straight in market. In such case, the cost of procurement would work out to be quite high. Hence, it is most essential that proper tracking of all the input materials and more precisely the packing material needs to be verified on continues basis to eradicate any chance of such shortages.

A similar situation would take place in P2P. The organization would be further damaged if the support manufacturer were to procure all the material from approved sources including packing

material and produce extra quantities and sell directly in open market.

The difference between the value addition for P2P transaction and net realization for sale to third party would be phenomenally different causing financial loss and dent in market share of the company. Thus, the issue needs serious consideration from risk management under Internal Audit function. While presenting these risks or opportunities to the management, the various reports to be submitted and discussed must relate to:

- **LL dependence analysis:** Dependence on a loan licensed manufacturing must be grouped on and estimated against the following:
  - Turnover from LL products.
  - Contribution to fixed expenses of companies.
  - Profit from LL products in value and as a percentage of total company profits.
- **Key Cost Analysis:** The key costs of the company relating to materials, supply chain, marketing, administration, and branding must be ascertained and considered while pricing products. When undertaking procurement through P2P or LL, the company must always be wary of recovering both material and LL costs at the minimum.
- **Market and Key Customer Analysis:** When analyzing the performance of the sales and marketing functions, the internal audit function must provide the management with detailed analysis of:
  - Business Group wise profit contribution
  - Business Group wise profit margins
  - Key customer profit contribution
  - Region wise turnover and margin
  - Regional and SBU profitability and turnover movements over time

  Based on the above-mentioned reports; products and customers may be grouped into various categories based on contribution to fixed costs and margin both.
- **Working Capital and Inventory Management Analysis:** When undertaking procurements through P2P or LL, the most critical area of management becomes the cost of working capital and its related inventory management. Since materials are to be provided by the company, in LL manufacture, there is a need for upmost care in calculating and monitoring the expected, actual and variances in yields. Also, any non-moving or slow-moving inventory severally damages the working capital requirements and may lead to a cash crunch.

The availability and regular use of these reports must be ensured and reported on by the internal audit function.

**Contract Manufacturing Organisation (CMO) Audits:**

Another important transaction which is widely implemented in the Pharmaceutical Industry relates to CMO (Contract Manufacturing Organization) Audit. In this transaction, the marketing company provides the Contract Manufacturing Organization with all Input materials and the Contract Manufacturer basically leases his working factory for converting the marketeer's input material into finished formulations. An Internal Auditor should entail verify the following information at every CMO location as per schedule:

(a) Contract Study to safeguard the interest of the company;

(b) Contract Deviation Report which records instances during which either party deviated from the original agreement and if any undue costs or profits were associated to these deviations;

(c) Input Output Report which correlates the material consumption patterns of CMOs, with a special focus on Packing material which in our experience has always been the source for identification of undeclared secondary market sales for CMOs.

(d) Costing of Formulations to ensure a fair price is paid for the conversion charges of formulations. This is also used as a benchmark for future negotiations.

(e) Price Negotiations with respect to not just the price of the formulation but also the quantum of assured production.

(f) CMO Dependency Rating which highlights if the marketing company is reliant on one CMO for its entire manufacturing of the product.

(g) Drug License verification which ensures that no product is produced without an adequate Drug License mentioning the Name of both Manufacturer and Marketing Company. Many instances of a CMO using one license to produce for various companies have been seen in past assignments.

**Other Peculiarities:**

The pharmaceutical industry is technology oriented and its business inter alia includes manufacturing and marketing lifesaving drugs and Vaccines against life threatening diseases and epidemics. In this industry all efforts are required to be put in to ensure for manufacturing under absolute hygienic condition and reaching the medicines to the length and breadth of this vast country. At the same time, ensure the cheapest and reliable source of medicine. There are several instances where Indian Pharmaceutical companies have made critical medicine available to various countries at 1/10 or 1/15 of prices prevailing. In some countries this is possible only on account of dedicated technical staff and continuous use of techniques of Cost and Management Accountancy in ensuring availability at right quantity and right price. Internal Audit has substantial role in plugging leakages in cost and losses to enable industry to continue the availability as stated herein above.

In year 2005 Government announced an incentive scheme for promoting manufacturing activities in Hilly States. The incentive included excise duty and VAT exemption for 10 yrs. and exemption from Income Tax for 5yrs (when excise was 16%, VAT was 4% and Income Tax was 33%). Consequently, states like Himachal Pradesh, Uttaranchal and Jammu Kashmir received lot of response. Nearly 200 Pharmaceutical projects came up in the state of Himachal Pradesh only. Most of the companies, which had huge manufacturing activities in other states put up plants in Hilly States increasing the capacity in Pharmaceutical Industry by almost 50%-60%.

However, the demand did not go up in the same proportion and consequently, it led to idle capacity at original plant. The benefit expected to be derived from the Hilly States stood diluted by cost of idle time at original plant and due to the cost of transport of input to Hilly States and transport of Finished Goods to market. Hence, it was very essential to ascertain the saving on land and additional cost on the other hand to assist the net benefit of going to Hilly States. Secondly, the benefit of excise and VAT could not be realized in respect of Formulation subject to price control as the company could not charge excise and VAT unless it paid the same.

A couple of companies which produce price control Formulation in Hilly States incurred losses as the CENVAT credit on material was not allowed as final product was not subject to excise duty and VAT. Had the product been manufactured at original plant such loss would not have taken place. This was one more issue from angle of risk management under Internal Audit.

Pharmaceutical industry like FMCG evolves detailed strategy to arrive at their products mix. They venture into small segment of all Indian market. The company always put thrust on following items:

1) The Formulation with high contribution (Net Sales Value – Direct Cost)

2) The Formulation with potential to grow fast at 25% - 35% per year namely, medicine for Cardiac, Neurological and Diabetic, which are new in market and have tremendous potential to grow.

3) The products which are compatible with your present group of Formulation doing well in the market EG: a company having strong presence for cardiac product may be able to grab larger market share for new sunrise Formulation in Cardiac Domain.

It is essential to ascertain, whether the company uses cost data to prepare the marketing strategy and compare the actual performance based on expected profitability. In distribution there are two options available:

1) To have own warehouses at all major cities and distribution by the company.

2) To appoint Clearing and Forwarding agents, who would hold goods for the company and dispatch as per instructions

The cost and benefit of both the actions need to be examined and decision for the distribution of material has to be taken. Secondly, all such storage places either of company or of Clearing and Forwarding agents needs to be outside the octroi limit of the city so that company can save octroi duty on Formulations sold to other cities and towns.

Some large companies have central warehouse facilities in central part of India and they forward goods to the location where demand is there to ensure that the company should monitor movements of each Formulation at each location and if it finds demand in one place is less and movement is slower then move those Formulation to area where they are fast moving.

Certain products like insulin, vaccines are atmosphere sensitive and they need to be stored and transported under air conditioning and controlled temperature both for domestic market and export. These products require "COLD CHAIN" transportation which will keep track of temperature at interval of every 15 minutes and if the temperature rises beyond permissible limit the Formulation is likely to be rejected.

**Illustration of Balanced Scorecard in Pharmaceuticals**

An Internal Auditor may also compare the Balanced Scorecard (BSC) being implemented by the pharmaceutical company. Over the years, various academicians have reviewed the close ties between Internal Audit and the Balanced Scorecard, a few noteworthy findings are as under:

Ziegenfuss[11] (2000) implemented the use of a 'performance measurement system' stead of the necessary data to ensure the quality of internal control. The BSC is found to be the solution to fill the gap resulting from the strategy design and the results of the implementation of the necessary practices to achieve the strategic goals.

Melville, R.[12] (2003) examined the use of the Balanced Scorecard by internal auditors based on the results of a survey of an international, specialist group of professionals. The participants were asked to evaluate their own and their organization's attitudes towards a range of statements about strategy and the BSC. The results showed that there is a significant awareness of the potential benefits of the Balanced Scorecard and its potential role in good corporate governance practice. It was also clear that 'soft' controls and qualitative issues are addressed and reported on Melville, R. (2003) examined the use of the Balanced Scorecard by internal auditors based on the results

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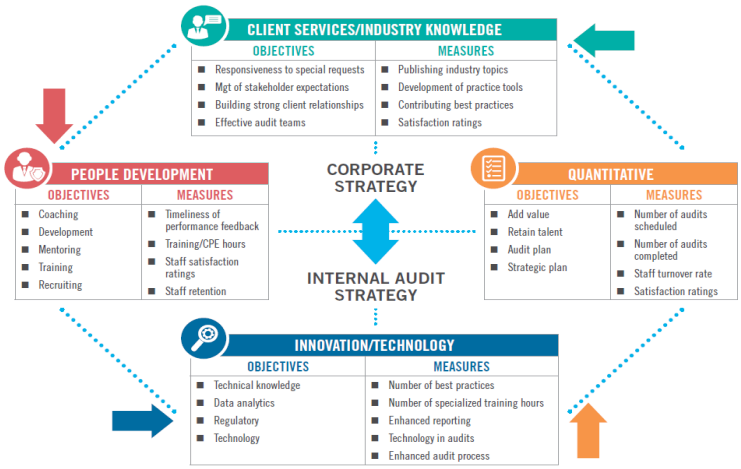
Seminogovas and Rupsys13 (2006) produced a comprehensive model to measure internal audit performance using the balanced scorecard framework, taking into consideration the linkage between internal audit and mission, goals, and strategy of the organization. Their framework for measuring internal auditing performance consists of four perspectives encompassing innovation, competence and capabilities; auditing process; audit clients; and value and status of internal audit. These four perspectives must include the short and long term performance measures, internal and external performance measures, leading and lagging indicators, and objective and subjective measures. The study argues that such a model will enable the internal audit function to play a significant role in achieving the organizational goals and strategy.

Bota-Avram C. et al14 (2011) focused on the methods of measuring the effectiveness of internal audit activity based on an analysis of the most recently internal audit practices at leading international companies. The findings concluded that the Balanced Scorecard instrument is one of the main metrics used by global leading enterprises for measuring and evaluating the performance of internal audit, while been among the key trends that will influence the internal audit activity in the future, from the performance's point of view.

Finally, Sfetcu, M.15 (2013) examined the usage of management methods on the internal audit activity through qualitative and quantitative indicators of performance assurance. The results showed that Balanced Scorecard is a management method used by the internal audit, helping to establish the general and specific objectives, but also a tool used to ensure the performance by analyzing the efficiency, the effectiveness, the economy and the quality of the audit. Moreover, BSC is used for planning the audit resources, analyzing the risks and assessing the internal control, based on specific audit techniques and tools and contributes to detecting problems, usage of efficiency and effectiveness.

Thus, it is clear that if the company follows a Balanced Scorecard based performance evaluation, then the results reported on the balanced scorecard should be included as a component of the periodic reporting process to the Audit Committee and support oversight of Internal Audit. A sample Balanced Scorecard is shared herewith below:




An illustration of a real Pharmaceutical Company's Balanced Scorecard for a quarter is shared herewith below:

| Vision | Perspective | Strategic Objectives |
|---|---|---|
| Through great people, superior processes and innovative solutions, we will be a leading company in making accessible medicine | Financial | Revenues |
| | | Costs |
| | | Gross Margin |
| | Market / Customer | Launch generic products |
| | | Increase the participation in the hospital and tendering businesses |
| | | Manage the transition from existing branded products to generic products |
| | | Lobby for NPPA price control |
| | | Focus promotion in Doctors for the prescription of generic products |
| | | Form and maintain partnerships with pharmacies |
| | | Build bridges between Doctors and pharmacies for the implementation of generics |
| | | Implement an XYZ company brand |
| | | Assure product quality |
| | | Produce and market a wide range of generic products |
| | Internal Processes | Identify target and lobby partners |
| | | Target Doctors' prescriptions |
| | | Leverage local knowledge in the generics market |
| | | Operate as a distributor for other international generics companies |
| | | Enable fast regulatory approval processes |
| | | In-source services from with the XYZ international structure |
| | | Position the company within the European generic market |
| | | Create an internal task force to support the hospital business |
| | | Assure a better sales force territorial management |
| | | Create and update a product wish list |
| | | Search for local acquisition opportunities |
| | Employee Culture | Development of commercial skills |
| | | Integration of the R&D skills |
| | | Increase of generics mindset |
| | | Improvement of IT skills |
| | | Improvement of product sourcing skills |
| | | Establishment of new brand values within the organization |

# ACTIVITIES/SERVICES OF THE INDUSTRY


The activities covered under this sector, are broadly defined as Pharmaceutical activities. Practically, the activities covered in this sector can be broadly classified into following segments:

1. Manufacturing of Bulk Drug/API: Over a period of time, China has emerged to be the cheapest source of Bulk drug/API and many of the Chinese APIs are available at a price far below the cost of Indian manufacturers. This has given a rise to a trend, unlike all other industries, the cost of input materials is either stagnant or reducing year after year. Thus, a sizable number of APIs are no longer being manufactured in India resulting in huge idle time costs. Yet, many companies continue to manufacture some of the APIs to meet their in-house requirements. However, the concept of 1980s that every pharmaceutical company must manufacture API is gradually diluting.

2. Manufacturing of Formulations for sale: As it is evident from previous paragraph, the manufacturing of API is gradually becoming a part of history primarily due to a cheaper source of API from China. Thus, Indian pharmaceuticals have started concentrating their activities on formulations. With the creation of good manufacturing facilities, MNCs and Large Indian pharmaceutical houses alike have started outsourcing from support manufacturers. Today in market, there are many MNC pharmaceuticals outsourcing upto and in excess of 90% of their requirements; domestic as well as international.

3. Manufacturing for others on loan License basis, that is, the principal will supply all the raw and packing materials and the company will convert them into Bulk Drug/ API or pharmaceutical formulations. This can be construed as labor jobs. In Pharmaceutical industry it is known as loan license activity meaning the principal has allowed his license to manufacture to this company to produce the same product under the same brand name. Loan license is duty bound to handover 100% of production to such principal.

4. There is one more way of producing for others. In such case, the support manufacturer will buy the requisite raw and packing material and manufacture and pack as per requirement of the principal. In such deal, the support manufacturer and principal deal with each other as independent principal to principal (P2P). In such cases, the Bulk Drugs / Formulations, as the case may be, are sold at a consolidated price to the principal.

5. Manufacturing of Bulk Drug/ API and/ or Formulations in 100% Export Oriented Unit (100% EOU) or in Special Economic Zone (SEZ) with an intent to export.

6. There are certain companies which outsource production activity either through Loan License or through P2P transaction. These companies are primarily marketing companies holding very good brand names and fully concentrate on marketing and distribution.

Over a period of time, India has emerged as a major manufacturing hub for pharmaceutical formulation to various countries world over. Several factories have come up in India, complying very stringent standards laid down in compliance of US FDA, UK MHRA (Medical and Healthcare Products Regulatory Agencies), Australian FDA, South African MHRA, European MHRA, WHO GMP etc. Hence, these companies can supply products to Indian Exporters exporting to those countries

or to importer or distributors in those countries.

The cost structure of each such approval is different as manufacturing standards than the same set by Drug Controller General of India (DCGI) for setting up pharmaceutical factory in India. At present, by and large India is one of the cheapest sources of pharmaceutical products world over.

The manufacturing standards have continuously been revised upwards by DCGI making cost of companies substantially dynamic. For exports the packing standards also keep on getting revised providing further dynamism to cost structures.

# AUDIT OF OPERATIONAL ACTIVITIES, COST RECORDS, AND COST AUDIT REPORT


Operating activities are the functions of a business directly related to providing its goods and/ or services to the market. These activities are the company's core business activities, such as manufacturing, distributing, marketing, research & development, and selling products or services. They help companies build long term and sustainable advantages or core competencies. Let us review how to audit them.

