



Importance of Drug Regulatory Affairs in Pharmaceutical Industry

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Abstract

A pharmaceutical company's Drug Regulatory Affairs (DRA) department is essential. This pertains to the lifecycle of healthcare products; it offers guidance on strategic, tactical, and operational matters as well as support in adhering to regulatory requirements in order to hasten the development and distribution of safe and effective pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics, and complementary and alternative medicine products to people worldwide. Professionals in regulatory affairs (RA) work for the government, the pharmaceutical sector, academic research centres, and healthcare facilities. India's pharmaceutical industry is expanding quickly, thus the country requires more regulatory affairs specialists to meet the demands of the global marketplace. Regulatory affairs specialists serve as the intermediary between global regulatory authorities and the pharmaceutical industry and worldwide regulatory agencies. A relatively recent profession, regulatory affairs sprang from governments' aim to protect public health. These kinds of submissions necessitate much data and documentation, which makes for big, complicated applications.

Keywords: Drug Regulatory Affairs; Regulatory Affair Departments; Drug and Cosmetics Act and Rules; GMP; GLP; WHO Guidelines and ISO 9000 Series

Introduction

Governments' aim to safeguard public health by regulating the efficacy and safety of goods in a variety of sectors, including as pharmaceuticals, veterinary care, medical devices, pesticides, agrochemicals, cosmetics, and complementary and alternative therapies, gave rise to the profession of regulatory affairs.

The modern Pharmaceutical enterprise is well prepared, systematic and compliant to international regulatory standards for manufacturing of Chemical and biological tablets for human and veterinary intake in addition to scientific gadgets, conventional herbal merchandise and cosmetics. Strict GMPs are being applied to the manufacture of blood and its byproducts, as well as to the regulated manufacturing of traditional herbal medicine treat-

ments, cosmetics, food, and nutritional items. which became in any other case otherwise a century before. Each regulatory gadget had confronted certain occasions which brought about modern-day well-defined managed regulatory framework. This has resulted into systematic manufacturing and advertising of secure, efficacious and qualitative pills. The growth of business has led to a need for regulatory professionals as a result of the complexity of each area's laws [1].

The pharmaceutical business and drug regulatory agencies worldwide are connected through regulatory affairs. Regulatory Affairs plays a significant role in each stage of the creation of new drugs as well as in postmarketing monitoring. It plays a significant role in the pharmaceutical industry's organizational structure [2].

The field of drug regulatory affairs is one that is always evolving and growing, and it is also the one that is least impacted by business mergers and acquisitions and downturns in the economy. A standardized method for regulatory filings has been produced by global standardization. The framework for creating all export registration dossiers is systematic formulation development [3].

Historical overview of Regulatory Affairs [4,5]

The drug industry in India was at very primitive stage till 20th century. Most of the drugs were imported from foreign countries.

1900-1960: The Poisons Act of 1919 was enacted by the government to regulate and monitor the availability of inexpensive drugs for sale. This Act facilitates the sale or administration of substances that are designated as poison. It also specified how poisons should be stored in a safe and secure manner, how they should be packaged and labelled, the maximum amount that can be sold, and how vendors should inspect and test the poisons they sell each year.

The Dangerous Drugs Act, 1930, which regulated the production, distribution, and possession of opium, superseded the Poison Act.

Following act and rules were passed in this era- (a) Drugs and Cosmetics Act, 1940: This act regulates the manufacturing, distribution, import and sale of allopathic, homeopathic, unani and siddha drugs. (b) Drugs and Cosmetics Rules, 1945: This act regulates manufacture of Ayurvedic drugs for sale only, and not for consumption and use or possession. (c) Pharmacy Act, 1948: This law was amended in 1986 and it generally controls and regulates the profession of pharmacy in India. (d) Drug and Magic Remedies Rule, 1955: This rule regulates the advertisement of drugs in India. (e) Drugs Prices Control Order, 1955 (DPCO) (under the essential commodities Act): DPCO was further amended in 1995. As per this rule, government has a jurisdiction to review and fix maximum sale price for bulk drugs as well as formulation.

1960-1970:

The Indian Pharmaceutical industry was not mature enough and major market share was dominated by MNC and very few Indian manufacturers were in competition. Focus on pure research and development was very little because of deficiency of patent

protection. The low availability and high drug price is because majority shares depend upon the high drug import.

