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Regulatory Affairs In Pharmaceutical Industry In Analytical Development

Ambekar Utkarsha Rajendra , Miss.Kaveri T Vaditke

Pravara Rural Education Society,[For Women],Chincholi,Sinnar Dist-Nashik,422103

1. INTRODUTION

In the realm of pharmaceuticals, where innovation meets patient care, a complex web of regulations and standards weaves its way through every facet of drug development and manufacturing. The precision and reliability of analytical methods are paramount in ensuring that pharmaceuticals meet the rigorous requirements set forth by regulatory authorities worldwide. Our journey into the world of Regulatory Affairs in Pharmaceutical Analytical Development commences with a deep dive into the critical role it plays in not only bringing innovative medications to market but also in upholding the standards that under pin public health and safety.(1)

The main objective of regulatory affairs is to provide the basis for the assurance of high quality of food products which can increase consumer's interest for ensuring the efficacy,safe(

2.Abstract

The pharmaceutical industry stands at the forefront of scientific innovation, dedicated to the development and production of **life-saving drugs**. At its core lies Regulatory Affairs, a critical function responsible for ensuring that pharmaceutical products meet the stringent requirements set forth by regulatory authorities. In this context, Analytical Development plays a pivotal role, providing the scientific foundation upon which product quality and efficacy are determined. This document explores the multifaceted world of Regulatory Affairs within the pharmaceutical industry, with a specific focus on its intersection with Analytical Development. It delves into the key responsibilities of Regulatory Affairs professionals, emphasizing their role in navigating the intricate web of regulations governing drug development, manufacturing, and quality control. Through case studies and practical insights, we shed light on the strategies employed to secure regulatory approvals and maintain compliance.(2)

Further more, this exploration highlights the dynamic nature of the regulatory landscape, with a keep eye on global harmonization efforts, post- market surveillance, and emerging trends. The document offers a comprehensive understanding of the symbiotic relationship between science and regulation, demonstrating how Analytical Development are ensuring that pharmaceutical products are safe, effective, and of the highest quality. As the pharmaceutical industry continues to evolve and respond to new challenges, this document serves as a valuable resource for professionals, researchers, and stakeholders seeking to navigate the complex world of Regulatory

Affairs in Pharmaceutical Industry in Analytical Development, where scientific rigor and regulatory compliance converge to safeguard public health.[3]

Keywords: Regulatory Affairs, Pharmaceutical Industry, Analytical Development,Regulatory Bodies.

3.Objective[4]

1.Pharmaceutical Legislations

2.Clinical Trials

3.Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical Industry

4.Regulatory Affairs Network in Pharmaceutical Industry.

5.Indian Pharmaceutical Industry & Drug Regulations development in different Era.

6.Major Rules and Act of India.

7.Drug Regulatory Affairs and Global, Regional and National Regulatory Network

8. Pharmaceutical Industry

9. Pharmacovigilance

10. Product information review

4 . What is Regulatory Affairs

Regulatory affairs is a comparatively new profession which developed from the desire of governments to protect a public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. company and the regulatory agencies across the

world."3 Evolution of regulatory affairs in 1950's[4,5] Regulatory Affaires in the pharmaceutical industry may be defined as"the interface between the pharmaceutical company and the regulatory agencies across the world."3 Evolution of regulatory

affairs:

In 1950's generation, many tragedies came about due to the misinterpretation of the

Employees during manufacture & some purposive addition of contaminated substances into the pharmaceutical product which has move forward to the execution of the patients. After so many occurrences, the regulatory bodie launched the new laws and guidelines which are going to ameliorate the quality, safety and efficacy of the products. This is again developed into severe standards for Marketing Authorization (MA) and Good

Manufacturing Practices (GMPs). That is the tragedies of SULPHANILAMIDE ELIXIR, VACCINE TRAGEDY & THALIDOMIDETRAGEDY[5]

FDA launched in 1906 as Bureau of chemistry, served simply to police claims made about food and drugs ingredients. At that time no formal government approval required to market new drugs.

The disasters provoked a public outcry that led to the passage of the 1983 Food Drug & Cosmetics Act, which gave the FDA power to monitor the safety of new drug.