The following records needs to be checked for input materials:

1) Production planning showing production proposed month wise.

2) The time for preparatory and testing etc, before production can be launched.

3) Procurement procedure including number of quotations/ tender desired.

4) Finalization and acceptance of quotation after comparative analysis of quantity, quality, delivery period, credit period, excise, octroi and service tax implication.

5) Receipt of material at factory.

6) Recording at gate.

7) Physical receipt and counting and weighing of material.

8) Testing, acceptance, rejection of material.

9) Forwarding Material Receipt Note and Test Report to Stores Dept. along with party's Challan, packing slip, Railway/Road Receipt and documents for octroi/ local body tax etc.

10) Landed cost register showing:

    a. Date of Receipt.

    b. Material Receipt Note.

    c. Supplier Code

    d. Specification of material received.

    e. Material code.

    f. Purchase within country/ imported.

    g. Quantity billed.

    h. Quantity received.

    i. Basic rate of material.

    j. Excise Duty rate and amount,

    k. VAT rate and amount,

    l. Transport cost.

m. Transit insurance if paid by purchaser.

n. Loading and unloading charges.

o. Octroi duty/ local body tax (rate and amount)

p. Total cost for domestic purchase.

q. For import custom duty payable/ paid (rate and amount)

r. Clearing and forwarding charges

s. Loading/ unloading charges.

t. Local transport cost to factory.

u. Loss in transit/ evaporation in quantity.

v. Value of quantity rejected and returned.

w. Net quantity received.

x. Net cost (total and per Kg)

y. Less Cenvat and VAT credit.

z. Net cost to company.

aa. Cost per Kg/ unit item 'Z' divided by item'w'.

**FORMAT FOR QUOTATION COMPARISON:**

The previous format for landed cost register can be used also for comparing quotation and finding out the eligible lowest bidder (L1).

**FORMAT FOR MATERIAL CONTROL SYSTEM:**

It is evident that in Pharmaceutical industry there are a large number of Formulations and few of them are produced every month. Depending on demand, the formulation may be manufactured every month or as and when required, once in 3 months, once in 5 months etc. This leads to 2 features namely; that though there will be repetition of production but it may or may not be next month.

Hence, the conventional method of minimum quantity of stock cannot be applied without modification. The stricter control would envisage the following format:

- The requirement of Bulk Drug/API for budgeted production during the next month.
- Minus Quantity held in stock.
- Minus quantity of API on order and expected during the month.
- Equal to quantity required to be purchased during the month.
- Excess quantity in stock (if any)
- Time frame within which, excess material in stock will be utilized for company's production.
- How much percent of total stock expected to be held at the end of current month is not likely to be utilized during next month.

- How much of stock not expected to be utilized in next 3 months.
- Any plan for disposal of such stock.
- Any packing materials lying in stock for formulation/s production of which is discontinued. Are these materials saleable
- Is there any residual quantity of API lying unutilized for several months?
- Is there any item of WIP which has not been converted into FG for over 1 month for which reasons may be?

o The quantum for maximum stock, minimum stock, reordering level and economic ordering quantity are determined and followed on regular basis.

o The significant cash discount (3% to 5%) is available for cash payment for purchase of inputs, if yes, has benefit for the same been taken by the company.

**CAPACITY UTILISATION:**

- Does company have capacity constraint for any of its product line. If yes, does company outsource on LL basis.
- Are there instances that company has production capacity available within plant and yet the formulations are outsourced.
- Are there set of machines like coating, the process of which is abandoned by company and machines are lying idle.
- Is generation of utilities like power, steam, DM water, RO water, air conditioning, air compression efficient, and how many percentages of the capacity is utilised.
- Power factor.

The Cost Records will give information an exact number of machine hours required for manufacturing actual production of a period/ year. Installed capacity for such machine is available in the company as under:

**No. of machines x 250 days x 8 hours per day**

And compare this with machine hours required for given production. If there is sizable difference between the 2, the concept of idle time cost needs to be brought in, clearly specifying the machine hours available and machine hours utilized. In the Pharmaceutical industry, the cost of manufacturing machines like compression machine for tablets, capsule filling machine, liquid/ injection filling machine, powder filling machine constitute a small fraction of amount invested in creating manufacturing infrastructure. Hence, in many cases there are stand by machines, capacity of such machines needs to be excluded from total capacity. If there are different capacities machines like 16 station, 27 station, 45 station compression machine, 1 representative capacity needs to be ascertained say, 27 station compression and 45 station compression machines should be considered 1.67 station machine and 16 station machines should be considered 0.6 machine

It is necessary to ascertain whether effectiveness of each size of machine for different product is being ascertained and used for management decision making. To understand the calculation of Capacity utilization and how to approach abnormal idle time, it is recommended to follow the Guidance Note on Cost Accounting Standard 2 (CAS 2) (Revised 2015) on Capacity Determination.

**MANPOWER:**

- What is the total requirement of manpower- skilled, semi-skilled, unskilled and helper/ own and contract labor?
- Is employment of manpower close to budgeted manpower comparable to the production levels achieved.
- How much percent of manpower is met through contract labor?
- What is the ratio between skilled and other labor? Last year and month wise during current year (live example of Satyam manpower resource abuse).

**STOCK POLICY:**

- What is the estimated sale of each formulation/month and what is the stock level of finished goods?
- What is the expected time frame to liquidate the finished stock on hand at the end of the last month?
- What is the stock level in terms of month's sale with various C & F agents/ Depots?
- Does company have policy of shifting stock from location where it moves slowly to allocation where movement is high to avoid expiry of formulations.
- What is the percentage of expiry, breakage, leakage of each formulation?
- Does company use any anti- counterfeit items to avoid duplication of product.

**HOW IS PERFORMANCE OF MARKETING STAFF ASSESSED:**

- Based on sales value only.
- Value addition generated.
- Based on number of units sold.
- Percentage of market share captured.
- Combination of new formulations in market having high profitability and substantial potential to grow.

**GST AND THE PHARMACEUTICAL INDUSTRY**

Each month, companies are required to file a summary return 'GSTR 3B' to report the sales and purchases. They are also required to compute and pay the GST based on this self-declaration. In addition, they are also required to file GSTR-1 monthly to report invoice wise details of all outward supplies. Thus, based on the GSTR-1 filed by suppliers, the GST portal will auto-populate GSTR 2A return for a particular recipient.

However, every company faces problems where there are differences between the figures declared in the GSTR-1 by a supplier and the corresponding summary figure declared in the GSTR-3B by the company. The Internal Auditor should include the following checkpoints to ensure nil data gap and avoid the notices from GST authorities –

1. Reconciling the total summary figures as per GSTR 3B with the total of the Outward Invoices as per GSTR 1 for a particular month

2. Outward supplies (other than zero-rated, nil rated and exempted),

3. Zero-rated outward supplies,

4. Nil rated and exempted outward supplies,

5. Inward supplies on which GST has to be paid by the recipient under reverse charge mechanism

6. Checking the amount of input tax credit as per GSTR 3B vis-à-vis details mentioned in GSTR 2A. Businesses are eligible for the final input tax credit on the basis of GSTR 2A.

7. Ensuring that the credit notes & debit notes have been mentioned in GSTR 1 at the correct places.

Further, the Internal Auditor should reconcile the GSTR 3B with GSTR 2A to ensure that the company shouldn't claim excess input tax credit, and where it has been claimed in excess, company should pay interest and tax amount on due date. Any and all data gaps should be amended at summary level in GSTR 1. The Internal Auditor should check the invoice payment date against the invoice issue date to calculate the transactions wherein the company has made the payment to the supplier after 180 days as If the company had failed to make the payment within 180 days, the input tax credit will be reversed and added to the output tax liability.

In Addition to the filing checklists, the Internal Audit must also help control transactions on job work or loan license basis. GST law does not have any special provision for loan and licensee units. Where the contract is performance of job-work, these units can opt to follow the procedure laid down in section 143 of the CGST Act, 2017 i.e., the principal can send any inputs to such units without payment of tax and the principal can clear the goods from the premises of such units if the principal declares these units as his additional place of business or where such units are themselves registered under section 25 of CGST Act, 2017. It is important to keep records of goods sent to Loan Licensee, as if the said sent goods not returned within prescribed period, then it would be taxable under GST.

Further, as per the FAQs issued by the CBEC on pharmaceutical industry, in case of return of expired/ near expiry drugs, the manufacturer may issue a credit note within the time specified in sub-section (2) of section 34 of the CGST Act, 2017 subject to the condition that the person returning the expired medicines reduces his input tax credit. Subsequently, when the expired goods are destroyed, the manufacturer has to reverse his ITC on account of goods being destroyed. Where the goods are returned after the time limit specified in section 34(2) of the CGST Act, 2017, the Government has clarified that the credit of the same should be given to stockists and should not be treated as supply.

**Cost Records and Cost Audit**

Cost Records are defined as 'books of account relating to utilization of materials, labour and other items of cost as applicable to the production of goods or provision of services as provided in section 148 of the Act'. Cost Records relate to data, information, documents, and submissions which help to calculate the cost of production, cost of sales and margin of each of the products/activities of the company on monthly or quarterly or half-yearly or annual basis are considered part of the cost records. It includes statistical, quantitative and other records which enable the company to exercise, as far as possible, control over the various operations and costs to achieve optimum economies in utilization of resources.

While there cannot be an exhaustive list of Cost Records to be maintained, considering the materiality of the company, obtaining any information relating to the lowest quantity for each Stock Keeping Unit (SKU) of products is a part of the Cost Records of the company.

The Institute of Cost Accountants of India has also published a Guidance Note on Internal Audit of Cost Records and it helps define the role that an Internal Auditor can play in the maintenance and review of Cost records. To quote:

"The internal cost auditor can provide a Performance Appraisal Report for an actionable insight into costs, efficiency, productivity, profitability and sustainability of various products/segments of the company for enabling the management to assess the performance in the strategic and operational context. The aim would be to discover various drivers of costs and profitability and their impact on the performance variables with the objective of helping the organizations to improve profits and profitability; to optimize resource allocation and utilization thereof; to optimize the product and services portfolio; to monitor performance of the company in various areas; and to know if company management is meeting its goals.

Internal Cost Auditor evaluates the cost accounting system followed by the company and its efficacy on reporting the resource utilisation and efficiency parameters. The internal cost reporting also follows the business process flow within the organisation. Hence, the management would like to have a report which is presented production/service unit-wise, SKU/SBU wise, business vertical-wise, domestic/export customer group-wise, process-wise and product/service/activity-wise analysis and not for the company as a whole. Therefore, the periodicity of performance appraisal report should be quarterly so as to enable the management to constantly guard the progress and facilitate better analysis. In this way, it would give a real-time data/analysis to the Audit Committee/Board to take effective business decisions. An internal audit of the cost records will assure the Management that the cost information, which is basis of their evaluation of performance, risk management and control, is reliable and timely"

Finally, to ensure compliance with CRA1 as issued by the Ministry of Corporate Affairs, Cost Accounting Standards, and Generally Accepted Cost Accounting Principles (GACAP), Internal Auditors may utilize the comparison in the table below. This will help them frame the company's cost accounting policy as well as recommend necessary changes.

| Cost Accounting Standards | | | |
|---|---|---|---|
| CAS No | Title | Objective | CRA 1 |
| CAS-1 * | Classification of Cost | For preparation of Cost Statements | 7. Overheads |
| CAS2** | Capacity Determination | To bring uniformity and consistency in the principles and methods of determination of capacity with reasonable accuracy. | 18. Capacity Determination |
| CAS3** | Overheads | To bring uniformity and consistency in the principles and methods of determining the Overheads with reasonable accuracy. | 7. Overheads |
| CAS4 | Cost of Production for Captive Consumption | To determine the assessable value of excisable goods used for captive consumption. | 20. Captive Consumption |
| CAS5** | Average (equalized) Cost of Transportation | To determine averaged/equalized transportation cost | 9. Transport Costs |
| CAS6** | Material Cost | To bring uniformity and consistency in the principles and methods of determining the material cost with reasonable accuracy in an economically feasible manner. | 1. Material Costs |
| CAS7** | Employee Cost | To bring uniformity and consistency in the principles and methods of determining the Employee cost with reasonable accuracy. | 2. Employee Costs |
| CAS8** | Cost of Utilities | To bring uniformity and consistency in the principles and methods of determining the Cost of Utilities with reasonable accuracy. | 3. Utilities |
| CAS9** | Packing Material Cost | To bring uniformity and consistency in the principles and methods of determining the Packing Material Cost with reasonable accuracy. | 15. Packing Expenses |
| CAS10** | Direct Expenses | To bring uniformity and consistency in the principles and methods of determining the Direct Expenses with reasonable accuracy. | 4. Direct Expenses |
| CAS11** | Administrative Overheads | To bring uniformity and consistency in the principles and methods of determining the Administrative Overheads with reasonable accuracy. | 8. Administrative Overheads |
| CAS12** | Repairs And Maintenance Cost | To bring uniformity and consistency in the principles and methods of determining the Repairs and Maintenance Cost with reasonable accuracy. | 5. Repairs & Maintenance |
| CAS13** | Cost of Service Cost Centre | To bring uniformity and consistency in the principles and methods of determining the Cost of Service Cost Centre with reasonable accuracy. | 14. Service department Expenses |
| CAS14** | Pollution Control Cost* | To bring uniformity and consistency in the principles and methods of determining the Pollution Control Costs with reasonable accuracy. | 13. Pollution Control |
| CAS15** | Selling and Distribution Overheads | To bring uniformity and consistency in the principles and methods of determining the Selling and Distribution Overheads with reasonable accuracy. | Not Covered |
| CAS16** | Depreciation and Amortisation | To bring uniformity and consistency in the principles and methods of determining the Depreciation and Amortisation with reasonable accuracy. | 6. Fixed Assets and Depreciation |
| CAS17** | Interest and Financing Charges. | To bring uniformity and consistency in the principles ,methods of determining and assigning the Interest and Financing Charges with reasonable accuracy. | 16. Interest and Finance Charges |
| CAS18** | Research and Development Costs | To bring uniformity and consistency in the principles and methods of determining the Research, and Development Costs with reasonable accuracy and presentation of the same. | 11. Research & developmental Fees |
| CAS19** | Joint Costs | To bring uniformity and consistency in the principles and methods of determining the Joint Costs. | 21. By-products & Joint Products |
| CAS20** | Cost Accounting Standard on Royalty and Technical Know-How Fee | To bring uniformity and consistency in the principles and methods of determining the amount of Royalty and Technical Know-how Fee with reasonable accuracy. | 10. Royalty and Technical Know how |
| CAS21** | Cost Accounting Standard on Quality Control | To bring uniformity, consistency in the principles, methods of determining and assigning Quality Control cost with reasonable accuracy. | 12. Quality Control |
| CAS22 | Cost Accounting Standard on Manufacturing Cost | To bring uniformity and consistency in the principles and methods of determining the Manufacturing Cost of excisable goods | Not Covered |
| | GACAP | | **17. Any other item of Cost** |
| | Guidance Note to Cost Audit Rules, 2002 | | 19. WIP & FG Stock |
| | Guidance Note to Cost Audit Rules, 2002 | | 22. Adjustments of Cost Variances |
| | Guidance Note to Cost Audit Rules, 2002 | | 23. Reconciliation of Cost and Financial accounts |
| | Guidance Note to Cost Audit Rules, 2002 | | 24. Related Party Transactions |
| | Guidance Note to Cost Audit Rules, 2002 | | 25. Expenses or Incentives on Exports |
| | Guidance Note to Cost Audit Rules, 2002 | | 26. Production Records |
| | Guidance Note to Cost Audit Rules, 2002 | | 27. Sales Record |
| | GACAP & Guidance Note to Cost Audit Rules, 2002 | | 28. Cost Statements |
| | Guidance Note to Cost Audit Rules, 2002 | | 29. Statistical Records |

Cost Audit Reports on the other hand enable the determination of accurate costs of production of various products, services and activities with a view to compare the same with the comparable figures of the earlier years and those of the peers or benchmarks in the industry. This report highlights the variations from the previous year's figures and make it possible to have reason wise analysis of variations so as to enable the management to propose suitable corrective measure for improvement of the company's performance.

