OVERVIEW OF DRUG REGULATORY AFFAIRS AND ROLE OF REGULATORY AFFAIRS IN A PHARMACEUTICAL INDUSTRY

N.G. Raghavendra Rao[1]*, Amit Tiwari[1], Amit Pal[1], Anuj Pathak[1], Aarati Maurya[2], Irfan Ali[1,3],

[1]Department of Pharmaceutics, KIET School of Pharmacy, KIET Group of Institutions, Delhi-NCR, Ghaziabad-201206, U.P, India.
[2]Department of Pharmaceutics,Metro College of Health Sciences and Research, Greater Noida, India.
[3]Department of Pharmaceutics, School of Pharmaceutical Education and Research, Jamia Hamdard, New Delhi 110062, India.

Corresponding author:
Dr. N. G. Raghavendra Rao, Professor
drngraghu@gmail.com, raghavendra.rao@kiet.edu

ABSTRACT:
The regulatory affairs (RA) team is dedicated in the pharmaceutical industry because they are concerned about the healthcare system lifecycle of a product. They offer strategic, tactical, and operational guidance and assistance in order to speed the design and deployment of secure and efficient medical supplies to people all over the globe while adhering to laws. The position of regulatory affairs is to develop and enforce a regulatory strategy to assure that the drug research group's collective work yields an outcome that is endorsed by global regulators but also stands out from the competition in some way, as well as to assure that the company's actions, from non-clinical research to advertising and marketing, are carried out in compliance with regulatory rules and policy.In the pharmaceutical industry, drug regulatory affairs are a critical unit. Because the pharmaceutical industry is continually growing, regulatory affairs specialists are in high demand to meet the current demands of companies in order to compete globally. Executives in drug regulatory affairs serve as a vital link between the pharmaceutical industry and international regulatory organizations. The approval of pharmaceutical products should be a vital step in ensuring that people have access to safe and effective medications. India's Central Drugs Standard Control Organization (CDSCO) has opted for using the CTD structure for technical criteria for drug registration.The use of CTD is intended to greatly decrease the amount of time and resources required by the industry to assemble global registration applications. A regulatory affairs professional is someone who serves as a link between pharmaceutical companies and government agencies all over the globe. The purpose of a regulatory affairs professional is to safeguard the wellbeing of people by guaranteeing drug safety, effectiveness, and quality, as well as assuring that product information is suitable and accurate. The emergence of regulatory affairs, its function in the pharmaceutical business, and its engagement in the application of regulatory rules that promote the sector's expansion are all discussed in this section.
Keywords: Regulatory Affairs professionals, Regulatory agencies, Drug Approval Process, CTD Worldwide Regulatory Agencies.

1. INTRODUCTION:

Regulatory Affairs (RA), often known as Government Affairs, is a career field in regulated sectors including pharmaceuticals, surgical instruments, energy, and finance. Specifically, for the health sector (pharmaceuticals, medical devices, biologics, and functional foods), regulatory affairs have a very specific meaning. The majority of businesses, whether they are

large, international pharmaceutical conglomerates or innovative, small-scale biotechnology businesses, have specialized regulatory affairs organizations[1-4]. For the manufacture of chemical and biological medications for human and veterinary use, in addition tomedical equipment, conventional herbal items, and cosmetics, the modern Pharmaceutical Industry is highly structured, methodical, and consistent with international regulatory requirements. Blood and its derivatives are subjected to strict GMPs, in addition tosupervised production for Conventional Herbal Medicines, Cosmetics, Food, and Dietary items, which was not the case a centenary ago. Each regulatory regime had to deal with its own set of conditions, which ultimately resulted in the present explicitly specified, tightly managed governance scheme. As a consequence, safe, effective, and high-quality pharmaceuticals are manufactured and distributed in a methodical manner. With the expansion of industry, regional regulation hasbecome more complex, requiring the appointment of regulatory experts. We shall look at the historical history of regulations in the United States, Europe, as well as India to comprehend the progression over time of the present period of the pharmaceutical industry and regulatory[5-6].

The pharmaceutical industry is well-organized, methodical, and adheres to worldwide regulatory requirements for the production of medical equipment, herbal medicinal items, cosmetics, and chemical and biological medications for human and veterinary usage.