5.History

During 1950s, multiple tragedies i.e., sulfanilamide elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of legislations for drug products quality, safety and efficacy. This has also resulted into stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs). To understand the chronological development of the modern era of pharmaceutical industry and regulatory framework, we will glance through the historical evolution of regulations in USA, Europe and India. Let us see what happened in USA, Europe andIndia.

India:

The drug industry in India was at very primitive stage till 20th Century. Most of the drugs were imported from foreign countries. **Post First World War,** the demand for drugs had increased tremendously and that led to the cheap & substandard drugs into the market, as like in USA post Mexican American war.

1.1900-1960: To control cheap drugs in market, Government passed the **Poisons Act 1919.** This Act regulates possession of substance or sale of substances as specified as poison. It also specifies the safe custody of the poisons, labeling and packaging of poisons, maximum quantity to be sold and inspection as well as examination of the poison sold by vendor during the year. The Poisons Act was followed by The Dangerous Drugs Act 1930. This act

regulates the **opium plant** cultivation, manufacture and possession of opium, its import, export, transship and sell of opium. The Narcotics and Psychotropic Substances Act was passed in **1985** which revoked the Dangerous Drugs Act 1930 and Opium Act, **1878**.

- Following acts & rules were passed during this era:

• **Drugs and Cosmetics Act, 1940:** Regulate the import, manufacture, distribute and sale of drugs. This act covers allopathic, homeopathic, Unani and Siddha drugs.

• **Drugs and Cosmetics Rules, 1945**: The rules under the Drugs and Cosmetics Act regulate only manufacture of Ayurvedic drugs for sale, and not for consumption, use or possession.

• **Pharmacy Act, 1948**: This law was amended lastly in 1986 and it regulates the pharmacy profession of India.

•**Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955**: These rules control the drug advertisement in India .

•**Drugs Prices Control Order, 1955 (DPCO) (under the essential commodities Act):** DPCO was further amended in 1995. Under this rule, government may review and fix maximum sale price for bulk drugs as well as formulation.(6)

2.1960-1970: The market share was dominated by multinational companies and very few Indian manufacturers were present. The market share was dominated by multinational companies and very few Indian manufacturers were present. The Indian Pharmaceutical industry was in an early stage Focus for pure research and development was very little due to lack of patent protection. Due to very high import dependency on drugs, the cost of drugs was very high as well as market availability was comparatively loss for patent protection in India. Based on this, only process and method of manufacture of Drug substance was allowed to get the patent. Product patent was not allowed under this act. Indian Patent Act of 1970 came into force from April 20, 1972. This new act replaced the Indian Patents and Designs Act of 1911.

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

Local companies begin to make an impact: Since the product patent was allowed by Indian

Patent Act 1970; local companies began manufacturing products/ drugs using different manufacturing process by reverse engineering. Due to these new drugs were available cheaply as well as many more substitute drugs were available in the marke against costly imported new drugs.

This has resulted in 1) increase the exports to countries like Russia, Africa, China, and South America.2) Export of Bulk drug post patent expiry(7)

3 1980-1990: The industry has started investing in API process development and created production infrastructure. Government has also issued export incentives.

The Narcotic Drugs and Psychotropic Substances Act, 1985 was issued which regulates the operation of narcotic drugs andsubstances.

4. 1990-2000: The pharmaceutical industry has observed a rapid expansion of domestic market and during same era globalization happened. The companies have enteredinto research activity. India joined **Paris Cooperation**

Treaty (PCT) in 1999 and implemented product patent effective from Jan 1, 2005.

5. 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:** With this act, provision for Black Box Application made, as per that if patent application is filed before Jan 1, 2005, then under the transit provision of **Trade Related aspects of Intellectual Property Rights** (TRIPS), manufacturer can market this product post 2005 without infringing product patent, if manufacturer has made significant investment in manufacturing of the product, produced and marketed on or before Jan 1, 2005.

•**Compulsory Licenses**: Such licenses can be granted for manufacture and export of the drug products "to any country having insufficient or no manufacturing capacity, for the said product, to address public health problems".Herbal preparations having medicinal values can be patented under new amended law. Major regulatory changes in terms of marketing authorization process as well guidelines have come into effect. Few to name are as below:

•**Drugs and Cosmetics (First Amendment) Rules, 2011**: It mandates registration of Clinical Research Organization (CRO) for conducting Clinical Trials (CT). Schedule Y1 suggests requirements and guidelines for registration of Clinical Research Organizations.