Since, Cost Audit Report comments on the efficiency of the company, namely, utilization aspect of the factors of production, cost audit report proves to be useful to the Internal Auditor for assessing the efficiency of the various aspects of the organization. The Cost Audit Report includes the following annexures:

A1. General Information about the Company;

A2. Cost Auditor Details;

A3. Cost Accounting Policy;

A4. Product Group Details with due reconciliation of activity-wise Net Sales with total Net sales as per Audited Cost Accounts and GST returns;

B1. Quantitative Information of Production Sales and Stocks;

B2. Abridged Cost Sheets of each one of the major group of products;

D1. Product wise Cost of Sales, Sales and Margin details

D2. Company level Profit Reconciliation;

D3. Value Addition and Distribution of Earnings;

D4. Financial Position and Ratio Analysis;

D5. Related Party Transactions; and

D6. Reconciliation of Indirect taxes.

# AUDIT OF SPECIAL AREAS W.R.T. PECULIAR TRANSACTIONS

6

## 1. LOAN LICENCING:

In case of Loan Licensing, the Raw Materials and Packing Materials are supplied by the principal and the same is converted by the support manufacturer into Formulations. A percent of Yield is agreed upon by both the parties and it is necessary to ensure that 100% of Quantity (of the agreed output) sent is either received back in form of finished product or debit note is raised on support manufacturer for the short fall. Detailed methods of working out requirement of Bulk Drug/API are required to produce the targeted quantum of output. Further Bulk Drug/Active Pharma Ingredient (API), the expensive input is generally available in pack of 25 kg. The batch size of the Formulation may require 20/22 kg then accounting of balance of quantity (25 - 22 kg) and recovery from support manufacturer will influence the overall profitability of the product.

On the other hand, generally there is an agreed percentage of yield. However, the underline condition is the actual production (even if it exceeds normative yield) will be required to be handed over to the principal, even if it is more than agreed yield. This point should be borne in mind when company is finalizing appointment of support manufacturer.

Other things being equal and product is not under Price Control, if it is outsourced from a Hilly State namely Himachal Pradesh, Uttaranchal, Jammu & Kashmir and Sikkim. The principal company can save in terms of Excise Duty minus Cenvat plus VAT.

However, procurement of Formulation subject to Price Control form Hilly State will not benefit the company as if the Excise Duty and VAT are not paid on Finished Goods, hence, the excise duty and VAT cannot be included in MRP of the final product. Hence, there will not be any Cenvat Credit for Excise Duty and VAT paid on input. The Cenvat Credit on the input material will be the net loss to the company.

In case of Loan License, it is always desirable that, there is substantial control over quantity of packing material required to be consumed and actually consumed because the checking will discourage the unauthorized use of Packing Material by unscrupulous support manufacturer.

**A live example of what can happen is narrated hereunder:**

A company placed an order of 100,000 plastic bottles of cough syrup from the support manufacturer and the agreed percentage of yield was 95%. Thus, the support manufacturer is required to deliver minimum 95,000 units, presuming manufacturing loss of 5 %, the support manufacturer will be able to manufacture 95000 units and it would require only 95000 empty plastic bottles. The crux here is, there can be wastage of Raw Material in process to the extent of 5%. The Packing Material required would be between 95000 and 96000 bottles and not 100,000 bottles. In most of the cases, damaged bottle could be returned to the supplier of bottle, who will replace the bottles free of cost. When bottles are consumed more than output it may happen that remaining bottles not returned might have been filled in by the support manufacturer and sold in open market at full value.

## 2. QUANTITY SOLD ON BONUS SCHEME:

In pharmaceutical and FMGC industry bonus/ deal/ free scheme is very regular feature and companies keep on declaring bonus/ deal/ free scheme for different formulations month after month to promote sale of such formulations. On the other hand, it is also mandatory for manufacturer to take back the product when it nears the expiry date. In such cases, it is utmost essential that the product supplied under bonus/ deal/ free scheme has an identification mark, so that at the time of giving credit on the returned product, the credit is not given to the trader only at the rate of the material given under deal scheme. Further, it is equally important to check the quantum of deal scheme to ensure that the scheme does not result in loss to the company.

**Justification of bonus/ deal scheme/ discount:**

Deal scheme are offered to achieve genuine increase in quantity of sale of subject formulation. Generally, a justification note is submitting to higher ups highlighting benefit expected from the scheme. A typical scheme will work as under:

A company selling 30000 strips of a formulation per month anticipated 20% increase in sales on giving the scheme that for price of 10, company gives 11 packs. Thus, the normal sale per year is 360,000 strips and the scheme will help sale to 36000 strips per month and 432,000 strips per year.

However, generally quantum goes up because traders pull forward purchases of future months till the cost of stock holding is less than the rate of scheme (10%) i: e; value of money at expected rate. If one presumes that the trader values his funds @ 2.5% per month. It is very essential for Internal Auditor to find out what is the genuine increase due to this deal/bonus scheme.

The word Bonus/Deal/Free Scheme means that for a price of say 10 strips the company will deliver 11 stripes. In other words, the trader will benefit by 10%. The traders have very good sense of calculating their benefits, if he values his money at 2.5% per month, he will buy his requirement for 4 months (i.e., 2.5% for 4 months = 10%).

In that case, if scheme is offered for Jan and Feb 2013 the trader will place order for four months at the end of Feb'13. Hence, there will be no or negligible sale in March and April and lower than normal sale (30000 strips) in May and June. The Internal Audit should question "has the company really gained market share and maximized profit for company by giving Deal Scheme".

The thought process for push marketing argues that "As the trader is holding large quantity of medicines, he will try to sell more of this company's medicine and thereby the company may gain in terms of market share." The benefits, however, need to be assessed by the company and only if it is beneficial, then this kind of scheme be allowed. These schemes have more implication that if trader is left with unsold quantity near expiry then the company will have to take it back. If it did not have the identification mark for the quantity sold under scheme then it may land up paying full price (instead of discounted price to such trader).

## 3. AUDIT FOR SPURIOUS DRUG

Spurious/Substandard/falsely labelled/falsified/ counterfeit (SSFFC) medicines are medicines that are deliberately and fraudulently mis-labelled with respect to identity and/or source. They range from random mixtures of harmful toxic substances to inactive, ineffective

preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a SSFFC medicine is unknown and its content unreliable. In India the term Spurious Drugs are defined by Section 17-B of the Drugs and Cosmetics Act 1940. Spurious drugs are often also called as 'counterfeit drugs.

A 2007 report of the National Accreditation Board for Testing and Calibration Laboratories (NABL) clearly outlines that of all samples of medicines procured at random pan India, at least 5% of the drugs being sold below an MRP of Rs. 20 failed the stability or bioequivalence test.

| Cost range (INR) | Result of NABL report | |
|---|---|---|
| | Fail | Pass |
| Less than 20 | 225 (5.2%) | 4078 (94.8%) |
| 20 - 50 | 75 (2.2%) | 3359 (97.8%) |
| 51 -100 | 31 (1.4%) | 2167 (98.6%) |
| 101 - 500 | 0 (0%) | 569 (100%) |
| More than 500 | 4 (1.7%) | 235 (98.3%) |
| Total | 335 (3.1%) | 10408 (96.9%) |

Source: Extent of Spurious (counterfeit) Medicines in India, 2007

In India, the SEAR Pharm Forum study showcased that medicines in the price range of less than Rs. 20 per pack are most likely to be targeted and based on therapeutics, the Anti-histamine category was found to be most targeted. For the purposes of Internal Audit, the following methods should be a part of the training program for marketing teams to identify Spurious Drugs on a continuous basis:

- Visual Inspection guidelines should be defined, streamlined, and communicated across the supply chain, including but not limited to the wholesalers, retailers, doctors, and nurses.
- Criteria for Selection of Suppliers: In many cases, spurious drugs infiltrated the legitimate supply chain through one of the operators procuring spurious drugs from unauthorized or unofficial sellers.
- A Formal channel for feedback on the administration of medicines can be established to record any deviations from standards or to highlight all quality issues from doctors and patients alike.
- Finally, technology such as SMS based batch number verification can be initiated to not just build trust among patients but also to identify potential cases of spurious drugs.

Good Distribution Practices (GDP) Guidelines as issued by CDSCO state as under:

1. The activities of persons or entities involved in the distribution of products shall be regulated by applicable National legislation.

2. The distributor or the organization to which the distributor belongs shall be an entity that is appropriately authorized by applicable legislation to perform the function(s) that it intends to perform and the distributor or the organization to which it belongs shall be held accountable for the activities that it performs related to the distribution of products.

3. Only authorized persons or entities who hold the appropriate license shall be entitled to import or export pharmaceutical products.

4. Distributors or their agents shall obtain their supplies of pharmaceutical products from persons or entities authorized to sell or supply such products to a distributor and shall supply pharmaceutical products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient or to his or her agent.

5. If the activity of a distributor or his or her agent is subcontracted to another entity, the person or entity to which the activity is subcontracted shall be appropriately authorized to perform the subcontracted activity and shall uphold the same standards as the distributor.

Finally, the Internal Auditor should ensure the compliance with the Return Policy of the company. A retail/hospital Pharmacy can return expired/damaged, suspected medicines or soon to expire (6 months prior to the expiry date) to the wholesaler/stockiest who in turn returns these medicines to C&F Agents of the manufacturers. Internal Auditors must count the costs of spurious drugs and act a formal channel for Audit Committee and Board to receive ground reports and incidences of concern to the company.

## 4. AUDIT OF MERGERS AND ACQUISITIONS

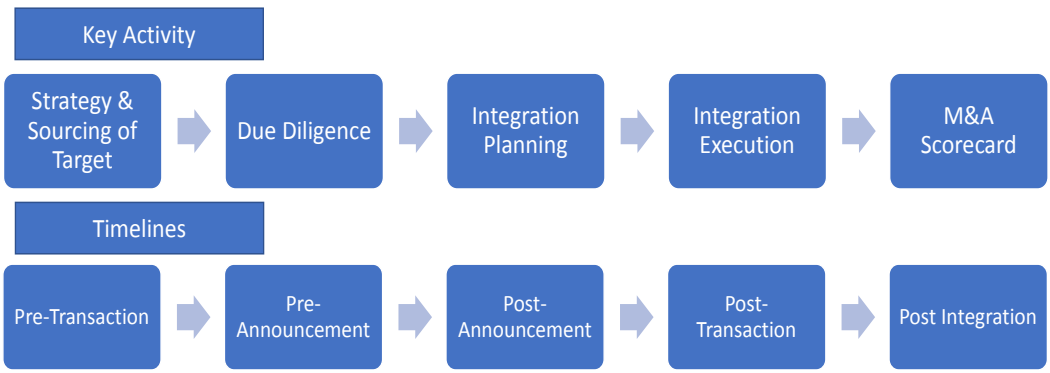
Recently, Mergers and Acquisitions have become a very common feature in the pharmaceutical Industry. M&As have provided companies with cash-on-hand as an additional means to achieve growth in market share, access to new distribution channels, entry to new markets, technology / innovations / products, and general organizational synergies.

In the post pandemic world, where growth opportunities for companies may be dependent on external factors such speed of economic recovery, revisions in price control laws, and classification of medical devices as 'drugs'; mergers and acquisitions will act as a key tool for the managements of pharmaceutical companies to create shareholder value. Prior to COVID-19, M&A activity was at an all time high in this industry with over 400 companies merging or being acquired in 2018, 2019, and forecasted for 2020.

The scope of an approach to the integration is dependent on the nature of the acquisition. In certain cases, like the Procter and Gamble acquisition of Gillette, while P&G was multiple times bigger than Gillette, the two businesses were deemed to be equals. At the same time, while Tata Steel was smaller than Corus in terms of balance sheet size, Tata Steel acquired Corus with an LBO (Leveraged Buy-Out). While different deals require different approaches to integration, usually size of the firms help determine the approach intuitively. The following

table provides the three most common approaches based on the size with examples from the Pharmaceutical Industry in India.

| Integration Type | Relative Size of target | Approach of Integration | Examples |
|---|---|---|---|
| Complete Acquisition | 20% or less of the acquiring company's pre-deal market capitalization | Complete Integration | > Torrent Pharma's Purchase of Elder Pharma Brands<br>> Dr. Reddy's Labs purchase of UCB India Brands |
| Major Acquisition | 20% to 70% of the acquiring company's pre-deal market capitalization | Situation based and usually driven by Value Drivers or target synergies | > Torrent Phrama's Purchase of Unichem brands<br>> Abbott's Purchase of Piramal |
| Merger of Equals | 75% or more of the acquirer's size | Best-of-Breeds or portfolio approach | > Sun Pharma and Ranbaxy |




**Merger and Acquisition Life Cycle**

The Merger and Acquisition Life cycle chart as shared above clearly indicates the five key activities and corresponding timelines to undertake them. While companies don't involve the Internal Audit function in the Strategy and Sourcing of Targets for mergers or acquisitions, Internal Audit plays an important role in all the remaining activities of a normal M&A life cycle. Before review of the key activities of M&A in detail, the list of key risks involved in the M&A are as under:

| Activity | Key Risks |
|---|---|
| Due Diligence | > Unclear target / counterpart selection criteria<br>> Incomplete deal evaluation<br>> Inadequate counterpart information<br>> Unclear Path to synergies |
| Integration Planning | > Over ambitious change management targets<br>> Delay in planning<br>> Lack of clear mandate from leadership<br>> Short term focus on cost reductions<br>> Delays in planning or plan at all<br>> Not having a cross functional team |

| | |
|---|---|
| Intergration Execution | > No transparency<br>> Lack of Trust<br>> Ambiguity among staff<br>> Failure to focus on synergies<br>> Focus on financial aspects only<br>> Lack of Customer, vendor, operation partners alignment<br>> Lack of Communication<br>> Conflicting targets for departments<br>> Cultural mis-alignment |
| M&A Scorecard | > Lack of Balanced Scorecard Approach<br>> Lack of responsibility accounting and delegation<br>> Reporting only financial aspects<br>> Loss of key human resources<br>> Inability to communicate with stakeholders<br>> Undue complexity in measuring success factors<br>> Undue delays<br>> Lack of clear reporting hierarchy |

While there are several due diligence checklists, usually, Checklists are only capable to act as guidance, but should never be used as check-the-box or AUDIT (All you do is tick) tools. The key to a good Internal Auditor is due diligence and while checklists are important, follow-up and counter questions play an important role in the internal audit process. However, as a guidance, here is an illustrative checklist for key departments in a merger is shared below.