1970-1980:

Government took control for the medicines regulation and issued few acts and rules.

Indian Patent Act 1970 (which came in force on 20 April 1972 and replaced Indian Patents and Designs Act of 1911): It serves as the basis for patent protection in India.

Under this Act product patent was not allowed but the process and method of manufacturing of Drug substance was allowed to get the patent.

Drug prices capped: Drug Prices Control Order (DPCO) was introduced to control the high price against consumers.

1980-1990:

The Indian industry has started investing in process development of API and created production infrastructure for the same.

1990-2000:

A rapid expansion in domestic market has observed in pharmaceutical industry.

2000-2010:

This period is considered to be the Innovation and Research era. During these years, innovative research activity, patenting of the drugs formula, process, indication as well as merger of companies was started.

Patent Amendment Act 2005: Indian Government brought out the Patents (Amendment) Ordinance, 2004 to address the issues relating to the patent in the country which was later replaced by the Indian Patent (Amendment) Act, 2005.

The new Act brought some crucial changes on the legal regime of patent protection so as to address patent issues in technology, chemicals and pharmaceuticals sectors.

Importance of regulatory affairs [6]

Regulatory affairs in the pharmaceutical industry are important because they ensure that drugs, medical devices, and food supple-

ments are safe and effective for consumers. Regulatory affairs professionals act as the interface between pharmaceutical companies, regulatory bodies, and consumers. They work to protect public health by ensuring the safety, efficacy, and quality of drugs. Regulatory affairs professionals are involved in all stages of drug development, including discovery, development, approval, and marketing.

Regulatory affair department

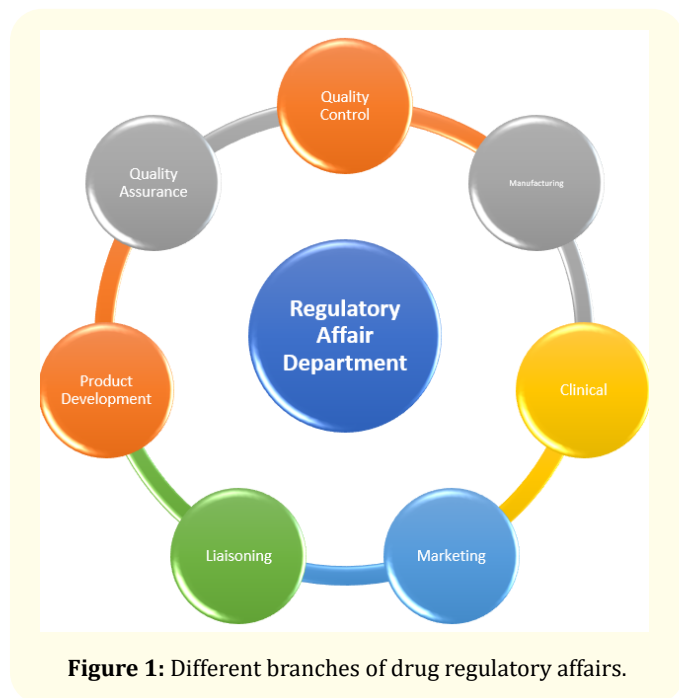


Figure 1: Different branches of drug regulatory affairs.

Regulatory bodies in different countries [7,8]

Pharmacy and the pharmaceutical industry are subject to strict regulations and oversight by various regulatory bodies and agencies around the world. These organizations play a crucial role in ensuring the safety, efficacy, and quality of pharmaceutical products.

Quality assurance [9-11]

Quality assurance is a systematic process that focuses on preventing defects and ensuring that products or services meet established quality standards and customer expectations. QA is not limited to regulatory compliance but extends to all aspects of product development and manufacturing. Key elements of quality assurance include:

Country	Regulatory Authorities	
India	CDSCO	Central Drugs Standard Control Organization.
UK	MHRA	Medicines and Health care products Regulatory Agency.
Japan	MHLW	Japanese Ministry of health, Labour and Welfare.
Canada	HC	Health Canada.
Australia	TGA	Therapeutic Goods Administration
Brazil	ANVISA	Agency Nacional degradation Vigilancia Sanitaria.
USA	FDA	Food and Drug Administration.
Sauth Africa	MCC	Medicines Control Council.
Europe	EDQM EMA	European Directorate for Quality of Medicines, European Medicines Evaluation Agencies.