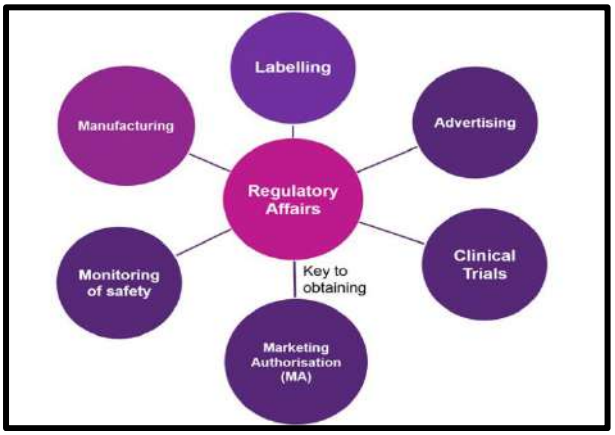

Figure 1:Regulatory Affairs Overview

From formulating regulatory plans after the identification of a novel chemical compound to arranging post-marketing operations, the pharma regulatory affairs specialist is essential for all levels[6].In the pharmaceutical industry, a new molecule might cost many crores of rupees or dollars to develop, and each error has a significant influence on the company's reputation. Because medications play such an important part in people's lives, there must be laws in place to ensure drug quality, safety, and efficacy. This regulation health specialist is solely responsible for ensuring that goods are compliant and for keeping track of all records and papers. Even a minor blunder in any regulatory, quality or safety-related activity can result in a massive recall, as well as the loss of millions of dollars.The whole process of drug discovery, from conception through marketing, is strictly controlled. Clinical studies are required before a medicine may be approved for sale to establish its safety, effectiveness, and quality. Regulatory authorities in their individual nations determine some of these criteria.Regulation has an impact on all areas of the pharmaceutical industry, including autonomous inventors, pharmaceutical firms, regulatory and administrative agencies, and patients. The regulatory department serves as a connection betwixt the firm, its goods, and the regulatory authorities, and its positive or negative aspects encourage the regulatory

authority's knowledge of the sector, for good or evil. As a result, the higher the scientific precision, the greater the possibility of a product reaching the market on time.

2. REGULATORY AFFAIRS OBJECTIVES

- Just why have the pharmaceutical business and drug laws evolved in the United States?
- The Medicinal Products Regulations in the European Union.
- The United States of America's Major Regulations
- The EU's legal framework and regulations.
- European Union Pharmaceutical Laws
- The evolution of the Indian pharmaceutical industry and drug regulations over time.
- In the EU market, there are many elements of marketing authorization procedures.
- India's Major Rules and Acts
- Responsibilities of Regulatory Affairs Professionals in the Pharmaceutical Industry and Health Authorities
- Assuring that their businesses are in compliance with all applicable rules and legislation**.**
- Advising firms on the regulatory elements and climate that would impact their intended operations. Collaborating with federal, state, and municipal regulatory authorities and staff on particular concerns affecting their industry[7].

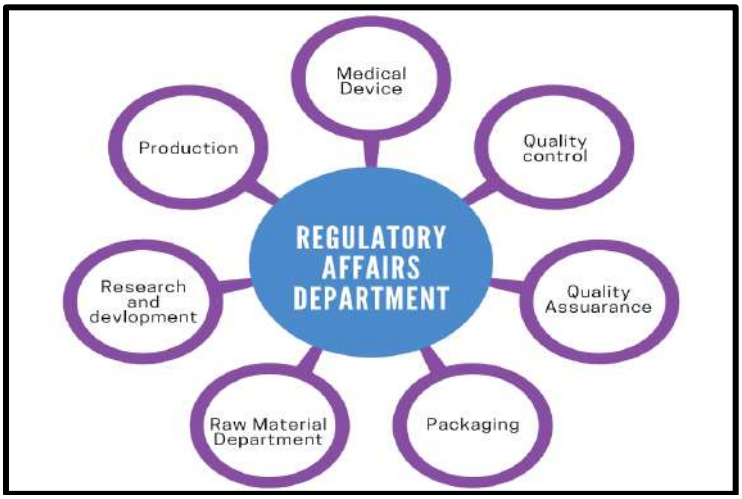

Figure 2:Regulatory Affairs' Role in the Pharmaceutical Industry

2.1.What does Regulatory Affairs entail?

To achieve a manufacturer-to-customer goal inside a drug development company, it needs a particular blend of science and management. It covers everything about medications, from nonclinical investigations through development to ordinary manufacturing and marketing, and it may have a big influence on sick people and drug firms[8].