•**Clinical Trial Registry- India (CTRI):** It has been set up by the ICMR's (Indian Council of Medical Research) National Institute of Medical Statistics (NIMS). India has developed on-line registry system and mandated registration of CRO before the enrolment of first patient for clinical trials. CRO needs to disclose mandatory items as mentioned under WHO International Clinical Trials Registry Platform (ICTRP) dataset.

- **Guidance documents**:

  CDSCO has issued guidance for Industry for Fixed Dose Combinations (FDCs) registration as well as Guidance for preparation of Common Technical Document for Import/ manufacture and Marketing Approval of New drugs for Human Use With this CDSCO has implemented system for preliminary scrutiny at the time of application receipt for the marketing approval of Fixed Dose Combinations(FDCs).

6.Regulatory strategy [10]

•Planning of regulatory affairs.

•Planning of addressing critical development issues, which is dynamic and changes during the process.

•Plan of how to register a product in the global market (to be in line with corporate, business and strategy of RA unit and projects)

•Plan how to balance time & cost & human resources Strategy is only as good as the analysis behind it.

•To ensure that a dossier results in a SmPC (Summary for the prescribers Package leaflet Information for the

patient) that results in sales.

•To ensure that the regulators are the first supportive customers for the product

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7 Regulatory Bodies in the world[11]

Every country has its own regulatory authority, which is responsible to enforcethe rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products

Table 1: Different regulatory bodies of countries

Country	Regulatory Body
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Italy	Italian Pharmaceutical Agency
Thailand	Ministry of Public Health

Europe[12]

National Authority: The European Medicine Agency (EMA) is an agency of the European Union (EU) in charge of the evaluation and supervision of medicinal products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency (EMEA) was set up in 1995, with funding from European Union and the pharmaceutics industry, as well as indirect subsidy from member states.

EMA was founded after more than seven years of negotiations among the EU governments and replaced the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, though both of these were reborn as the core scientific advisory committees.

The agency was located in London prior to the United Kingdom's vote for withdrawal from the European Union, relocating to Amsterdam in March 2019.

➢ **United State (FDA)**[12]

The FDA is led by the Commissioner of Food and Drugs, appointed by the President with the advice and consent of the Senate. The FDA has its headquarters in unincorporated White Oak, Maryland. The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands and Puerto Rico.

National Authority:The Food and Drug Administration (FDA) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments .

. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over the counter pharmaceutical drugs, vaccines, biopharmaceutical, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED) cosmetics, animal food and feed and veterinary

products.

➢ **India (CDSCO)**[12]

- The CDSCO of India is main regulatory body for regulation of pharmaceutical, medical devices and Clinical Trials.
- Head office of CDSCO is located in NEW DELHI and functioning under the control of Directorate General of Health Services, ministry of health and family welfare Government of India.

Zonal Office:-

Mumbai

Kolkata

Chennai

Ghaziabad

Ahemdabad

Hyderabad

These are involved in GMP audits and inspection of manufacturing units of large volume parental, sera, vaccine and blood products.

Sub-zonal office:-

I. Chandigarh

II. Jammu

III. Benglore

These centre co-ordinate with state drug control authorities under their jurisdiction for uniform standard of inspection and enforcement.

Functions of CDSCO in Center

• Approval of new drugs and clinical trials.

• Import Registration and License

Licensing of Blood Banks, LVPs, Vaccines, r-DNA products and some Medical devices and Diagnostic agents.

• Amendment to D&C Act and Rules.

Participation in WHO GMP certification schemes.

➢ **Japan**[12]

Regulatory Authority of Japan is Pharmaceuticals and Medical Devices Agency, Its key services include; review of regulatory dossiers, relieve services .

8.Responsibility of Regulatory Affairs Professional's[13]

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating.

They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to maintain marketing authorization for the products concerned.

They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole. It may take anything up to 15 years to develop and launch a new pharmaceutical product and many problems may arise in the process of scientific development and because of a changing regulatory environment 15.

Regulatory affairs (RA) professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labelling or in advertising.