| Department | Checklist of Documents / Actions |
|---|---|
| Legal | An organizational chart |
| | Governing and constitutional documents of the corporation |
| | A list of jurisdictions in which the business is permitted to do business |
| | Minutes of any board, shareholder, and managerial meetings |
| | List all related party transactions |
| | Include the firm's policies with respect to related party transactions |
| | Compile the CVs for all board members, managers, and vital employees |
| | Compile all information about the capital structure of the company that is not included on the Statement of Shareholder Equity |
| | Compile a list of all of the firm's permits, licenses, and authorizations |
| | Describe the firm's compliance policies and provide any related documentation |
| | Disclose if any officers or persons holding substantial numbers of shares qualify as Bad Actors |
| | Disclose if the firm is currently restricted from doing business under any regulatory or legal provision |
| | Collect any communications with a regulatory agency |

| | |
|---|---|
| | Include a list of all previous product recalls and significant warranty claims |
| Valuation | Obtain a current, "as-is" valuation of the firm |
| | Conduct Discounted Cash Flow analysis |
| | Compare to industry benchmarks |
| Compliance | Look for inaccurate or misleading government or claim forms |
| | Investigate the payment of any improper kickbacks, bribes, or benefits to healthcare providers in violation of the Uniform Code of Pharmaceuticals Marketing Practices ("UCPMP Code") |
| | Investigate possible violations of the Foreign Corrupt Practices Act (especially in Regulated Markets) |
| | Investigate all instances of impermissible, "off-label" promotion of pharmaceuticals and biologics |
| | Ensure all compliance with CDSCO, NPPA, FSSAI, and Ministry of Ayush |
| | Review all policies and procedures involving employees and contractors of the firm |
| | Review all compliance functions and personnel |
| | Review any past instances of non-compliant conduct and the firm's response thereto |
| | Examine the firm's treatment of "protected health information" and compliance with HIPAA in case of US operations |
| | Review compliance with, and results of State FDA inspections, observations of US FDA or EUMHRA |
| Sales and Marketing | Confirm all marketing materials comply with FDA regulations |
| | Confirm if any products are covered by restricted distribution programs or a Risk Evaluation and Mitigation Strategy |
| | Confirm if the target analyzes marketing metrics? |
| | Confirm that any direct-to-consumer marketing is undertaken |
| | Identify your largest and most important clients and products/services |
| | Identify any significant sales prospects |
| | Identify any significant new products |
| | Identify any significant discontinuances or potential losses of clients |
| Manufacturing | Confirm all contracts with manufacturers accord with Good Manufacturing Practices (GMP) |
| | Confirm Good Manufacturing Process manual accords with WHO, CDSCO, USFDA, EUMHRA, etc requirements on the subject |
| | Review the target's Adverse Experience Reports |
| | Confirm that adverse experience trends were analyzed and reported on |

| | |
|---|---|
| Finance and Taxation | Identify any deferred tax liabilities or assets and valuation allowances |
| | Outline all transfer pricing policies |
| | Outline all tax sharing or allocation agreements |
| | Justify and provide a written explanation of the classification of employees and contractors |
| | Include all tax audits conducted in recent history (up to five years prior) |
| | Include any loss surrenders made in exchange for research and development credits |
| | Describe property taxes paid by the firm in recent history (up to five years prior) |
| | Describe any overseas activity |
| | Describe any sale and leaseback transactions |
| | Disclose any matters related to the firm under investigation by any tax authority |
| | Disclose the tax base of any asset when it differs from its original cost |
| | Explain the firm's current approach to tax planning and strategy |
| | Collect all complete and current financial statements |
| | Specify and list any departures from GAAP and IFRS used during the preparation of the financial statements |
| | Collect all budgets and financial projections |
| | Include all Management Representation letters and any other communications regarding accounting controls |
| | Identify and highlight all recent capital expenditures and their likely impact on future cash flows |
| | Identify capital expenditures likely to be required in the near future and their likely impact on future cash flows |
| | Identify any seasonal or cyclical cash flow trends (in order to avoid under- or over-pricing the business, depending on the time of year) |
| Legal Contracts | Written contracts |
| | Verbal contracts |
| | "Handshake agreements" |
| | Joint venture or partnership agreements |
| | Any contracts terminable upon a change of control of the firm |
| | Indemnification agreements |
| | All real estate contracts and contracts involving real property or for the insurance thereof |
| | Employment, independent contractor, consulting, compensation, and severance agreements |

| | |
|---|---|
| | Identify any contracts to be entered into in the near future, including Letters of intent, Ongoing negotiations, Identify any crucial relationships with vendors, distributors, etc., and Examine all agreements with manufacturers and suppliers |
| Intellectual Property (IP) | Compile a summary of all of the firm's trademarks, patents, copyrights, and web domains and sites |
| | Examine the basis and substance of all trade secrets currently held by the firm |
| | Determine the ability of the firm to protect and keep secure and confidential its trade secrets |
| | List all agreements and contracts under which the firm is granted the use of a third party's intellectual property |
| | Determine whether the firm is using IP for which the assignment of rights is incomplete or defective |
| | Determine whether the firm is using IP developed in collaboration with, or acquired from, a third party. If so, examine the agreements that allow for use of that IP |
| | List all agreements and contracts under which a third party is granted the use of the firm's intellectual property |
| | List all intellectual property used by the firm that is not solely owned by the firm |
| | Create a summary of all intellectual property litigation involving the firm that is either concluded, ongoing, or reasonably foreseeable |
| | List all instances in which a third party has infringed on the firm's intellectual property (even if it did not result in litigation) |
| | Describe the company's process for developing and protecting its intellectual property |
| | List all subsisting patents and their remaining terms |
| | Compile a list of all pending patent applications and determine their likelihood of success |
| | Determine likely ability of the firm to protect the IP of all pending patents' should a patent be granted |
| | Determine the eligibility of any patents for term extension |
| | Determine the market exclusivity terms attaching to each of the firm's products and whether those terms can be extended |
| | For each biologic and pharmaceutical product, determine its stage in the FDA approval process and, for those products not yet approved, the likelihood of their eventual approval |
| | Consider the likely timing and impact of the introduction of generic and biosimilar drugs on the firm's market share and profitability |

## 5. AUDIT OF DPCO COMPLIANCE

The following steps are the most common flow chart activities that are encountered in ensuring a company's DPCO / pricing compliance. Please note that certain additions or deletions may be required to tailor these based on the internal setup of the company, but for the majority, these steps should work as a full proof guide to DPCO regulatory compliance.

1. Get list of all domestic formulations: Before taking the first step towards compliance, it is necessary to know what you have to comply for. Many companies find it difficult to answer the total number of brands, SKUs, and generics that are manufactured or procured or imported or sold by their company. Without the exhaustive list of all sales, it is difficult to assess the extent of compliance requirements. Additionally, many companies are into sales of food supplements, ayurvedic medicines and even food products. Identifying formulations as per the definition is trivial but an important step as many notices for food supplements have been received as they may contain certain scheduled API as an ingredient. The database thus formed, must contain the following:

    a. Name of Brand;

    b. Composition with Strengths;

    c. Dosage type;

    d. Pack Size;

    e. Drug License number;

    f. Price details namely Prices to stockists, retailers and Maximum Retail Price;

    g. Effective batch number of last price revision with month and year.

2. Get list of manufacturing locations and corresponding formulation: In India, the manufacturing locations determine the taxes applicable and control mechanism to be used. If a formulation is being manufactured across multiple locations, then the onus of price compliance for every revision is shared between all locations. This step has gained special relevance since many companies today have outsourced manufacturing on loan license basis or on P2P basis. Keeping an updated database of corresponding drug licenses (company wise) is also important for Contract Manufacturing Locations (CMOs). Many companies have faced severe regulatory problems due to lapses in maintenance of correct and updated drug licenses.

3. Classify Scheduled and Non – scheduled formulations: Now that the company has formed an exhaustive database of domestic formulations, and their manufacturing locations, the next step to compare individual compositions, strengths, and dosages to the First Schedule of DPCO, 2013. It must be noted if any of the three attributes vary in comparison to the First Schedule, then the formulation is to be considered as "non-scheduled". Also, in cases where incremental innovation such as lipid injections or sustained release delivery systems are introduced, the formulations would be considered as non – scheduled unless specifically mentioned in the list.

4. Check against Ceiling / Retail price for Compliance: The output of the last step would have been a clear understanding of which formulations are scheduled and non – scheduled. For all scheduled formulations, compliance with Ceiling prices as notified

by the National Pharmaceutical Pricing Authority (NPPA) and for all new drugs compliance with retail prices is a necessity. Companies can find the latest ceiling prices on NPPA website and accordingly verify their compliance levels. It must also be reiterated that Ceiling price is now different from MRP and no local taxes must be excluded from MRP prior to comparison for compliance.

5. Register with IPDMS: Registration with the Integrated Pharmaceutical Database Management System for every company of its activities, suppliers, manufacturing locations and formulations is compulsory from 2014.

6. Filing of forms 2, 3, and 5: Forms 2, 3 and 5 as notified under the DPCO 2013 are forms which need to be filed at regular intervals by companies. While the data for submission in forms 2 and 5 should be available from the database, form 3 data relating to production and sales must be made available every quarter and filed within 15 days from the end of the quarter.

7. Maintain an updated database: This is the most difficult exercise in ensuring total DPCO compliance of the company. Many companies make mistakes at this stage despite having the best computer-based systems, as updating the database takes personal interest and a sense of responsibility from the individual who is in charge of it. Thus, the Internal Auditor must ensure the updating of the database at frequent intervals.

8. Monthly Review of Price revisions: Revision of prices must be undertaken in accordance with para 16 for scheduled formulations and para 20 for non – scheduled formulations. It is necessary that the company maintains separate databases and then sorts them based on month of last price revision. With respect to scheduled formulations, the date for price revision has been predetermined in the act itself as 1st April every year and the quantum of revision been defined under Para 16. However, this exercise is vital for non – scheduled formulations where one year from last price revision can occur at different dates throughout the year. Thus, it is important to track and update the database for non –scheduled formulations on a monthly basis and communicate upcoming price revisions throughout the supply chain in a timely manner.

9. Reduce Inventory for formulations close to price revision: Most companies undertake production planning without consideration to upcoming price revisions for formulations. A sale of drug at a high rate once lost can never be added back. Since, most pharmaceuticals maintain three to six months of inventory in the sales pipeline, an early indication of price revision would help reduce inventory. Unfortunately, most companies go for promotion schemes in the months of January and February. This is ill timed for all scheduled formulations wherein the company tries to pre-sale inventory which would ideally be sold in months of April and May. This leads to loss of revenue for the company as those sales would have been made at the new and higher price in most years.

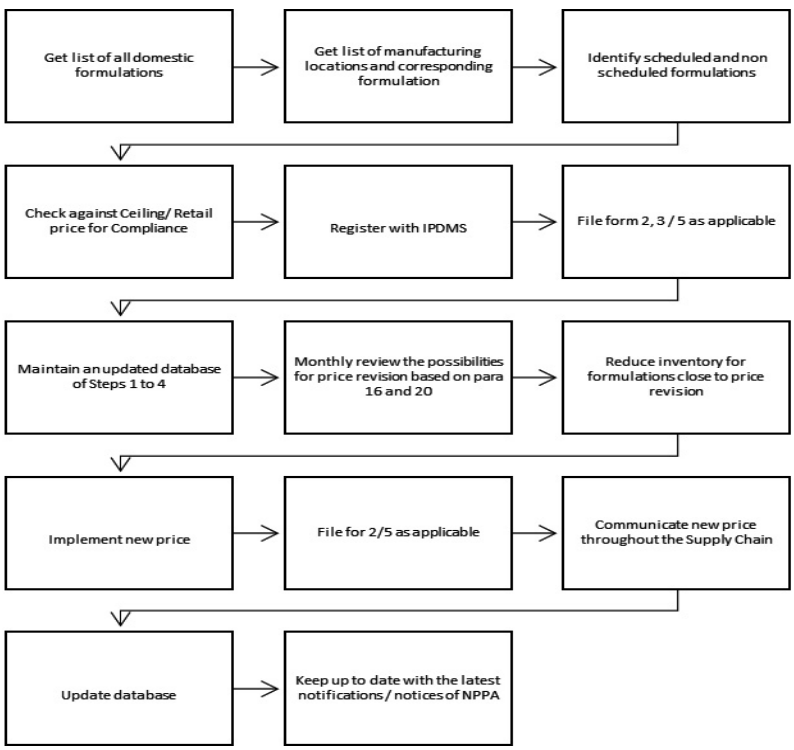
10. Implement new price: Implementation of a new price is usually simple as it is earmarked by the manufacturing of a new batch. For formulations being manufactured at multiple locations, synchronization of price revisions is of paramount importance. More importantly for scheduled formulations, in case of reductions in price, there is only a 45 days transition period for implementation of new price across the supply chain. This challenge has haunted the entire industry in 2013 and again in April of

2016. Thankfully, due to a change in definition of manufacturer and provisions of para 24, the next step allows for secure compliance with DPCO.

11. File and share form 2 & 5: Revision of price in isolation is not adequate. Communication of new price to NPPA, SDC and all stakeholders throughout the supply chain is also important. Filing of form 2 and form 5 is not only to NPPA but vide para 24 of DPCO 2013 to every 'dealer' which includes wholesalers, retailers, clinics, and hospitals.

12. Update Database: Most companies who decide to implement the preventive DPCO compliance process successfully implement the first cycle. The real challenge is to continuously update the database with accuracy and within the prescribed time. Despite well set processes, unless a manager with good repute within the company or a director is not personally involved in taking stock of the compliance, most companies begin to slack off after the first cycle. This is where the role of an Internal Auditor takes precedence.

13. Keep up to date with the latest notifications / notices of NPPA: The last and final step is a perpetual one. It is the easiest to delegate and yet near impossible to complete without some outside help. Certain companies utilize external consultants to make sure they are abreast of the latest notifications, irrespective of whether or not it affects them. Thus, the Internal Audit team should setup and monitor a process for receiving regular updates from the NPPA website, look for updates from industry associations such IDMA and IPA.




**CONTINUOUS PROCESS FOR DPCO 2013 COMPLIANCE**

Despite the company's best and earnest efforts, most companies receive one or more of the following types of notices from NPPA and the Internal Auditor should not only be familiar with them, but also ensure documentary evidence is available to prepare legally acceptable replies.

Non- Implementation of Ceiling Prices

- Once, NPPA notifies the Ceiling price for a scheduled Formulation, these prices are applicable to all the manufacturers, immediately on notification. Every manufacturer has to ensure due compliance for all the formulations leaving their factory, duty paid go-down or the place of C&F agent.
- For the formulations already sold and are still in pipeline, the manufacturer needs to issue revised price list and anyone who is holding these formulations can charge the price printed on formulations or as per the latest price list issued by the manufacturer, whichever is less.
- As it could be understood from recent notifications that even the wholesaler, retailer, stockiest, hospitals or Doctors has to sell formulations at a maximum retail price printed on formulation or exhibited in the latest price list of the manufacturer.
- In such cases, it is the responsibility of manufacturer to issue price list and ensure that every party mentioned in the previous paragraph need to observe the price discipline, else they would be liable to pay overcharge.

Not obtaining Price Approval for Scheduled formulations prior to launch.

- If a manufacturer desires to launch a new Scheduled formulation after May 2013, it is mandatory to make a price application in Form I in Schedule II to DPCO, 2013.
- If the manufacturer has not sought price approval from NPPA and unilaterally launched a new scheduled formulation, NPPA will issue notice to such manufacturer and levy penalty for not obtaining price approval as provided in Para 4 read with Form I of Schedule II to DPCO, 2013.
- Hence, it is mandatory to obtain price approval prior to launching a formulation.
- If a manufacturer proposes to introduce a non-scheduled formulation in the market, it is required to file a price list with NPPA, SDCs, As also provide Price List or additional Price List to all the parties involved in supply chain.

Increase in Price of Scheduled formulation beyond increase in Whole Price Index (WPI).

- The government notifies increase or decrease in WPI in respect of previous calendar year in month of February/March (i.e., increase or decrease in Wholesale Price Index (WPI) in respect of calendar year January to December 2015 is notified in February/ March, 2016.
- A manufacturer of Scheduled formulation is allowed to increase the price of formulation by increase in % of WPI notified by government. A manufacturer may select not to increase the price though permitted.
- In case of reduction in WPI, a manufacturer of Scheduled formulations is duty bound to reduce the price by percentage of reduction in WPI, irrespective of fact, whether the price was increased in earlier years or not.