2.2.The Purpose of Regulatory Affairs:

Therapeutic development and promotion are heavily controlled, and the road to drug registration (Marketing Approval) is well-intentioned but may be difficult. Things are continuously changing.

2.3.Regulatory Affairs Parameter

Design = A plan for development.
Construction= Assembling & Submission
Management Coordination= Writing/reviewing, overseeing
Testing = Where are the flaws?
Drug laws and regulations

National Statutes (e.g. UK - Medicines Act, US- CFR)
Regional Regulations (EC directives)
National and Regional Recommendations
International Standards (ICH)

3. IN THE PHARMACEUTICAL INDUSTRY, REGULATORY AFFAIRS:

Regulatory affairs professionals collaborate with marketers and R&D to create creative outcomes that embrace technology and regulatory advancements to reduce time to market. Small reductions in time to market correspond to huge material wealth in revenue and profit, with new goods projected to bring considerable earnings for the business's bottom line. Adaptable clinical trial tactics, rapid regulatory approval, and ignoring traps in procedures can assist speed up the creation of new medicines while reducing costly mistakes and measurement errors.

3.1.Different Regulatory Bodies Around the World:

Table 1 shows the many regulatory bodies around the world.

Country	Regulatory Authority
India	▪ Central Drugs Standard Control Organization ▪ Drug controller general of India (DCGI)
US	Food and Drug Administration (US FDA)
UK	Medicines and Health care products regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
Japan	Japanese Ministry of Health, Labor and Welfare (MHLW)
Canada	Health Canada
Brazil	Agency National degradation Vigilance Sanitaria (ANVISA)
South Africa	Medicines Control Council (MCC)
Europe	▪ European Directorate for Quality of Medicines (EDQM) ▪ European Medicines Evaluation agencies (EMEA)

Regulatory Affairs specialists offer creative and tactical support for R&D, Production, and QC departments, etc., from the very beginning of a product's life cycle, contributing significantly to the research and commercial viability of a development plan and organization. The creation of a fresh pharmaceutical product could take up to 15 years and commercialization, and various issues might occur during the scientific research process and due to changing regulatory environments. Regulatory experts assist the firm in avoiding difficulties created by irrelevant records, erroneous scientific reasoning, or sloppy data presentation.

3.2.Regulatory Affairs Professional's Role in Industry:

Professionals in regulatory affairs work in industry, government regulators, and academia. In these domains, there is a vast spectrum of regulatory specialists:

- Pharmaceuticals,
- medical gadgets
- in vitro diagnostics are all examples of industries.
- Biotechnology and biologics
- Nutritional Supplements
- Cosmetics

3.3.A Brief History of Regulatory Affairs:

Several tragedies, like the sulfanilamide elixir, vaccination tragedy, and thalidomide disaster, occurred in the 1950s, resulting in a significant rise in regulations governing drug product quality, safety, and efficacy. That’s why, the Marketing Authorization (MA) and Good Manufacturing Practices (GMP) requirements grew to be more stringent (GMPs).

3.4.Regulatory Affairs for Pharmaceuticals:

This division is in charge of understanding the regulatory requirements for new product approval. They are aware of the company's promises to the regulatory bodies that authorized the products. They also provide the agencies with yearly reports and supplements. Regulatory Affairs usually contacts one of the FDA's Centers likethe Center for Drug Evaluation and Research rather than the FDA's regional offices. Regulatory Affairs does not specifically relate to Dumbs, but they must comprehend and analyze alterations to medication production and evaluating processes in order to identify if and when the FDA must be alerted[9].Regulatory Affairs is a comparatively recent field that commenced from governments' aim to safeguard the public's well-being by monitoring the security and efficiency of products in fields like pharmaceuticals, veterinary medications, medical equipment, pesticides, agrochemicals, cosmetics, and alternative therapies[10-12]. Businesses involved in the development, testing, manufacturing, and selling of these items likewise want to ensure that the product they sell are safe and contribute to protecting health. Regulatory Affairs specialists are usually called in to provide advice on such problems because of their extensive understanding of the laws and norms[13].