Table 1

- **Quality Control (QC):** Implementing QC processes to inspect, test, and monitor products at various stages of production to identify and rectify defects or deviations from quality standards.
- **Process Validation:** Validating manufacturing processes to ensure that they consistently produce products that meet quality requirements.
- **Good Manufacturing Practices (GMP):** Adhering to GMP standards to maintain product quality, cleanliness, and safety during manufacturing.
- **Risk Management:** Identifying and mitigating risks to product quality through risk assessment and management processes.
- **Supplier Audits:** Evaluating and auditing suppliers to ensure they meet quality and safety standards and adhere to agreed-upon specifications.
- **Product Testing and Analysis:** Conducting thorough product testing, including chemical, physical, and microbiological testing, to confirm quality and safety.
- **Documentation and Traceability:** Maintaining accurate and complete records of product specifications, manufacturing processes, and quality control measures to ensure traceability.

- **Continuous Improvement:** Embracing a culture of continuous improvement to identify areas for enhancement and optimize quality assurance processes. In summary, regulatory compliance and quality assurance are intertwined functions that are essential for ensuring the safety, effectiveness, and quality of products and services. While compliance focuses on meeting legal and regulatory requirements, quality assurance encompasses broader quality management practices that aim to prevent defects and consistently deliver high-quality products. Both functions are crucial for building trust with consumers, minimizing risks, and achieving longterm success in highly regulated industries.

Objective of regulatory affairs [12]

- How and why the pharmaceutical industry and drug regulations have developed in USA
- Major Regulations of USA
- Framework of EU and its regulatory
- “The Rules Governing Medicinal Products in the European Union”
- Pharmaceutical Legislations of EU
- Indian Pharmaceutical Industry and Drug Regulations development in different Era
- Types of Marketing Authorization Procedure in EU Market
- Major Rules and Act of India
- Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical industry.

GMP [13,14]

GMP is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standard appropriate to their intended use and as required by the marketing authorization.

Good manufacturing practice (GMP) is the part of quality assurance (QA) that :

- Ensures that products are consistently produced and controlled: (i) quality standards; (ii) marketing authorization
- Ensures consistent production and control of products
- Cover both production and quality control
- Assure the quality of medicinal products
- Assure the safety, well-being and protection of the patient.

The aim of GMP is diminishing risks that cannot be controlled by testing of product:

- Contamination and cross-contamination and
- Mix-ups (confusion).

COMPONENTS OF GMP

GMP mandates that all facilities must be available and that the manufacturing process be thoroughly defined before beginning. In actuality, employees need to be properly trained, proper facilities and equipment must be used, the right materials must be used, approved procedures must be followed, appropriate storage and transportation facilities must be available, and pertinent records must be made [15].

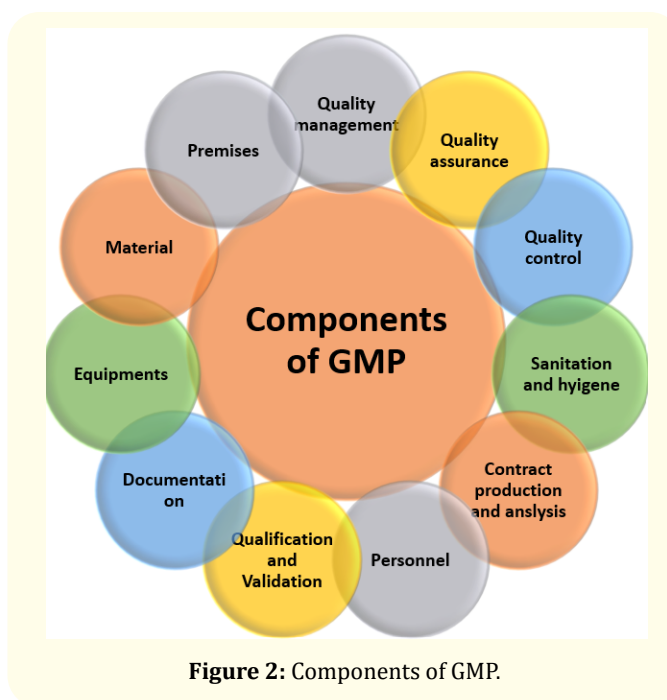


Figure 2: Components of GMP.

Good manufacturing practice for medicinal products

A component of quality assurance known as GMP makes sure that goods are consistently manufactured and controlled to the quality standards necessary for their intended use as well as those mandated by product specifications or marketing authorizations. The main goal of GMP is to reduce the risks that come with producing pharmaceuticals [16].