List of responsibilities of Regulatory Affairs Department:

a.Keep in touch with international legislation, guidelines and customer practices

b.Keep up to the date with a company's product range

c.Ensure that a company's products comply with the current regulations.

d.The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and

requirements, and collect, collate, and evaluate thescientific data that their research and development colleagues are generating.

e. Formulate regulatory strategy for all appropriate regulatory submissions for domestic, international and/or contract projects.

f. Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified time frame in conjugation with theorganization.

g. Prepare and review of SOPs related to RA. Review of BMR, MFR, change control and other relevant documents.

h. Monitor the progress of all registration submission.

i. Maintain approved applications and the record of registration fees paid against submission of DMF's and other documents.

j. Respond to queries as they arise, and ensure that registration/ approval are granted without delay.

k. Impart training to R&D, Pilot plant, ADl and RA. Team members on current regulatory requirements.

l. Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e., describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.

m. Manage review audit reports and compliance, regulatory and customer inspections.

n. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labelling or in advertising.

o. Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the product.

9 Challenges to Regulatory Affairs Profession[14]

Regulatory affairs include complete dynamics:

- Multi –dimensional
- Knowledge in science and technology
- Prolific communication skill
- Deal with people with diverse background, skills, culture, and personalities
- Deal with conflicting loyalties, motivations, social and ethicals, responsibilities

Guided by various regulatory guidance

- Receiving input from various department within the firm about process capabilities andproduct attribute
- specification
- Receiving advice from peers about easy way to get approvals
- Receiving motivation from the management through incentives for achieving speedyapprovals.

10.Evaluation of Regulatory Affairs[15]

Evaluating regulatory affairs in the pharmaceutical industry is essential for assessing the effectiveness of regulatory processes, compliance with regulations, and the overall impact on product quality and patient safety. Here are key aspects and methods for evaluating regulatory affairs:

10.1 Compliance Assessment:

- **Regulatory Audits:** Conduct regular internal and external audits to assess compliance with regulatory requirements and identify potential areas of non- compliance.

- **Regulatory Gap Analysis:** Identify gaps between current regulatory practices and evolving regulatory standards. Address these gaps to ensure ongoing compliance.

10.2 Regulatory Submission Success Rate:

- Measure the success rate of regulatory submissions, including the approval rates for new drug applications (NDAs), marketing authorization applications (MAAs), and variations. Evaluate reasons for any rejections or delays.

10.3 Quality Metrics:

•Monitor key quality metrics, such as the number of product recalls, deviations, and non-conformities related to regulatory compliance. Lowering these numbers indicates improved compliance.

10.4 Timeliness and Efficiency:

Assess the efficiency of regulatory processes by tracking the time taken for regulatory submissions, approvals, and product launches. Identify bottlenecks and streamline processes.

10.5 Regulatory Intelligence:

Evaluate the effectiveness of mechanisms for monitoring and staying updated on evolving regulations, guidelines, and industry trends. Ensure timely integration of regulatory intelligence into decision-making processes.

10.6 Documentation and Record-Keeping:

Review the accuracy and completeness of regulatory documentation, include RA

11.Role of Regulatory Affairs In Pharmaceutical Industries[16]

Regulatory Affairs professionals provides tactical and practical guidance to R&D, Production, QC department etc. Just aid the drawn of the progress of a product, making main benefaction both together economically and scientifically to the triumph of a evolution scheme and company as a entirely. It takes time of about up to 15 years to evaluate and to put a new pharmaceutical product and many issues may stand up in the process of scientific progress and because of an altering regulatory habitat. Regulatory professionals help out the company to keep out

of issues originated by immaterial documentation, unsuitable scientific reasoning or impoverished presentation of records.

The roles of regulatory affairs professional is to act as cooperation with regulatory agencies:

1.To audit on constantly changing constitution.

2.Adapted documents to regulatory agencies.

3.To give tactical and practical advice to **R&D, Production, QC Department**.

4.Preparation of well ordered and Ensure fidelity and complaisance with all the applicable **CGMP, ICH, GCP, GLP** guidelines regulations and laws.