3.5.Regulatory Issues' Importance:

In today's business environment, reducing the time it takes fora product to be sold, and thus the profitability of the organization is important. As a result, the company's Regulatory Affairs operations must be carried out properly. A quick positive review of a marketing application may be hampered by insufficient data reporting. A new medication may have cost tens of Billions, of dollars, or euros to be prepared, with a 3-month hold up for getting it sold,which has significant financial implications. So much awful, failure to provide all relevant data or the launch of a product with misleading labelling might easily necessitate a product recall[14-16]. Either event might result in the loss of millions of dollars in sales, in addition to a decline in investor, healthcare professional, and patient trust[17]. The Regulatory Division is frequently the key point of contact between the corporation and government officials.

3.6.Product Management Regulatory Affairs:

The essential duty of a RA expert goes over product registration; they provide tactical and technical advice to organizations at the top levels. Their role starts with product creation and continues with marketing and post-marketing activities. Their counsel at all levels, both in regardto legislative and technological requirements, saves industriesa significant amount of time and resources when it comes to producing and selling a product. The World Health Organization's instructions on health concerns and the World Trade Organization's trade laws between states are accepted by countries that don't have their own ordinance[18].

3.7.Regulatory affairs (RA) and clinical trials:

The RA specialist acts as the company's major point of contact with international regulatory organizations, including the European Medicines Agency, the Organization for Economic Cooperation and Development (OECD), the Therapeutic Goods Administration (TGA) in Australia, the United Kingdom's Medicines and Healthcare Products Regulatory Agency (UKMCA), and Health Canada.The firm's other departments are also informed about and given interpretations of the seemingly endless web of laws, regulations, and norms by RA professionals. To receive quick approval and reduce the time it takes for innovative drugs to be licensed, the RA team develops tactics to avoid hold-ups and delivers clinical trial results to regulatory agencies. At its core, regulatory agencies, healthcare systems, and the public at large are helped by RA professionals in obtaining, analyzing, and disseminating knowledge on the benefits and dangers of health products. Concerning operations, RA is in charge of making certain decisions that various stakeholders comprehend and take into account legal requirements, market demands, expanding scientific treaties etc[19-20].

3.8.Research and development in regulatory aspects:

Specialists in regulatory affairs work together with marketing and R&D to create innovative products that take use of technological and regulatory enhancements to reduce the amount of time spent in marketing. New goods are anticipated to significantly boost the bottom lines of the company, whereas small savings in time to market correspond to enormous matter income advantages. Speedy regulatory authorization, adaptable clinical trial tactics, and ignoring procedural problems are all beneficial[18-20].

3.9.Information on How Regulatory Affairs Operate:

Regulatory serves as a link betwixt the business or client and the external world. Information flows in and out of the regulatory department through this hub. To successfully practice regulatory law and have both internal and objective public outcomes such as approvals, recognition, and reward etc.

The pharmacy curriculum ought to have covered regulatory affairs. Regulatory affairs specialists are required to satisfy the current needs of industries in order to compete worldwide as India's pharmaceutical industry grows swiftly. The pharmaceutical sector and foreign regulatory bodies are connected through regulatory relations experts. They need to be knowledgeable about the laws, rules, policies, and instructions issued by the regulatory organizations. In order to equip students with the most recent innovations to serve the industries, there is an expanding requirement to incorporate current pharmaceutical industry objectives into the pharmacy college core curriculum[18-20].

3.10. The expert in drug regulatory affairs:

To fulfill regulatory standards and enable a positive review of the quality, efficiency, and security in the smallest period of timefeasible, it is essential that the procedure be carefully controlled from the beginning till the end. Bringing a novel medicine to market takes many years.All stage of this procedure, from creating efficient regulatory strategies after the identification of a novel chemical up to organizing post-marketing activities, involves the professional in drug regulatory affairs (DRA). The primary responsibility of a DRA professional in the pharmaceutical industry is to ensure that drug submissions are approved by the Health Therapeutic Products Plan, experimental and commercial pharmaceuticals are in conformity with applicable laws, regulations, and guidelines. The DRA professional must have a strong scientific background, an in-depth understanding of both domestic and international legislation, and be qualified for the post.It is a significant issue for the DRA personnel to maintain and upgrade policy and to ascertain how these upgrades in policies affect the regulatory authorization because the regulatory standards are advancing for globalized and mutual acknowledgment amongst various health officials worldwide. As a result, during the past ten years, DRA has become increasingly crucial in the development and approval of novel medications. The DRA expert must actively engage in meetings and direct team efforts to gather all required paperwork before checking its correctness and completeness. As an outcome, a successful DRA expert must have the interpersonal and organizational qualities of a "team player" in addition to being meticulous and detail-oriented. Contingent upon the pharmaceutical company's corporate framework, the range of duties is quite broad and may differ greatly. Some DRA professionals' duties may center on pharmacovigilance initiatives or electronic data representation (electronic submissions). Activities related to product launches, DMF applications, formulary submissions, reviews of marketing collateral, and quality assurance are examples of additional duties. The Ministry of Health and Company interaction is a major duty.