- If a manufacturer had increased price beyond increase in percentage of WPI, it amounts to overcharge and following actions are required:
  - The price of the formulation should be reduced to permissible level.
  - Supplementary price list may be issued, filed with authorities and sent to entire supply chain for the correction.
  - The overcharged amount will have to be deposited with NPPA with interest and penalty.
  - No increase in price is allowed during the period of overcharge.

Increase in Price of Non-Scheduled formulation beyond 10%.

If a manufacturer had increase price beyond 10%, it amounts to overcharge and following actions are required:

- The price of the formulation should be reduced to permissible level.
- Supplementary price list is required to be issued for the correction.
- The overcharged amount will have to be deposited with NPPA with interest and penalty.
- No increase in price is allowed during the period of overcharge.

Sale of formulations at MRP higher than notified beyond 45 days.

When NPPA notifies new ceiling prices of NLEM (also known as Scheduled) formulations, the manufacturer is given a period of 45 days:

- To call back the medicine for reducing MRP or
- Issue price list with notified prices and ensures that every wholesaler, retailer, chemist, hospital, doctor is advised about the reduction in price with clear cut mandate to the trade to sell at a reduced price.
- The revised form V - Price List is required to be filed with department of Pharmaceuticals, NPPA and all the State Drug controllers of the states, in which the formulation is intended to sell as also all the parties involved in supply chain namely, wholesaler, super stockiest, stockiest, distribution hub, retailer, hospital, doctor etc.
- NPPA may call upon Manufacturers to prove that their notices to this effect were delivered to all concerned.

Sale of drugs at a price higher than notified.

- Every manufacturer is required to communicate a reduction in price to all the concerned parties including wholesaler, retailer, chemist, hospital, doctor, department of Pharmaceuticals, NPPA and all the state Drug controllers of the states in which the formulation is intended to sale.
- Anyone who is responsible for not communicating such reduction will be responsible to pay overcharged amount with interest and penalty to NPPA.

Sharing data with NPPA for fixing ceiling price or specific price of a scheduled formulation for a manufacturer.

- Every manufacturer or trader is duty bound to furnish the details of price being charged by the manufacturer for a particular formulation.
- If the enquiry is for fixing price for other manufacturer, the recipient does not have anything to lose and he is legally duty bound to furnish such information, however, some manufacturers are wrongly advised not to furnish the information.

Shortage of formulations in retail market

- Sometimes a particular formulation is not available in some areas, primarily because of some epidemic or changed preference for medicine by doctors. Further, sometimes manufacturer cuts down production either because of glut in market or the price being uneconomical.
- Under the circumstances, NPPA directs the manufacturer to supplement the availability in that area. This could be done either by transferring more quantity from the manufacturing plant or transferring from other regions. The manufacturers having better logistic management generally do not run out of formulation.
- As a result of notice from NPPA, the manufacturer is required to augment the supply of such formulation in such areas.
- There was a situation in year 2013-14, the availability of silver-based API was affected because of very significant increase in cost of API and with no chance of getting corresponding increase in price the availability of such medicines was affected

Pricing in Monopoly situation

- Para 6.1 of DPCO, 2013 discusses pricing in monopoly situation. If there are less than five manufacturers, it is called Monopoly and if the formulation was not under price control under DPCO 1995, the NPPA may announce reduction in price as per formula provided in Para 6.1.
- It may please be appreciated that NPPA has power to reduce the price considering the monopoly or nearly monopoly situation, and a manufacturer has to be prepared for the same.

Notice for special delivery system (SR, ER or CR)

- There had been confusion regarding such notifications, the latest interpretation is that unless words like SR, ER or CR are prescribed in NLEM the formulations with SR, ER or CR are not included and they continue to enjoy exemption.

Price declaration for other specific manufacturer:

- If a new manufacturer files price application in Form I under para 4 of DPCO 2013 the government has to fix the price for formulations of such manufacturer. If one reads the provision of Para 4 of DPCO 2013, it is clear that the price has to be average price of all the existing and proposed manufacturers.
- Thus, the price of a Scheduled formulation will always be less than the ceiling price announced earlier by NPPA. These are specific price for specific brand

or manufacturer. The names of the manufacturers are always mentioned in such notification. Hence, it applies to those manufacturers only. Surprisingly, several existing manufacturers were advised to reduce the price of their brands also.

- If this mistake is made by manufacturer, he will not get an opportunity to correct its mistake and reduction would be eternal.

Non-Compliance with IPDMS filings

- Under Para 29 of DPCO 2013, NPPA had mandated furnishing of certain information by specified day in Integrated Pharmaceutical Database Management System (IPDMS). Many manufacturers have still not furnished the desired information in spite of repeated reminders. Gradually, matter is getting more and more serious and impact of non-compliance may have serious consequences especially in light of recent notifications/office memos.

Increase in price of formulations twice in a year:

- Certain manufacturers had, due to oversight, revised price twice during span of a year. NPPA views this seriously and insist on immediately rolling back the price and file form II and V (as the case may be) with reduced price. The procedure to be followed is as under:
  - Reduce the price to correct level,
  - File form II (for scheduled formulations) and Form V for reduced price,
  - Intimate NPPA about the mistake and send them a certificate of cost accountant/chartered accountant for quantities sold.
  - Wait for demand notice from NPPA.
  - Pay the demand notice with interest and penalty if any.

Increase in price of Non-scheduled formulations:

- Certain manufacturers had due to oversight, revised price by more than 10% for Non-scheduled formulations. NPPA views this seriously and insist on immediately rolling back the price. The procedure to be followed is as under:
  - Reduce the price to correct level,
  - File form V for reduced price,
  - Intimate NPPA about the mistake and send them a certificate of cost accountant/chartered Accountant for quantities sold.
  - Wait for demand notice from NPPA.
  - Pay the demand notice with interest and penalty if any.

Notice for price of cosmetic or food products:

Sometimes, NPPA issues notice for cosmetic or food products. Cosmetic and Food products are not covered under DPCO, 2013 or DPCAO, 2016. Hence, the Drugs (Prices Control) Order, 2013 or DPCAO, 2015 does not apply to cosmetic products. A simple reply to NPPA with Cosmetic or FSSAI manufacturing license should suffice.

In addition to DPCO 2013, an Internal Auditor must also ensure of the company's compliance with the submissions of SUGAM portal. It is the online portal of CDSCO (Central Drugs Standard Control Organization) which was implemented in January of 2016 and is to be used for online submission of applications requesting for permissions related to drugs, clinical trials, ethics committee, medical devices, vaccines and cosmetics. The system also builds up the database of approved drugs, manufacturers & formulations, retailers & wholesalers in India. The types of Licenses to be applied and maintained through SUGAM portal are as under:

- Registration Certificate – Form 41 for Drugs
- Registration Certificate – Form 41 for Medical Devices
- Registration Certificate – Form 41 for Diagnostic Kit
- Import License – Form 10 for Drug
- Import License – Form 10 for Medical Devices
- Import License – Form 10 for Diagnostic Kit
- Test License for Clinical Trials
- BE (Bio-Equivalence) NOC for Clinical Trials / Import or manufacture of New Drugs
- Registration Certificates for Cosmetics

# AUDIT OF FUNCTIONAL AREAS


**1. ADMINISTRATION DEPARTMENT:**

As it is evident from earlier chapters, there are lots of activities both in production and technical department on one hand and marketing and distribution department on the other hand. The Administration function is very crucial because it is utmost necessary to coordinate efforts of both the set of functions namely, production and technical as well as marketing and distribution. Administration department is service center with primary objective of coordinating efforts among production, technical, marketing and distribution. In nutshell, administration has to coordinate the direction of effort between these departments. In layman's language one can say the production department has to produce what can be sold effectively at a remunerative price and marketing department will sell what can be manufactured efficiently and at effective cost.

For example: the finance function is part of Administration and it has to judiciously make funds available for procuring raw material, funding production activity, holding WIP and Finished Goods and extending credit to customers and recover the money from them. Thus, it is a tight rope walking to ensure that every lac of rupee has to be deployed in such a way that all the function take place without much adverse effect.

Further, all Integrated Business Plan (IBP) for long term and then broken down in smaller periods like year-end quarter to achieve short term and long-term goals to be monitored consistently. The overall performance of the company and setting up and achieving long term goal is the activities of Administration Department. As companies carry out operational audit of various functions it is equally important to carry out management audit of corporate level activities. The concept has not been readily accepted in the Indian scenario primarily because of control of business by their family or group of individuals. However, with professional management the company becoming rule of the game, especially in fast growing Pharmaceutical Company. This kind of management audit is gaining importance primarily because the ownership and responsibility are separated.

**2. MATERIAL MANAGEMENT:**

As discussed earlier the number of items to be purchased or procured and variety of combinations of procurement available in the market influence the function of material management. The company generally divides its input material into ABC Category. Generally, Bulk Drug/API are considered in A category which has small volume but substantially higher value and on the other hand the excepients (the other material having very low cost) are required in larger quantity, it may be going to more than one product and has low value. To keep the procurement department efficient many pharmaceuticals companies, invite tenders for C class and some of the B class items and sign rate contract for the whole year and the supplier will supply quantities as required from month to month.

**PROCUREMENT FROM HILLY STATES:**

The product from Hilly States plant may result in saving of excise duty and VAT and has substantial impact on cost structure of the product.

When company has invited quotation/tender from different parties, it is utmost essential to analyze comparative price considering all ingredients of landed cost. As per format given vide annexure 1 further, there are 2 more points pertaining to material ordering and holding which should be practiced consistently.

Format to clear a proposal for Purchase:

| Serial Number | Material Name | Material Code | Expected Requirement | Less: Free Stock | Less: Material on Order | Quantity to be purchased | EOQ (Economic Order Qty) |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

It is a must that all the columns are filled and taken in to consideration.

Format for control over unnecessary Purchase:

| Serial Number | Material Name | Material Code | Quantity in stock | Expected Consumption in April | Expected Consumption in May | Expected Consumption in June | Others (Contigency) | Plan to clear current stock by: |
|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

When a company's purchase department has to purchase several thousand types of Materials, it is advisable that the company gets into rate contract for C class items and one contract will ensure supply for several months. The same thing applies for some of the B class items also.

Sometimes, the company receives the export order or local tender for a formulation. Some quantity of inputs and Packing Material are left over after completion of the order. In pharmaceutical Industry for every input and finished Formulation, there is an expiry date, therefore utmost care should be taken in ensuring that the left-over stock is NIL or negligible and such left over materials are disposed off at the earliest.

For comparison of Tender/Quotation/Bid the following format of quotation needs to be followed and the lowest eligible supplier needs to be identified. The term lowest eligible supplier pre-supposes following conditions:

a) His goods are of acceptable quality.

b) His technical and financial capacity is satisfactory to supply the size of order.

c) He has financial capability to procure requisite Working Capital and execute the order within the time frame.

d) The origin of such supplier may be given due weight-age, if his factory is located in Hilly Areas and enjoys excise and VAT exemptions or

e) If the input material is volatile and transport appears to be dangerous as in case of sulphuric acids etc, then a supply from nearly manufacturer is more advisable.

When procurement is for a unit in SEZ, the supply may be preferred from 100% EOU or SEZ Unit to get the benefit of exemption available to EOU/SEZ.

**3. STORES ACCOUNTING:**

It is necessary to check the method of valuation of issue of materials as only two methods are allowed under Income Tax namely First and First Out (FIFO) and Weighted Average Method. This rate should be factual rate and not predetermined rate for ERP/SAP System. In ERP/SAP language, it is called Moving Weighted Average. The Companies Act, and tax Authorities like Income Tax, Central Excise Duty, VAT, Sales Tax, Octroi/ Local Body Tax etc. always insist on actual value of the materials and will not accept standard or Pre-determined rates are not acceptable. Thus, if a company does not maintain accounts on actual basis, it has far reaching effects.

There should be detailed system to account for left over material, slow and non-moving material and unless these materials are likely to be utilized within forcible time, they should not be carried forward as the closing stock.

Due provision should be made for evaporation and deterioration in storage and only net quantities should be considered for carry forward.

When a pharma Company planning to enter a highly regulated market like USA, UK etc., it is necessary to manufacture full size batch for validation by concerned authority. Such validation batches are not allowed to be sold. Hence, it has no commercial value at the end of the year. Following the principle of "Cost or Market Value, whichever is less", the value of such stock cannot be included in value of closing stock.

**4. FINANCE AND ACCOUNTS DEPARTMENT:**

Finance is a crucial function and efficient management of the same can ensure efficient functioning of the unit. Clear cut plan for mobilization of funds or collection of trade debtors and deployment of resources for various functions of business is the function of Finance Dept. It is most important function as flow of liquidity from raw materials >> Work-in-process >> Finished Goods >> Receivables >> Cash.

Further, Financed Dept. in consultation with Marketing Dept. should fix credit limit for each stockiest and wholesaler. It may also exercise control over level of inventory. Fund Requirement for CAPEX and to ascertain the viability of CAPEX whether the projects under consideration meet the expected payback, fund flows and Internal Rate of Return (IRR).

**5. MARKETING AND DISTRIBUTION:**

For Internal Audit of Marketing Function, it is utmost essential to start with the marketing budget for the year because depending on the marketing budget the production procurement and distribution plan will be finalized and more importantly the effect of deviation from budget would be very crucial to control the operations.

The production plan for the company will always be based on marketing budget read with stock policy and deviations are monitored and production plan may be altered by adhering to following table:

| Serial Number | Name of Product | Product Specification | Product Code | Expected sales in Next month | Add: Stock at end of month | Less: Stock at beginning of month | Quantity to be produced |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

Any excess production in a month should be monitored with a view to keep slow moving and non-moving stock at the lowest.

Same way the stock at Carrying and Forwarding Agent needs to be managed with following statement:

| Serial Number | Name of Product | Product Specification | Product Code | Expected sales in Next month | Add: Stock at end of month | Less: Stock at beginning of month | Quantity to be supplied | Quantity to be Transferred |
|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

**6. HRD AND PERSONNEL DEPARTMENT:**

Pharmaceutical company is considered to be more dynamic than other industries because the option available on procurement and putting up facilities are wider than other industries. A large number of companies in Pharmaceutical Sector have gone to Hilly States and are marketing their products to several countries world over in addition to marketing its product in every state in India. In addition to this, new product ranges including specialty products are continuously introduced making it necessary to continuously assess the requirement of manpower in next quarter, in next year, for new plant or new marketing area in India and abroad and for R & D Activities. The manpower is a must to convert the projections and budgets into reality with the help of right kind of people, in right number, at right place. Thus, all plants and projections will materialize if right kind of manpower is mobilized more so for marketing efforts and timely replacement of people who leave the company. The company should avert loss of production, loss of market share or loss of opportunity for want of requisite right kind of people at right place.

**7. IT DEPARMENT:**

Pharmaceutical companies on an average grow at the rate of 13%-14% per year and the requirement of data is increasing year after year to effectively manage the business and to grow faster than competitors. In such scenario, all good companies try to grow in each segment at a rate higher than industry's average and under such circumstances very effective and proactive IT Department is a must and the efforts of IT Department will go long way in converting the potential into business at an early date and at a rate higher than industry average. The IT Department should either be capable of developing additional programs or augmenting data from additional systems or help assisting, generating additional data in requisite format and at requisite frequency.

**8. TRANPORTATION:**

Generally large Pharmaceutical Companies like FMGC Companies sell their products to the length and breadth of the country and it is utmost necessary to ensure that almost all the products are available where company has promoted the product or is penetrating into the market. Under such circumstances, logistic and transport of medicine to the length and breadth of the country is a must and is key to success of marketing efforts.