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified. Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicine. The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

11.1 Regulatory Affairs In Product Management[17]

The key role of RA professional is broader than registration of products, they advise companies both strategically and technically at the highest level. Their role begins right from development of a product to making, marketing and post marketing strategies. Their advice at all stages both in terms of legal and technical requirements help companies save a lot of time and money in developing the product and marketing the same. For countries that do not have their own regulations the World Health Organization guidelines on health matters and World Trade Organization on trade regulations between nations is followed

11.2 Regulatory Affairs In Clinical Trials:

The RA professional is the primary link between the company and worldwide regulatory agencies such as **US Food and Drug Administration** (USFDA & Center for Devices and Radiological Health) **Medicines and Healthcare Products Regulatory Agency, United Kingdom** (UKMCA), Therapeutic Goods Administration, **Australia European Medicines Agency, Organization of Economic Collaboration and Development (OECD) and Health Canada**. He also communicates and interprets the seemingly endless mace of laws, regulations and guidelines to the other departments of the company. The RA personnel develops strategies to overcome delays and

presents finding of clinical trials to the regulatory bodies so as to get quick clearance thus reducing the time for approval of new molecules. At its core, the RA professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical and health systems and the public conventions are understood and addressed by various stakeholders.

11.3 Regulatory Affairs In Research & Development:

The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market. With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit. Employing adaptive clinical trial strategies, obtaining quick approval from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags.

12 Scope of Regulatory Affairs In Pharmaceutical Industry[18]

The regulation of medical products has been expanding since early 20th century. Regulatory agencies are being established in an ever increasing number of countries across the globe. Those that have established are reorganizing their systems and attempting to harmonize with organizations of other countries. The pharmaceutical, biotechnology and medical devices are among the most highly regulated industries in the world. Regulatory affairs (RA) professionals are employed in pharmaceutical industry, government, academic research and clinical institutions.All companies engaged in R&D worth its salt has an individual RA department to aid them in new product development. The clinical research industry ,which provides opportunities for RA professionals, is also growing at an unparalleled rate. It has opened up new vistas of employment for a large number of trained professionals. The clinical trials market worldwide is worth over USD 52 billion. A study by Ernst and Young indicates that the total market value of Clinical Research activities performed

in India is expected to grow to around USD 1.5-2 billion. There is expected to be a huge demand for qualified RA personnel in clinical research.

13 Future Development[19]

In the Regulatory Affairs Profession count on the make overtures to regulation will ultimately be acquired for all healthcare products as it constitutes the best model for delivering new healthcare proceeds to market in a appropriate time with justifiable safety. Regulatory Affairs departments are enlarging within the bounds companies. Due to the changing assets it is essential to attain the regulatory necessities, some companies also go for to redistribute or out task regulatory affairs to exterior amenity supplier. Regulatory Affairs department is persistently extending and enlarging and is the one which is slightly influenced during the investment and alliance, and besides throughout downturn. Global harmonization in excellence has led to reconcilable solicits in regulatory capitulation and hence its review.

14. Involvement Of Regulatory Affairs In Pharmaceutical Industry[19]

Regulatory Affairs plays a central and essential role in the pharmaceutical industry throughout the entire lifecycle of pharmaceutical products, from early development to post- market surveillance. Here is a breakdown of the involvement of Regulatory Affairs professionals in the pharmaceutical industry:

14.1 Early Development Phase:

Regulatory Strategy: Regulatory Affairs professionals work closely with research and development teams to define regulatory strategies for new drug candidates.

Preclinical Planning: They help ensure that preclinical studies are designed to meet regulatory requirements for safety and efficacy data collection.

IND Application: Regulatory Affairs teams prepare and submit Investigational New Drug (IND) applications to regulatory authorities, seeking permission to initiate clinical trials.

14.2 Clinical Development Phase:

Clinical Trial Planning: Regulatory Affairs professionals contribute to the planning, design, and execution of clinical trials, ensuring they adhere to ethical and regulatory standards.

Regulatory Submissions: They are responsible for preparing and submitting regulatory documents related to clinical trial conduct, including clinical trial applications and amendments. **Safety Reporting:** Monitoring and reporting of adverse events and safety data during clinical trials, as well as communicating with regulatory agencies regarding safety issues.

14.3 Drug Approval Phase:

New Drug Applications (NDAs) or Marketing Authorization Applications (MAAs): Preparing comprehensive regulatory submissions containing clinical trial data, safety data, product information, and quality control data for approval to market the drug.