4. The qualities and skills needed to be a successful RA:

Influence IT literate Work autonomously Convince accuracya skilled negotiatorcurrent conditionExcellent communication and writing abilitiesActively to hearConsolidate and interpret datapersuasive and possess strong follow-up skillsto sound technical knowledge.

4.1.The Impact of Emerging Trends on Regulatory Strategy:

robust expansion in emerging marketsPossibilities for licensing and purchasingMarket growth for biologics and biosimilarpopulation agingtechniques for developing new productsrare illnessesQuality concerns across the supply chainICH enlargement
regulatory authorities working together.

4.2.The segments of the world market:

- **a. Regulated Market:** US, EU (UK, Germany, France, Ireland, Sweden etc.), Japan, Canada, Australia, New Zealand, South Africa.
- **b. Semi-regulated Market: (ROW Countries):**Asia (India, Sri Lanka, Bangladesh) and ASEAN: 10 Countries group also includes Brunei Darussalam, Vietnam, Philippines, Cambodia, Thailand, Indonesia, Laos, Myanmar, Singapore, and Malaysia.
- **c.** African nations such as Sierra Leone, Tanzania, Zimbabwe, Zambia, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Namibia, and others.
- **d.** Nations of the Middle East (Gulf Co-operation Council countries i.e. Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE).
- **e.** South America (Mexico, Brazil, Panama, Peru, Guatemala, Argentina, Chile, Dominican Republic).
- **f.** Russia, Ukraine, and OFSUs (Armenia, Georgia, and Tajikistan) make up the CIS (commonwealth of independent states).
- **g.** Tajikistan, Turkmenistan, Uzbekistan, Azerbaijan, Belarus, Georgia, Kazakhstan, Kirghizstan, Moldova, etc.).

4.3.Professionals in regulatory affairs are accountable for:

1. Confirm that all relevant system regulations and legal requirements are followed by their firms.
2. Working together on specific issues that are harming local, state, and federal governments' economies with employees from regulatory agencies. cooperating with agencies like the FDA or the EMA (pharmaceuticals and medical equipment).
3. Consulting their organizations on potential effects of regulatory considerations and the environment affecting planned activities. i.e. defining the "regulatory climate" in the context of issues like the promotion of prescription drugs.

The regulatory affairs specialist's priority is to keep an eye on the constantly evolving legal systems in all of the countries where a company wants to register its goods. Due to their aid at every level with technical and legal requirements and constraints, businesses may save a considerable amount of time and money while developing and marketing a product.

These professionals must prepare and submit registration documentation to regulatory organizations, as well as manage all subsequent discussions to obtain and retain marketing authorization (MA) for the products in issue. These are their principal duties inside a corporation. Every nation where a business wants to sell its product has rules, and those laws are always changing, so the corporation needs to keep up. The scientific research and commercialization of a new pharmaceutical product might take up to 15 years, and as the regulatory environment changes, various problems can arise.

5. DRUG APPROVAL PROCESS:

To obtain permission from the licensing authority (DCGI) to manufacture or bring in a new medication, a business must submit Form 44 and the data listed in Schedule Y of the Drugs and Cosmetics Act 1940 and Rules 1945. Clinical trials must be carried out in compliance with the regulations set out in Schedule Y and presentany country that has a rather challenging procedure for approving new medications. Additional requirements need to be accomplished in addition to filing an NDA to the FDA.According to the Pharmaceuticals Control Department of the Government of India, the present effort is required to investigate, document, and maintain the prerequisites for the licensing of new drugs in India, with a focus

on clinical studies[21]. Figures 4 and 5 show a graphic representation of India's drug approval procedure.