**9. OTHERS:**

In Pharmaceutical Industry it is unwritten law like FMGC to keep a track not only of your company but effective planning and effort of the other company. Like when company creates additional production facility in Hilly States there has to be detailed planning of how manufacturing facility and manpower will be deployed at original location. What is the long-term integrated business plan for next 5 years and 10 years and where do they expect company to be after 10 years, both in terms of volume and international presence?

# RPA, AND AI IN PHARMACEUTICALS

The Pharmaceutical Industry is bracing for the advent of Robotic Process Automation (RPA), and Artificial Intelligence (AI) to take over and disrupt business across sectors and geographies. As an Internal Auditor, it is imperative that similar disruptions are not only anticipated but led. The need to reimagine business processes and resource deployments are being driven by shifts which are disturbing the industry's status quo – pressure to reduce costs, and demonstrate greater value, transitioning from treatment to prevention, and personalized treatments. These tectonic shifts are challenging the overall business model of pharmaceutical companies. Internal Auditors can play an important role in monitoring these automated processes and the key drivers for implementation of these technologies are16:

- Need to enhance internal efficiency
- Reduction in R&D expenses
- Optimization of quality and compliance processes
- Increasing patient retention and interaction
- Enable faster and better disease detection and prevention
- Increasing the precision of Demand estimation to bridge the supply-demand gap
- Broaden the portfolio of services offered

Currently, while AI companies have tried to influence pharmaceuticals for faster adoption of AI and ML in various processes, the most prevalent functions for adoption of these technologies are as under:

a) R&D – Major companies are either developing their own AI capabilities or partnering with AI startups to accelerate drug discovery and for personalization of medicines

b) Drug Dosage and Safety – With AI, the dosages are customized for patient after duly considering the patient's vitals, stage of disease, and characteristics. AI is implemented at every stage of safety value chain to improve the quality, compliance, and administration.

c) Manufacturing and Supply Chain – AI is also being used to optimize drug manufacturing along with identification of counterfeits

d) Regulatory Approvals – While still in development, implementation of AI in the regulatory approval process is expected to significantly streamline the clinical drug approval process

AI is used in drug discovery and development in a number of ways such as17:

- Organic synthesis and design
- Scoring synthetic complexity
- Automation of molecule design
- Predicting organic reaction outcomes

- Computer-aided synthesis
- Computer-assisted retrosynthesis based on molecular similarity
- Predict drug performance in testing
- Discover off-label use
- Predict toxicity prior to clinical trials
- Personalized medicine

Apart from AI, another technology that is being implemented rapidly is Robotic Process Automation or RPA. A 2020 Bain survey shows that 84% of the companies across the industry spectrum plan to take action in the direction of accelerating automation efforts. In fact, with the advent of COVID 19 Crisis, pharmaceutical companies have implemented RPA to speed up vaccine development, or accelerating data entry and analysis. Considering the number of tedious and routine tasks relating to compliances, regulatory filings, and clinical trial data, RPA is the easiest and most common tool that we expect to be implemented over the next decade.

Today the Internal Auditors need to be able to Audit not just conventional business processes but also automated processes being executed by BOTs. An illustrative list of questions for Auditing an Automated process is shared herewith below:

1. RPA Strategy –
    - Does the RPA strategy include Internal and External Auditors?
    - Does the management have a pre- and post-RPA organization matrix?
    - Are the standard Operating Process well laid down?
    - What are the criteria to identify processes for automation?
2. RPA Governance
    - Are the KPI and KRA clearly defined for RPA implementation?
    - Are the internal personnel driving the automation identified?
    - Are the processes being automated critical to business sustainability? If yes, then what are the back ups in case of incidents in implementation?
    - How will roles and responsibilities change post RPA implementation?
3. RPA environment
    - Has the company assessed changes to automated/ manual controls environment due to RPA implementation?
    - Are critical systems, programs, and/or jobs monitored before, during, and post RPA implementation?
    - How do you ensure processing errors are corrected to successful completion/ posting?
    - Do you have change management process for the RPA environment?
4. RPA Center of Excellence (RPA CoE) Audit
    - Are the internal resources clearly identified for the RPA Center of Excellence?

- Are the resources adequate for smooth implementation of all target processes?
- Is there a need for functional managers to be involved in RPA CoE?
- Does the RPA CoE have formal communication channels for queries and feedback?

5. Data Leakages and Privacy
   - How do you ensure accuracy, security and completeness of the stored data?
   - Is the automated process accessible to non-related personnel?
   - Is the RPA output stored in a private drive / location?
6. Cyber Security and Threats
   - Is there a cyber-risk matrix?
   - How is cyber risk controlled?
   - What are the communication channels in case of an incident?
   - Does the current vulnerability management program cover the BOT landscape?
7. Incident management systems
   - How are the incidents remediated in the RPA environment?
   - Does the company have log monitoring for all critical actions to and by the BOT?
8. Licensing requirements
   - What is the expected cost of software license compliance post automation?
   - Is the license updated and paid for?
9. Legal and Regulatory Compliances
   - What procedures are followed for Change management?
   - Are BOT security and protection requirements documented and agreed by all stakeholders of the target process?
   - What is the mechanism in place for data lineage and traceability?
10. Identity and Access Management
    - How are the privilege accounts for RPA environment controlled?
    - Whether access is appropriately segregated between BOT IDs and the end users?
    - Are passwords encrypted, stored and set as per policies and procedures?

Despite the obvious challenges and benefits to the pharmaceutical industry, RPA implementations are gathering momentum and the Internal Audit team too can benefit from RPA implementations in the following ways18:

- Data gathering and cleansing for analytics: An RPA Center of Expertise (CoE) can generate and standardize data to run custom analytics, doing the work of pulling the data to be used by internal and external auditors, including automation checks for completeness of fields, duplicates and validation, etc. This frees Internal Audit from time spent coordinating and gathering this data.

- Risk assessment: Bots can help automate the initial data gathering and classification for the annual risk assessment process. They do this by soliciting feedback from participants up front and identifying core trends. This allows for the in-person meetings to be focused on trend analysis and deep dives into the risks of the organization.
- Population gathering: During the sampling and initial evidence gathering for standard evidence for controls, bots can help process data populations and do so more efficiently and accurately than humans can. This is especially valuable when it comes to large populations requiring heavy resources to process, such as analyzing thousands of statement documents.
- Automation of controls: Bots can run controls testing - especially for control areas that are standardized, such as where tickets and fields are consistently used. This frees Internal Audit from performing those standard required checkmarks.
- Internal Audit areas. Several areas where RPA can additionally assist Internal Audit teams include:
    - Identifying open items, sending follow-up emails and documenting status, etc.
    - Tracking progress against the project plan or annual audit plan (can use RPA to monitor KPIs in process)
    - Automating reporting - including report templates, audit committee decks, etc.

# RISK BASED INTERNAL AUDIT : SPECIAL CONSIDERATIONS FOR PHARMACEUTICALS

9

**Introduction - Management vs. Internal Audit**

The Internal Audit teams in the Pharmaceutical Industry are required to establish and implement systems, processes, and control points to ensure quality, compliance, and growth. A management control system in any organization can be defined as the responsibilities, procedures, processes, and resources that the company has implemented to ensure quality, efficiency, and effectiveness throughout the manufacturing, sales, marketing, and supporting processes. Internal Audits are a component of the company's management control systems, and provide a systematic and an independent means of evaluating overall quality, efficiency, and compliance status. The intention of the Internal Audit process is to focus on key areas within the quality system and may not cover all relevant areas during each audit.

**Why Risk Based Internal Audit in Pharmaceutical?**

While Risk based approach to Internal Audits has been discussed at length in the earlier chapter, the common areas that an Internal Auditor must focus on for a pharmaceutical company are as under:

- Documentation and record control
- Manufacturing process and equipment
- Training
- Validation and qualification
- Facility and processes, such as
- HVAC and clean rooms
- Unidirectional airflow devices
- Sterilization systems
- Water system
- Sanitation procedures
- Preparation of laboratory reagents and controls
- Finished product test releases
    a. Pure gases line
    b. Freeze dryers,
    c. Aseptic filling lines and production equipment.
    d. Material and product flows,
    e. Process and system specifications.

f. GMP policy,

g. Planning and follow up.

Thus, a Risk based approach to Internal Audit in pharmaceuticals will allow the management to discuss not only the overall risk exposure, but also to discuss the impact of risk events, simulation of potential risk interactions, prioritization of risk mitigation, identification and coordination of risk management silos, and finally to make risk-informed strategic decisions.

**Industry Specific Risks**

Certain Risks have been identified as specific to the Pharmaceutical Industry are:

- Patient compliance tracking is limited even in controlled drug trial and there is no recourse available for the companies
- The industry is characterized by very high "Gross Margins" as the costs of marketing, supply chain margins, sales, distribution, and promotion outweigh the production costs
- There is uncertainty in India regarding Intellectual Property Rights and their enforceability. This has led to many multinational companies deciding against launching their patented drugs in India.
- The list of data requirements and costs of maintaining integrity of that data for following Good Manufacturing Practices (GMP) is ever increasing.
- While the drug dosage form may be the same (for example a tablet), the supply chain structure to be implemented for different drugs varies significantly. Some drugs can only be administered by Medical Professionals, others can be self-medicated, and certain drugs are prescription based
- One of key issues bothering Investor relations is the Pipeline of the company with regards to new launches and ability to trust the management assessment of these trials
- Most companies have tried to Out-licensing the production in part or whole and thus, maintaining pharmaco-vigilance is a major risk in Internal Audit
- With the advent of CRAMS as discussed in Chapter 13, Clinical Trials are also being outsourced which has let to questions regarding data integrity and corresponding outcomes
- In many cases, reporting of Adverse Effects or incidents regarding drugs are often mired in long paper trails which doesn't always allow Internal Auditors to ascertain the risk associated with a drug for its users
- While the Supply chain for the entire Industry works on transfer of ownership and possession, the manufacturers retain the responsibility for destruction of expired products. This leads to a need for continuous monitoring the batch wise aging throughout the Chain of custody.
- The risk of spurious drugs has been explained in the earlier chapters
- Revenue recognition for new products is a contentious issue as most companies would like to write off the drug developmental costs as soon as possible. This leads to issues of revenue recognition for the Auditors
- The Regulatory process is often unpredictable and at times it is subject to political interventions. Especially, during 2020, many drug trials not relating to COVID were forced to suspend trials or received delayed permissions.

**Areas to be covered**

Risks are usually categorized into two distinct groups: those without reward (compliance, reporting, and fraud) and those with a reward (investments, R&D, acquisitions) Therefore, the management of a company and the Internal Audit Team are in a perennial battle to balance the risk-based audit oversight and while the management prefers focus on areas with tangible rewards, the Internal Audit Team must also focus on the associated areas with intangible rewards such as reputation, goodwill, and trust of stakeholders. It must be noted that today's Internal Auditors are responsible for providing assurances to management of the companies on the risk management process, and that risks are effectively identified and evaluated. Thus, risk management processes are Expected to be both effective, and efficient to ensure key risks are appropriately reviewed and reliably reported to all relevant stakeholders.

The following risks have been long associated with the Pharmaceutical industry and they continue to be key challenges for the Industry as a whole.

- Research and Development entails high risks on account of long development cycles, along with investments in time, money, and expertise. In spite of life-saving benefits, the industry is often exposed to risks for the users and these hamper shareholders value
- The regulatory environment is ever changing and complex
- Continuous Issues of efficiency (low-capacity utilization), pricing (DPCO), and input (API) availability
- Uncertainty regarding the patents, and intense competition for new intellectual property rights along with competition from Generic players
- Address increasing demand for lower-priced products from consumers, physicians, politicians, and regulators, is in sharp contrast to demands of higher returns from investors
- Calls for greater transparency on the effects to consumers along with focus on safer or risk-free breakthrough therapies
- Media scrutiny and escalating litigation costs, which highlights legal and financial exposure

It may be noted that the pharmaceutical industry has also been characterized by various initiatives within the industry to tackle these risks include forming joint ventures, in-licensing, mergers & acquisition, and outsourcing of a part or whole of an activity. This has also led to new risks wherein the continuously changing risk environment requires the industry to look at risk from new perspectives and simulate potential risk-reward decisions.

# PHARMACEUTICAL INDUSTRY AND IMPACT OF COVID

10

**Introduction & Example of "Heparin"**

COVID stands for 'Corona Virus Disease' and it struck global supply chains with China being the first to cut API exports in the months of February 2020. Later, by April 2020, almost the entire world supply chain came to a grinding halt due to travel restrictions, restrictions on exports, delays in customs clearances, etc. In this chapter, we will look at the impact of COVID on the pharmaceutical industry, the key risks that will persist until recover is complete, and how to mitigate them. We will finally end with a list of schemes introduced by the Government of India over the years which may prove to be convenient to companies looking for expansion or incentives.

It must be noted that from February 2020 to May 2020, the prices of raw materials had shot up amid limited supply, production schedules have been interrupted, factories have been shut down or are operating on partial occupancy, and distribution costs have increased substantially. The impact on the Indian pharma sector is typically evident, given that most raw materials are procured from China, which was the epicenter of the outbreak in the initial months of 2020.

A case in point to the immediate impact of lockdowns was the drug "Heparin". Heparin Sodium is a scheduled formulation, and its Active Pharmaceutical Ingredient (API) is not manufactured by more than 4 companies across the globe. Moreover, during February and March 2020, there was an astronomical increase in the price of this API and thereby manufacturing the formulation became unviable for most local manufacturers. By late April 2020, Market reports suggested an acute shortage in the availability of Heparin Sodium which is critical due to its anticoagulant properties. It may please be noted that even if the API was secured within one week, the formulation manufacturing process takes at least 2 more weeks after which manufacturing and pan India distribution of the formulations took another week. Thus, no company could foresee any increase in supply of this scheduled formulation for the month of May 2020 without an interjection by the Government of India. In an unprecedented move, to ensure the availability of this life saving drug, the NPPA issued a one-time hike in the MRP of 'Heparin' by nearly 50%. This timely and necessary move not only avoided acute shortages but also helped ensure the manufacturers were able to procure APIs urgently.

Even though the pharmaceutical industry was exempted from the lockdown, with the movement of people and goods restricted amid lockdowns, manufacturers of generic drugs were unable to launch products or conduct clinical trials. Thus, timelines for drug filings have been indefinitely extended. Furthermore, cash flows from new generic drug launches have significantly delayed. Indian drug manufacturers faced many other challenges such as low sales and volatile demand. Certain companies had to be shut as workers tested positive for COVID–19 while, plants that were operational produced lower outputs due to manpower crunch amid lockdown and social distancing measures. Finally, the supply chain for distribution of drugs was complete tormented. While prior to COVID, the pharmaceutical industry would only be charged for part truck loads, during COVID, the same companies not only paid for the full truck costs, they paid additionally to empty return trips of the Third-Party Logistics companies.

**Impact - Short Term & Long Term**

There were various short term and long term impacts of the COVID lockdowns on the Pharmaceutical Industry20. While the short-term impacts include changes in demand of drugs, supply shortages, panic buying and stocking, regulation changes, and shift of communications, and promotions to remote interactions through technology and research and development (R&D) process changes, the long term impact includes approval delays, moving towards self-sufficiency in pharma-production supply chain, industry growth slow-down, and possible trend changes in consumption.