Labeling and Packaging: Ensuring that product labels and packaging meet regulatory requirements, including accurate representation of product information and safety warnings. **Regulatory Liaison:** Serving as the primary point of contact between the pharmaceutical company and regulatory authorities during the review process, responding to queries and addressing regulatory concerns.(FDA, EMA) for pharmaceuticals, or the FDA for medical devices.

Quality Control and Assurance: Regulatory Affairs professionals collaborate with quality control and quality assurance teams to establish and maintain product quality standards and ensure

15 WHO guideline In pharmaceutical industry for analytical development in RA[20,25]

The World Health Organization (WHO) provides guidelines and recommendations for various aspects of regulatory affairs in the pharmaceutical industry, including analytical development. These guidelines are intended to help regulatory authorities, pharmaceutical companies, and other stakeholders ensure the quality, safety, and efficacy of pharmaceutical products. While the WHO doesn't have specific guidelines titled "Regulatory Affairs for Analytical Development," it offers a range of documents and guidelines that cover aspects related to analytical development and regulatory affairs. Here are some key WHO guidelines and documents that are relevant to regulatory affairs in pharmaceutical analytical development:

15.1 WHO Technical Report Series: WHO publishes a series of technical reports that cover various aspects of pharmaceutical quality, safety, and efficacy. These reports often provide guidance on analytical methods and regulatory considerations.

15.2 WHO Good Manufacturing Practices (GMP) Guidelines: These guidelines cover the manufacturing and quality control aspects of pharmaceutical products, including the requirements for analytical methods, validation, and quality control testing.

15.3 WHO Guidelines on Quality Practices in Pharmaceutical Laboratories: These guidelines provide recommendations on establishing and maintaining a quality management system in pharmaceutical laboratories, including analytical development laboratories.

15.4 WHO Guidelines on Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products: These guidelines include requirements for conducting stability studies, which are an essential part of analytical development to assess product quality over time.

16 Guidelines for Regulatory affairs in the pharmaceutical industry[21,24]

Regulatory affairs in the pharmaceutical industry involve ensuring pharmaceutical products comply with regulations and laws. Here are some general guidelines for regulatory affairs in the pharmaceutical industry:

1. **Stay Informed**: Keep abreast of the latest regulations and guidelines from regulatory authorities such as the FDA (United States), EMA (European Union), and other relevant bodies in your region.

2.Quality Control: Implement robust quality control processes to ensure that products meet required standards of safety, efficacy, and quality.

3 Documentation: Maintain detailed records of all processes, tests, and results. Accurate documentation is crucial for regulatory compliance.

4 Clinical Trials: If applicable,conduct rigorous and ethical clinical trials.Ensure compliance with good clinical practice (GCP) guidelines.

a. **Regulatory Submissions**: Prepare and submit regulatory documents and applications accurately and on time. This

includes Investigational New Drug (IND) applications, New Drug Applications (NDA), or Marketing Authorization Applications (MAA) in the EU.

b.**Labeling and Packaging**: Ensure that product labels and packaging meet regulatory requirements, including proper information about usage, dosage, and warnings.

c.**Pharmacovigilance**: Establish procedures for monitoring and reporting adverse reactions (pharmacovigilance). Promptly report any adverse events to regulatory authorities.

d.**GMP Compliance**: Adhere to Good Manufacturing Practices (GMP) to ensure the quality and consistency of pharmaceutical products.

e.**Compliance Audits**: Conduct regular internal audits to identify and rectify compliance issues. Be prepared for external audits by regulatory agencies.

f. **Post-Market Surveillance**: Monitor products after they have been approved and marketed. Report any safety concerns and address them promptly.

g.**Global Compliance**: If operating internationally, be aware of and compliant with regulations in different countries. Different regions often have unique requirements.

h.**Professional Expertise**: Employ professionals well-versed in regulatory affairs. Consider hiring regulatory consultants if necessary.

Conclusion [22,23]

Numerous in the practice of regulatory affairs which have been persuaded by this newly extended approach In general, regulations are to be accepted in conjunction with all healthcare products as they appear the best model. In order to bring new healthcare developments, together with tolerable welfare, on the market in a reasonable time. The department that is least impacted by mergers and acquisitions, as well as economic downturns, is regulatory affairs, which is continually growing and expanding. Within the companies, regulatory affairs departments are expanding. Due of the fluctuating assets required to meet the regulatory requirements, several businesses additionally choose to Redistribute or delegate regulatory affairs to an outside provider of amenities. This includes the brutal environment of today. The length of time it takes to launch a product is detrimental to its success and, by extension, that of the firm. triumph. Because of this, the real management of its regulatory affairs endeavor has significant economic value other than the business.