The basic requirements of GMP are that:

- All manufacturing processes are clearly defined, systematically reviewed in the light of experience, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications.
- Qualification and validation are performed.
- All necessary resources are provided.
- Instructions and procedures are written in clear and unambiguous language, specifically applicable to the facilities provided.
- Operators receive training on proper procedure execution.
- Records are kept throughout the manufacturing process to demonstrate that all the actions specified in the instructions and procedures have actually been completed, and that the product's quantity and quality are as anticipated. Any notable deviations are thoroughly documented and looked into.
- Manufacture and distribution records are kept in a readable and understandable format, allowing for the tracking of a batch's entire history.
- Any risk to the products' quality is reduced by distributing and storing them properly.
- Any batch of product can be recalled from sale or supply using an available system.
- Product complaints are reviewed, quality defect causes are looked into, and necessary action is taken in respect of the defective products to prevent recurrence [17].

Ten Principles of GMP [18]

- Design and construct the facilities and equipments properly
- Follow written procedures and Instructions
- Document work
- Validate work
- Monitor facilities and equipment
- Write step by step operating procedures and work on instructions
- Design ,develop and demonstrate job competence
- Protect against contamination
- Control components and product related processes
- Conduct planned and periodic audits

GLP

Good Laboratory Practice (GLP) is a regulatory requirement to help ensure the quality, reliability, and integrity of pharmacologi-

cal and toxicological studies during drug development. This article overviews GLP regulations and related public standards, focusing on practices relevant to analytical and bioanalytical chemists [19].

GLP expectations for nonclinical studies undertaken to register new medical products have been produced by multiple regulatory agencies, beginning in 1978 with the US Food and Drug Administration (US FDA) [20,21].

Principles of GLP

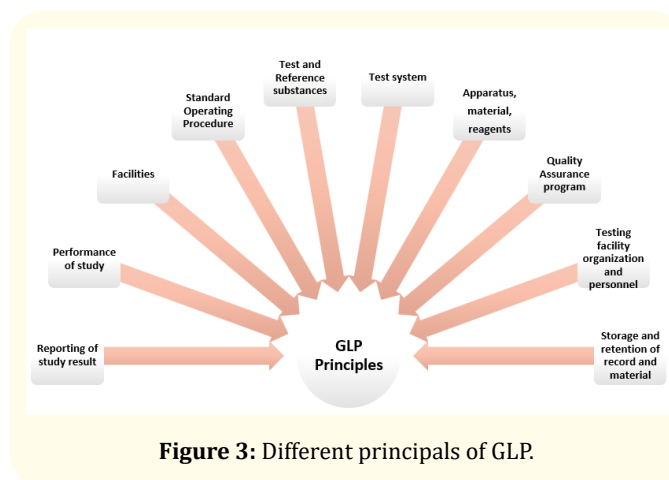


Figure 3: Different principals of GLP.

Objectives of GLP [22]

- GLP makes sure that the data submitted are a true reflection of the results that are obtained during the study. GLP also makes sure that data is traceable.
- Promotes international acceptance of tests.
- Improve efficient performance of the job.
- Prevent unsafe and hazardous acts which could affect individuals and/or properly.
- Prevent equipment errors in measurements.
- Prevent human errors in the performance of the job.
- Adopt good and safe operating procedures and recording systems.

Conclusion

Experts in regulatory affairs are involved in every stage of the development process, continuing even after a drug is approved and brought to market. They have a special blend of managerial and scientific abilities to accomplish a crucial business objective in a drug development company. At such companies, the Regulatory Affairs

department offers technical and strategic advice at the highest level. In this sense, they significantly advance the company's overall performance as well as the success of a development programme from a scientific and commercial standpoint. The interpretation, application, and communication of regulations both inside organisations and to external stakeholders are more important to the success of a regulatory strategy than the actual regulations themselves. In the pharmaceutical industry, regulatory affairs is critical and involved in all phases of drug development, as well as post-approval and post-marketing activities. The process of developing new drugs is drawn out, intricate, and very expensive, but it is also an essential one. All the information gathered during the drug's discovery and development phases is used by pharmaceutical companies to register the product and subsequently market it. The company's economic growth and public safety will both be enhanced by the appropriate application of legal and regulatory requirements.

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