**Key Risks and Mitigation Actions**

A general list of key Risks and how to mitigate them during Internal Audit is shared herewith below:

1. Liquidity Crisis: The management of the company's cash flows, repayment plans for debt, and potential for investments should be reviewed in detail. The management should focus on:

    a. Managing Payables by prioritizing crucial payments

    b. Questioning all Variable Costs

    c. Focusing on cash conversion cycle as a whole

    d. Reviewing and revising debt repayment or retirement scheduled

    e. Trying to expedite receivables or supply on cash basis

    f. Reducing inventory holding (after considering sales pipeline and lead times)

    g. Hedging of FOREX transactions

    h. Review of the process for calculating financial loss due to supply chain changes

2. Insurance Risks related to existing policies and for employees should be mitigated by:

    a. Increasing the coverage of the existing policy

    b. Obtain adequate risk covers for protection of employees, inventory, and assets

    c. Consulting with insurance providers and experts on the eligibility of claims due to the impact of COVID-19 on business activities

    d. Creating an adequate documentation plan for recording business interruptions and associated costs

3. Research & Developmental risks associated with clinical trials and regulatory approvals can be mitigated by:

    a. Identifying the drugs whose trials that could be affected due to lockdowns

    b. Incorporate COVID-19 risk and impact tracking trial management plans

c. Communicate with investigators to understand the specific issues COVID-19 is creating at their sites (such as local lab testing capacity, patient retention, serious adverse event risks)

d. Investigate alternative timing or locations, and prioritizing initiation of new investigator sites in countries with a low potential risk

e. Establish strong patient communication plans and an internal regulatory perspective on COVID-19 to guide communications with regulators

4. Supply chain risks pose the biggest test for risk mitigation for companies across the following areas:

i. Quality checks of material received

ii. Shortage of raw materials/API/ solvent due to dependency, inadequate materials to complete BOMS/batch size processing

iii. Shut down of contract manufacturers

iv. Quality control check at contract manufacturers or traded goods

v. Potential expiry of materials – monitoring for re-assessments and quality certificates

vi. Risk of contamination after final packing (LL/TP)

vii. Contractual compliance

viii. Non-availability of local transportation for dispatch of material and finished goods

ix. Risk associated with contractual terms with domestic and export customers, especially contractual obligations and force majeure clauses

x. Contamination issues with respect to trucks and other vehicles used for dispatch

5. Risks associated with the plants and warehouses (Hub and Spokes) operations are as under:

a. Inadequate focus on regulatory compliance with FDA/CGMP norms, manpower resource, and schedule maintenance

b. Inadequate segregation of duty controls

c. Contamination of work place

d. Contamination risk from visitors, contractors, and third-party staff

e. Contamination at warehouse or stockiest locations

f. Inadequate social distancing

g. Risk of movement of infected vehicles in the plant/warehouse

h. Risk of dependency on third-party service providers (especially those dealing with HVAC systems)

6. Another risk associated with plants and all non-administrative locations are Non-compliance of orders from the labour commissioner

7. Finally, with the advent of Work from Home, cyber security risks are significant and relevant to Internal Auditors from the perspective of data leakages, malware, or ransomware attacks, etc.

# AUDIT FOLLOW UP


Once the Internal audit has been completed and the internal audit report has been discussed and submitted to the management, a list of findings, recommendations and prescribed actions are compiled with specific timelines for completion clearly indicating the manager responsible and for longer projects, the various crash-gates to be followed and periodicity of the interim report. It is the duty of the internal audit function to establish a follow-up process that helps the management ensure whether or not the recommended actions have been effectively implemented or has the management accepted the risk of not taking the requisite action. An annual review and Report of Outstanding Audit Comments has to be adopted by the Internal Audit function to meet the needs of the management and to be complied with the follow-up requirement noted above.

To facilitate the follow-up process, Internal Audit function maintains a database of outstanding audit comments. This database tracks identifying information about each Internal Audit report or close-out letter along with a summary of each finding in the report or letter, the manager responsible for taking corrective action, and the estimated completion date for corrective action. Audit comments issued by external audit groups should be loaded into the database when they are received. The database will also track whether or not a finding has been corrected, what was done to correct the issue, whether corrective actions should be tested, and the date corrective action was complete.

In most cases, follow-up reviews will be done jointly by the head of internal audit team and the management. However, if requested by management, follow-up on the status of selected findings in a separate review may be presented on a more frequent basis. Also, as time is available during the year, inquiries about and status of previously issued findings may also be reviewed. Approximately 3 to 4 weeks before the annual follow-up is scheduled to begin, the completeness of the Findings database is compared to list of pending issues. If any reports have not been entered into the database, have the internal audit function must complete the report and findings forms and have this information added to the database. Once the database is confirmed as being current, the queries and report programs that are used to create reports shall also be updated.

The head of Internal Audit team should prepare a memorandum for the management that notifies them that the internal audit activities are underway and describes the follow-up process. This memo should include:

- timeframes for the project,
- a copy of the outstanding findings relating to areas reporting to the manager responsible,
- a request that they distribute the findings to these areas and ask the managers to provide Internal Audit team with the information requested,
- a statement that these comments were previously distributed as part of an audit report or close-out letter, and
- notification that the results will be reported to the management.

The notification memo should be sent to each functional head along with the status of internal audit findings for each finding related to the function's areas of responsibility.

As the finding's status are updated and returned to Internal Audit team, the information should be reviewed for reasonableness, completeness and adequacy. The internal audit team, with the approval of the functional heads, shall determine which of the responses need to be tested and what level of testing is appropriate. Working papers and work programs should be generated and reviewed as with any other audit project.

At the conclusion of the test work and after updating the Findings database, reports of outstanding or closed findings and a cover letter of explanation should be generated and distributed to the following groups allowing approximately 2 weeks for each group to review and respond:

- Functional Heads – also receives list of report of Corrected Findings
- Functional Directors
- Audit Committee
- Executive Management
- Board of Directors

After each of these groups has reviewed the reports and any necessary corrections to the database have been made, the final versions of the Outstanding Findings report, the Repeat Findings report, and, if necessary, the Closed Findings report should be produced for the management and issued.

Generally, the agenda for monthly meetings is finalized by considering issues arising out of Internal Audit Report. The Internal Audit Report needs to be discussed at monthly meeting and areas requiring attention are zeroed down. The functional Managers are assigned task arising out of this report, line of action is worked out and a senior manager is directed to supervise the task entrusted. When the task is complete and situation is brought under control or project is accomplished, final action taken report is submitted to monthly meeting and higher ups. The comment owner or designee should give written communication to the Internal Auditor, upon completion of corrective action in response to an internal audit finding. If the event corrective action has not been completed by the established target completion date, the comment owner should provide a written communication to the Internal Auditor on the status of corrective action, circumstances or reasons that have prevented the completion of corrective action, and specify a revised target date by which corrective action will be completed.

Management should complete corrective action measures in response to reported external audit findings in a timely and reasonable manner. The Internal Auditor is typically requested to act as the coordinator of remedial efforts between management and external auditors. In such a case, the comment owner or designee should give written communication to the Internal Auditor upon completion of corrective action in response to an external audit finding. In the event corrective action has not been completed by the established target completion date, the comment owner should provide a written communication to the Internal Auditor a progress report on the status of corrective action, circumstances or reasons that have prevented the completion of corrective action, and specify a revised target date by which corrective action will be completed.

# CHECKLIST

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A general checklist for undertaking Internal Audit of a pharmaceutical organization is as under:

| Sr. No. | Particulars | Documentation | Remarks |
|---|---|---|---|
| | **Basic Input Files** | | |
| 1 | Trial balance of the period | | |
| 2 | Quantity Reconciliation File (Production, Sales, Opening and Closing Stock, Wastages, Breakages, Expiries, Sales & Purchase Returns, issued to QA/QC, lost in transit, etc) | | |
| 3 | GST returns | | |
| 4 | Report of the Tax Auditor for the previous year | | |
| 5 | Final / Provisional P&L and Balance Sheet for the period | | |
| 6 | Input Material Consumption | | |
| 6A | Standard Consumption X Standard Batch Size X No. of batches Manufactured | | |
| 6B | Actual Consumption for each product (batch-wise) | | |
| | **Technical Basis for Overhead Allocation and Apportionment (plant-wise / product-wise)** | | |
| 1 | Area Occupied | | |
| 2 | No. of Employees | | |
| 3 | No. of Workers | | |
| 4 | Connected HP (KWH/Hr) | | |
| 5 | Compressed Air (CFM/Hr) | | |
| 6 | Steam (KG/Day or per Shift) | | |
| 7 | Nitrogen (CFM/hr) | | |
| 8 | ETP Generation (Slurry or waste) | | |
| 9 | Water Consumption (KL/Day) | | |
| 10 | Value of Plant and Machinery (Gross and Net) | | |
| 11 | Cost Center wise Man and Machine Hours split into: | | |
| 11A | Changeover Time (applicable upon change in campaign) | | |

| | | | |
|---|---|---|---|
| 11B | Cleaning Time (applicable after each batch) | | |
| 11C | Line Clearance (applicable after each batch) | | |
| 11D | Process Time (variable to size of batch) | | |
| | **Process of Manufacturing (Usual Cost Centers)** | | |
| | **Tablet Manufacturing** | | |
| 1 | Dispensing | | |
| 2 | Mixing | | |
| 3 | Granulation | | |
| 4 | Compression | | |
| 5 | Coating (only for coated tablets) | | |
| 6 | Inspection | | |
| 7 | Blister Packing | | |
| 8 | Alu-Alu Packing | | |
| | **Capsule Manufacturing** | | |
| 1 | Dispensing | | |
| 2 | Sifting | | |
| 3 | Mixing | | |
| 4 | Granulation (Optional) | | |
| 5 | Encapsulation (Filing) & Polishing | | |
| 6 | Inspection | | |
| 7 | Packing | | |
| | **Liquid Manufacturing** | | |
| 1 | Dispensing | | |
| 2 | Manufacturing / Mixing | | |
| 3 | Bottle Washing | | |
| 4 | Filing and Sealing | | |
| 5 | Inspection | | |
| 6 | Labelling and Packing | | |
| | **Ointment Manufacturing** | | |
| 1 | Dispensing | | |

| | | | |
|---|---|---|---|
| 2 | Manufacturing / Mixing | | |
| 3 | Cartooning | | |
| 4 | Empty Tube inspection and cleaning | | |
| 5 | Filing, Sealing and coding | | |
| 6 | Inspection | | |
| 7 | Labelling and Packing | | |
| | **API / Bulk drug Manufacturing** | | |
| 1 | Dispensing | | |
| 2 | Reactor | | |
| 3 | Filtration | | |
| 4 | Centrifuge | | |
| 5 | Dryer | | |
| 6 | Sifter | | |
| 7 | Multi / Single column Distillation | | |
| 8 | Crystallizer (optional) | | |
| 9 | Inspection | | |
| 10 | Packing | | |
| | **Injection Manufacturing** | | |
| | **Liquid & Lypholisation Injections** | | |
| 1 | Dispensing | | |
| 2 | Mixing | | |
| 3 | Filtration | | |
| 4 | Filing | | |
| 5 | Lyophilisation with sealing | | |
| 6 | Liquid Injectable Sealing | | |
| 7 | External Vial Washing | | |
| 8 | Inspection Packing | | |
| | **Service Centers / Utilities** | | |
| 1 | Workshop & Engineering | | |
| 2 | D G Set / Power | | |

| | | | |
|---|---|---|---|
| 3 | Input Stores - RM / PM / Stores & Spares / Consumables | | |
| 4 | Stores Outward / BSR | | |
| 5 | Boiler | | |
| 6 | Compressed Air | | |
| 7 | Nitrogen | | |
| 8 | DM Plant | | |
| 9 | Chiller | | |
| 10 | Cooling Tower | | |
| 11 | Multi Columnar Distillation | | |
| 12 | AHU – Air Handling Unit | | |
| 13 | ETP – Effluent Treatment Plant | | |
| 14 | R&D – Research & Development | | |
| 15 | QA – Quality Assurance | | |
| 16 | QC – Quality Control | | |
| 17 | Factory Administration | | |
| | **Warehouse (RM, PM, Consumables, Stores, Spares, and Finished Goods)** | | |
| | **Prior to / during GRN process for Input Materials:** | | |
| 1 | All necessary and relevant documents are received. | | |
| 2 | The vehicle is free from any oily, grease, dyes or any foreign materials. | | |
| 3 | Manufacturer's / Supplier's labels are visible and approachable. | | |
| 4 | All relevant details like Name, B. No., Mfg. and exp. Dates, storage Condition are mentioned on labels. | | |
| 5 | The material is received from the vendor listed in the approved vendor list. | | |
| 6 | All containers / packs / bags are in intact condition. | | |
| 7 | COA of RM is provided by the manufacturer. | | |
| 8 | Physical quantity/count of material is the same as mentioned in received documents. | | |
| 9 | Any other discrepancies observed during the period | | |

| | **A specific Warehouse Audit of Pharma company will include:** | | |
|---|---|---|---|
| 1 | Whether the storage area is adequately designed for better storage conditions? (i.e., temperature, light, humidity & cleanliness). Whether Cleaning record is maintained or not. | | |
| 2 | Is there adequate space for orderly storage of all starting materials, intermediates, bulk, finished product, and also a product in quarantine, released, rejected, returned, or recalled. | | |
| 3 | Are the materials properly checked with BOM respect to Quantity, Item code and suppliers' name by Store & production officers and cross-checked by QA before and after dispensing? | | |
| 4 | Are the containers of incoming materials cleaned before storage? Is there any provision for that? | | |
| 5 | Whether each container of every consignment is passing the qualifications like integrity, type of materials, delivery details, material details (mfg. & exp.), PO references & damage etc? | | |
| 6 | Inspect process of at least one material receipt and check whether the SOP of material receipt is followed. Check that, during receipt materials are checked physically for any damage and damaged containers are treated as per SOP. | | |
| 7 | Whether starting materials after receiving and finished products after processing are quarantined immediately? | | |
| 8 | Whether the received material is properly stored with segregation and status labels? | | |
| 9 | Check that material requiring storage under controlled temperature are stored separately under controlled temperature. | | |
| 10 | Whether the SOPs are available & followed for receipt of the materials? Also, check the SOPs are of the latest version. | | |
| 11 | Check the material stock ledger and check the physical correctness of the material stock of one material | | |
| 12 | Whether each batch of each material (separate sample of separate batch No. In a single consignment) is taken for sampling, testing and release? | | |

| | | | |
|---|---|---|---|
| 13 | Checks that the assigned pesto-flash and roda-box are kept at the position and check the cleaning records. | | |
| 14 | Check the pest control records. | | |
| 15 | Observe the warehouse personnel for material movement from warehouse to sampling room and dispensing room. | | |
| 16 | Inspect dispensing operation of one batch and check whether the SOP of dispensing is followed. | | |
| 17 | Whether the materials are sampled in the sampling area under RLAF booth? Whether the area is clean? | | |
| 18 | Whether the RLAF pressure is within the specified limit? Whether the sampling log book is maintained? | | |
| 19 | Check that after sampling of every raw material sampling booth is cleaned. | | |
| 20 | Whether the materials are segregated and stored with proper status labels of Quarantined, sampled, Under Test & Approved with a proper readable label with QC AR No.? | | |
| 21 | Check that after sampling of every raw material sampling booth is cleaned. | | |
| 22 | Whether dispensing is done in the identified areas under Reverse LAF? | | |
| 23 | Whether the secondary gowning procedure is followed? | | |
| 24 | Is there a written procedure to follow FIFO/FEFO for starting materials used in Mfg. and also the products transferred at different stages of production? | | |
| 25 | Whether raw materials are dispensed only by designated persons? | | |
| 26 | Whether each dispensed material and its weight or volume are independently checked and recorded? | | |
| 27 | Is there a control on unauthorized access to the printed packaging material? | | |
| 28 | Is the Utensils and equipment used for Dispensing of raw materials cleaned from all types of extraneous matters? | | |
| 29 | Are the dispensed materials with proper status labelled? | | |
| 30 | Is there any disposal operation after a spillage of any materials in the floor? | | |

| | | | |
|---|---|---|---|
| 31 | Is there provision for dispensing of raw materials as per sequence and colour & actives dispensed at the last stage of Dispensing? | | |
| 32 | Whether packaging materials are issued by only designated persons? | | |
| 33 | Whether the balance is checked daily for performance checks? Whether the balance is calibrated monthly? Whether the status labels are appropriate? | | |
| 34 | Whether the standard weights are calibrated and stored properly? | | |
| 35 | Is the utensil wash area cleaned? Are the cleaned utensils stored and identified? | | |
| 36 | Whether each consignment/lot of material is being identified by reference number? | | |
| 37 | Whether outdated or obsolete primary and printed packing material is destroyed and recorded? | | |
| 38 | Verify the physical stock of any printed packaging material. | | |
| 39 | Check that packaging material of different product or strengths are segregated | | |
| 40 | Check that rejected material list is maintained. Check whether Material Destruction Record is maintained. | | |
| 41 | Is raw and packing materials stores are separated and provided with adequate space, storage racks, pallets, etc.? | | |
| 42 | Check the record of material issuance. | | |
| 43 | Is the approved vendor list available in the stores? | | |
| 44 | Are starting materials issued against an authorized work order only? | | |
| 45 | Is dispensing activity is carried out under RLAF or not? | | |
| 46 | Is dispensing checked independently by Stores / Production / QA? | | |
| 47 | Are the materials measured into clean, properly labelled containers? | | |
| 48 | Are the stocks dispensed in FIFO/FEFO order and ledgers signed by the responsible person? | | |