References

1.H Rahalkar Historical Overview of Pharmaceutical Industry and Drug Regulatory Affairs. Pharmaceutical Regulatory Affairs S11:002. doi:10.4172/2167-7689.S11-002(~~2012~~)

2.J.K. Badjatya, International Journal of Drug Regulatory Affairs, IJDRA Publishing Group, 2013.

3.P. Praneeth, SSRG International Journal of Pharmacy and Biomedical Engineering Volume3 Issue 1, 1-2, Jan-Apr 2016

4.Douglas J Pisano and David S. Mantus, Text book of FDA Regulatory Affairs, A Guide for Prescription Drugs, Medical Devices, and Biologics, 2nd edition , August 2008.

5.Douglas J. Pisano and David S. Mantus, Text book of FDA Regulatory Affairs, A Guide forPrescription Drugs, Medical Devices, and Biologics, Second Edition, August 2008.

6.Hasumati Rahalkar, Historical Overview of Pharmaceutical Industry and Drug Regulatory Affairs, Pharmaceutical Regulatory Affairs, Pharmaceutical Regulatory Affairs: Open Access; 2012.

7.Sri Harsha, IJPRBS, 2017; Volume 6(2): 170-177; 2017

8.Miss. Priyanka s. Bandgar, prof. Vijay g. Rokade, mr. Lahu d. Hingane; review on regulatory affairs in pharmaceutical indusrties; jetir janaury 2020, volume 7, issue 1

9.Mr. Rajesh dumpala1, mr. Chirag patil; an overview of regulatory affairs in pharmaceutical industry; international journal of universal pharmacy and biosciences;2020

10. Geetanjali Sengar, Pranab Tripathy, Drug Regulatory Affairs Dept, Pharmaceutical RegulatoryAgencies and Organizations around the World: Scope and Challenges in Development.

11. Srivastava DA. Country level report on the pharmaceutical sector in India'. Report commissioned byDFID, UK

12. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty seventh Report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 908).

13. Guide to good storage practices for pharmaceuticals, WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty seventh Report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 908, Annex 9).

14. WHO Expert Committee on Specifications for Pharmaceutical Preparations; Thirty-eighth Report, Geneva, World Health Organization, 2004 (Technical Report Series, No. 917).

15. Good trade and distribution practices for pharmaceutical starting materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty eighth Report. Geneva, World Health Organization, 2004 (WHO Technical Report Series, No. 917, Annex 2).

16. Quality Assurance of Pharmaceuticals; A compendium of guidelines and related materials, Volume 1.Geneva, World Health Organization, 1997.

17. Quality Assurance of Pharmaceuticals, A compendium of guidelines and related materials, Good manufacturing practices and inspection; Volume 2 (updated version), Geneva, World Health Organization,2004

18. Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic)Products A Manual for a Drug Regulatory Authority, Geneva, World Health Organization, 1999 (Regulatory Support Series, No.5, WHO/DMP/RGS/98.5).

19. A Model Quality Assurance System for Prequalification, Procurement, Storage and Distribution of Pharmaceutical Products. Geneva, World Health Organization, 2003 (unpublished draft).

20. Managing Drug Supply, The selection, procurement, distribution, and use of pharmaceuticals. Management Sciences for Health in collaboration with World Health Organization, 2nd Ed. Connecticut, USA. Kumarian Press, Inc., 1997.

22. Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C63/03), European Agency for Evaluation of Medicinal Products, Directive 92/25/EEC of 31March 1992.

23. Y. Sri Harsha, IJPRBS, 2017; Volume 6(2): 170-177; 2017.

24. Miss. Priyanka s. Bandgar, prof. Vijay g. Rokade, mr. Lahu d. Hingane, review on regulatory affairs in pharmaceutical indusrties, jetir janaury 2020, volume 7, issue 1.

25. Mr. Rajesh dumpala1, mr. Chirag patil; an overview of regulatory affairs in pharmaceutical industry; international journal of universal pharmacy and biosciences, 2020.