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| 49 | Is dispensed area supplied with filtered air & return raiser? | | |
| 50 | Is adequate post measuring staging area available? | | |
| 51 | Is there a provision for storage or reprocessing or destruction of the rejected materials/products? | | |
| 52 | Whether these are recorded and approved by authorized personnel? | | |
| 53 | Whether the recalled products are appropriately identified and stored? | | |
| 54 | Is there an SOP to critically evaluate the reprocessing of the returned products or if required destruction of the same? | | |
| 55 | Is there a separate rejection area provided with lock and key? | | |
| 56 | Whether the temperature and humidity are recorded in Raw material stores and BSR? (wherever applicable) | | |
| 57 | Whether the temperature and humidity are recorded in Packing material stores? (wherever applicable) | | |
| 58 | Is there an effective system to highlight raw materials due for retesting? | | |
| 59 | Are there any expired raw materials in stores? | | |
| 60 | Is the distribution record in the finished goods stores enable specific batches to be traced? | | |
| 61 | Whether each container or pack is labelled appropriately during the period of storage in stores like the name of the material, code reference, batch no., lot no. & material status label like quarantine, on-test, released, rejected, returned & also retest date? | | |
| | **Warehouse (BSR – Bonded Store Room and Advance Licensed Procurements)** | | |
| 1 | Check current status of BSR and Advance license | | |
| 2 | For BSR refer Annexure A (enclosed) | | |
| 3 | For Advanced Licenses refer Annexure B (enclosed) | | |
| | **Engineering & Maintenance (Detailed audit would include)** | | |
| 1 | Is there an organogram for the dept? | | |
| 2 | Is no. of personnel adequate? | | |
| 3 | Is the department manual available for reference? | | |

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| 4 | Is responsibility of the personnel available? | | |
| 5 | Are all SOP's w.r.t. procedures are correct & followed? | | |
| 6 | Is revision status/ date mentioned in all the documents? | | |
| 7 | Is any obsolete document found floating in the dept? | | |
| 8 | Are proper breakdown entries made in history card? | | |
| 9 | Are Boiler, D.G. set, M.S.E.B, Log books maintained? | | |
| 10 | Is the list of equipments available? | | |
| 11 | Are the preventive maintenance schedule & plan available? | | |
| 12 | Is the list of critical spares available? | | |
| 13 | Is proper indent given for required material with proper authorization? | | |
| 14 | What is the identification mark for cleaned & un-cleaned filters? | | |
| 15 | Are all service lines well defined by displaying coded/ colour details? | | |
| 16 | Is buffer stock of filter kept with proper identification? | | |
| 17 | Whether all filters with proper identification mark? | | |
| 18 | Whether all calibration carried out by third parties have traceability to national standards? | | |
| 19 | Is the ETP tank labelled properly? | | |
| 20 | Is preventive maintenance schedule done as per schedule? | | |
| 21 | Is the IQ, PQ, OQ done for new equipment? | | |
| 22 | Are the breakdown records maintained? | | |
| 23 | Are levels of underground water, sufficient diesel, boiler & D.G. set tanks inspected regularly? | | |
| 24 | Are there checks on Humidity & Temperature controller? | | |
| 25 | Are calibration tags available on each equipment? | | |
| 26 | Are procedures along with frequencies available for calibration? | | |
| 27 | Whether temp. & pressure gauges used are calibrated as per frequency? | | |
| 28 | What is the procedure for 'Out of Calibration' equipment? | | |

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| 29 | Is proper status label for critical spares? | | |
| 30 | Is proper status label of filters clean? | | |
| 31 | Is calibration status being available on calibrated equipments? | | |
| 32 | Is any non-conforming product / utility identified properly? | | |
| 33 | Are records maintained if documented procedure changes due to corrective/ preventive action? | | |
| 34 | Whether proper authorisation is taken for any deviation? | | |
| 35 | Is work permit taken for critical activities? | | |
| 36 | Are critical spares stored properly? | | |
| 37 | Whether safety wears are used during maintenance work? | | |
| 38 | Are all records (controlled copies) of SOP's kept / displayed in proper locations? | | |
| 39 | Is there a retention period for each of these documents? | | |
| 40 | Are all operators & workers trained? | | |
| 41 | Are records of training properly maintained? | | |
| 42 | Is employee assessed after training? | | |
| 43 | Is retraining given if required? | | |
| 44 | Is there a training calendar? | | |
| | **Purchase / Procurement** | | |
| 1 | Is the current list of Vendors available? | | |
| 2 | Is the list of TSE / BSE certificate available? | | |
| 3 | Verify the addresses of manufacturers/suppliers from the current vendor list. Is it concurrent? | | |
| 4 | Check the Purchase Orders for SAP codes. Are the SAP codes current and approved? | | |
| 5 | Check the Purchase Orders from vendor list. Is it concurrent? | | |
| 6 | Is the list of SAP codes available against specifications? | | |
| 7 | Is the list of current specifications available? | | |
| 8 | Check the Invoice as received along with consignments, is the material as per agreed specification? | | |
| 9 | Check the vendor approval process. Are all the approval qualification/questionnaire available as per SOP? | | |

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| 10 | Check the number of vendors against for material. Are there stand by vendors available? | | |
| | **Pricing / DPCO Compliance and Roadmap includes** | | |
| 1 | Get the list of all domestic Formulations | | |
| 2 | Get list of manufacturing locations and corresponding formulation | | |
| 3 | Identify scheduled and non scheduled formulations | | |
| 4 | Check against Ceiling/ Retail price for Compliance | | |
| 5 | Register with IPDMS | | |
| 6 | File form 2, 3 / 5 as applicable | | |
| 7 | Maintain an updated database of Steps 1 to 4 | | |
| 8 | Monthly review the possibilities for price revision based on para 16 and 20 | | |
| 9 | Reduce inventory for formulations close to price revision | | |
| 10 | Implement new price | | |
| 11 | File for 2/5 as applicable | | |
| 12 | Communicate new price throughout the Supply Chain | | |
| 13 | Update database | | |
| 14 | Keep up to date with the latest notifications / notices of NPPA | | |
| | **Information required when company receives a notice for overcharging:** | | |
| 1 | Batch wise and month wise production details | | |
| 2 | Batch wise pricing | | |
| 3 | Batch wise sales quantities | | |
| 4 | Sales returns including expiries and damages | | |
| 5 | Drug License of the product | | |
| 6 | Composition of the product | | |
| 7 | All branded and generic versions sold by the company | | |
| 8 | Pack size of different SKUs | | |
| 9 | Notices as received from NPPA | | |
| 10 | All communications with NPPA for the said product | | |

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| 11 | Various communications to supply chain regarding price of product | | |
| 12 | Primary list of reasons why the company need not be penalized | | |
| | **What to do when NPPA notifies an incorrect / inaccurate ceiling price for your formulation** | | |
| 1 | Receive the Notice from NPPA | | |
| 2 | Immediately implement the notified price | | |
| 3 | Decide on next steps (Review / Appeal / Writ) | | |
| 4 | Collate Records from company | | |
| 5 | Ask Supply chain to validate records | | |
| 6 | Collate relevant proofs | | |
| 7 | Prepare Short notes on facts of case | | |
| 8 | Hire a consultant / counsel | | |
| 9 | Draft Review petition / Writ | | |
| 10 | File Review / Writ | | |
| | **CDSCO Compliance - Verify Schedule L 1 (Checklist for GMP to be filed by every plant)** | | |
| | **How to check Batch Manufacturing Report** | | |
| 1 | Issuance of BMR and Label claim is proper. | | |
| 2 | All the pages are available and comply with the index. | | |
| 3 | Are manufacturing and expiry are correctly allotted? | | |
| 4 | Dispensing is carried out on calibrated balance. | | |
| 5 | Raw Material Requisition is available. | | |
| 6 | Coating Material Requisition is available. | | |
| 7 | Line clearance is taken prior to all dispensing and manufacturing activities. | | |
| 8 | Dispensing is carried out as per work order. | | |
| 9 | Raw Material Assessment Sheet is available. | | |
| 10 | All dispensing labels are properly affixed. | | |
| 11 | Environmental conditions comply during all the manufacturing steps. | | |

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|---|---|---|---|
| 12 | No overwriting is observed and all wrong entries have been a strikeout and signed. | | |
| 13 | Actual equipment used is as specified. | | |
| 14 | Pre sifting check, sifting & pre mixing checks are performed and recorded. | | |
| 15 | Mixing & Preparation of Binding Agents is proper. | | |
| 16 | Granulation Pre drying checks are performed and recorded. | | |
| 17 | Size Reduction, Final Drying & inclusion of Residue. | | |
| 18 | Lubrication & Pre-Compression Checks are performed and recorded. | | |
| 19 | Yield reconciliation of blend is within the acceptable limit. | | |
| 20 | QC approval for bulk is available on technical information sheet and release label is affixed. | | |
| 21 | In- Process checks are performed at a defined frequency and are as per Specification during Compression or capsule filling. | | |
| 22 | QC approval for compressed tablets or filled capsules is available on technical information sheet and release label is affixed. | | |
| 23 | Yield reconciliation of compressed tablets or filled capsules is within the acceptable limit. | | |
| 24 | Preparation of coating solution and coating is performed as per the defined procedure. | | |
| 25 | Yield reconciliation of coated tablets is within the acceptable limit. | | |
| 26 | QC approval for coated tablets is available on technical information sheet and release label is affixed. | | |
| 27 | All the in-process checks results comply with the acceptance limit. | | |
| 28 | Is there any deviation during the process and deviation is raised and approved? | | |
| 29 | If any deviation, incident, change control raised related to the batch attached with the batch record. | | |
| 30 | Deviation, incident, change control is closed before the release of the batch. | | |

| | **How to check Batch Packing Report** | | |
|---|---|---|---|
| 1 | Issuance of BPR and Label claim is proper. | | |
| 2 | All the pages are available and comply with the index. | | |
| 3 | Manufacturing and expiry are correctly allotted. | | |
| 4 | Packing Material requisition is available. | | |
| 5 | Dispensing is carried out as per Requisition. | | |
| 6 | Line clearance is taken prior to all packing activities. | | |
| 7 | No overwriting is observed and all wrong entries have been a strikeout and signed. | | |
| 8 | In-Process checks are performed at a defined frequency. | | |
| 9 | All the in-process checks results comply with the acceptance limit. | | |
| 10 | Approved specimens of foil, cartons, labels or shipper stencilling are affixed. | | |
| 11 | Finished Good Transfer Note is affixed. | | |
| 12 | Packing Material Return Note is affixed. | | |
| 13 | Finished Product Release Slip is affixed. | | |
| 14 | Extra Material Requisition is affixed. | | |
| 15 | F.P. report/ In process Report is affixed. | | |
| 16 | Reconciliation of material is performed and is correct. | | |
| 17 | Yield reconciliation of finished goods is within the acceptable limit. | | |
| 18 | Is there any deviation during the process and deviation is raised and approved? | | |
| 19 | If any deviation, incident, change control raised related to the batch attached with the batch record. | | |
| 20 | Deviation, incident, change control is closed before releasing of the batch. | | |

# ABBREVIATIONS

13

- Center for Monitoring Indian Economy (CMIE)
- U.S. Food and Drug Administration (USFDA)
- European Directorate for the Quality of Medicines (EDQM)
- World Health Organisation (WHO)
- Good Manufacturing Practices (GMP)
- United Kingdom Medicines and Healthcare products Regulatory Agency (UKMHRA)
- Active Pharmaceutical Ingredient (API)
- Research and Development (R&D)
- Contract Manufacture And Research Services (CRAMS)
- Foreign Direct Investments (FDI)
- Private Equity (PE)
- Venture Capital (VC)
- Compounded Annual Growth Rate (CAGR)
- Key Starting Material (KSM)
- Over-The-Counter (OTC)
- Central Drugs Standard Control Organization (CDSCO)
- Drugs (Price Control) Order (DPCO)
- National Pharmaceutical Pricing Authority (NPPA)
- Department of Pharmaceuticals (DoP)
- Ministry of Chemicals and Fertilizers (MCF)
- Ministry of Health and Family Welfare (MoHFw)
- National List of Essential Medicines (NLEM)
- Standing Committee on Affordable Medicines and Health Products (SCAMHP)
- Good Clinical Practices (GCP)
- Drugs Controller General of India (DCGI)
- Indian Council for Medical Research (ICMR)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

- Drugs and Magic Remedies (Objectionable Advertisement) Act (DMROAA)
- Narcotic Drugs and Psychotropic Substances Act (NDPSA)
- Organization for Economic Collaboration and Development (OECD)
- European Medicines Agency (EMA)
- Therapeutic Goods Administration, the Australian regulatory body (TGA)
- Essential Commodities Act (ECA)
- National Pharmaceutical Pricing Policy (NPPP)
- Carrying & Forwarding (C&F)
- Center for Disease Control and Prevention (CDC)
- Central Drugs Laboratory (CDL)
- Central Drugs Testing Laboratory (CDTL)
- World Health Professions Alliance (WHPA)
- World Medical Association (WMA)
- Indian Medical Association (IMA)
- Spurious/ Substandard/ falsely labelled/ falsified/ counterfeit (SSFFC) medicines
- National Accreditation Board for Testing and Calibration Laboratories (NABL)
- Contract Manufacturing Locations (CMOs)
- Principal to Principal (P2P)
- Loan License (LL)
- Indian Drug Manufacturers Association (IDMA)
- Indian Pharmaceutical Alliance (IPA)
- Robotic Process Automation (RPA)
- Artificial Intelligence (AI)
- Machine Learning (ML)
- Corona Virus Disease (COVID)
- Good Manufacturing Practices (GMP)

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Website: www.icmai.in
E-mail:iaasb@icmai.in
Toll Free: 1800 345 0092 / 1800 110 910

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Follow us on

**HEADQUARTERS**
CMA Bhawan
12 Sudder Street, Kolkata-700 016, India
Tel:+91-33-2252 1031/1034/1035/1492/1602/1619/7373/7143
Fax: +91-33-2252 7993/1026/1723

**DELHI OFFICE**
CMA Bhawan
3, Institutional Area, Lodhi Road, New Delhi - 110 003
Tel: +91-11-24622156/57/58, 24618645
Fax: +91-11-43583642