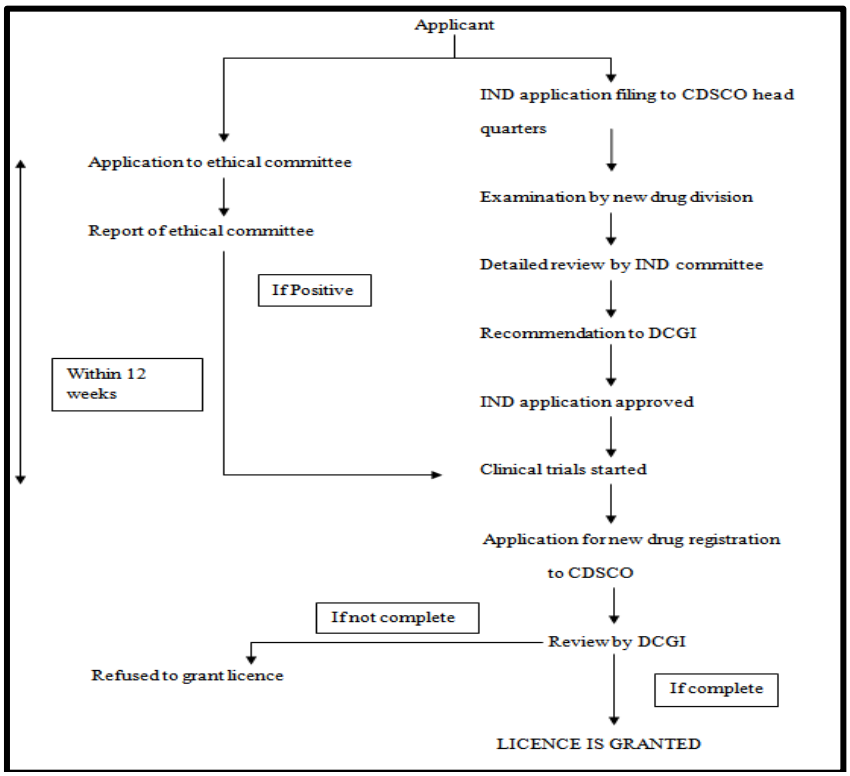

Figure 4: Pictorial representation of drug approval processes in India.

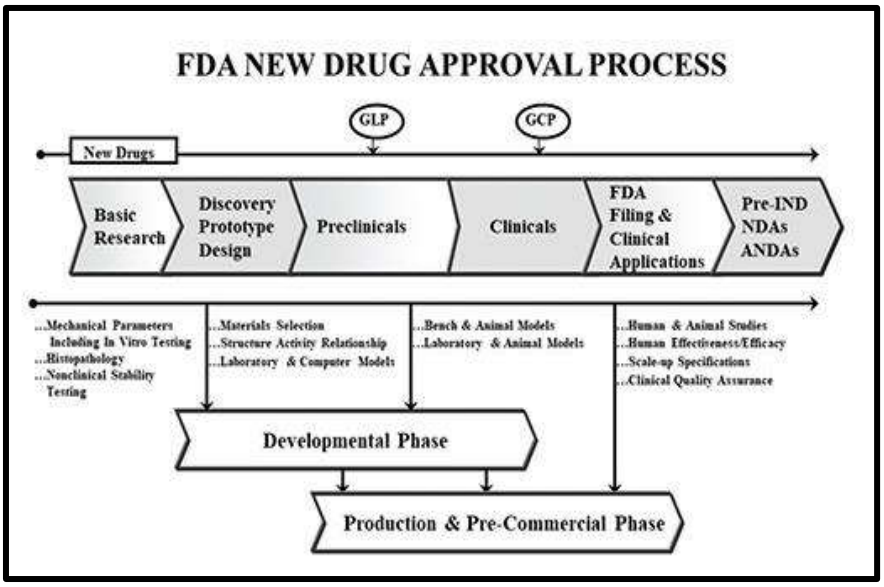

Figure 5: FDA India has implemented a new method for medication approval.

5.1.NEW DRUG APPLICATION:

First, before FDA will allow a new medicine to be sold, an NDA application must be submitted. In order to get this license, a sponsor must also present preclinical and clinical test details to NDA for examination of the drug information and documentation of the production methods. NDA is examined technologically after being approved by the agency.It must be determined through this evaluation and the accompanying documentation if there is sufficient data and proof in every region to support "filing" the application for official FDA review. The entire sequence for registering an NDA is shown in Figure 6.

1. Following the FDA evaluation of an NDA, the sponsor may get one of three possible actions:
2. List the errors in this letter and explain why they are unacceptable.
3. A drug is said to be "approvable" if just a few minor conditions are met, such as labeling changes and potentially a guarantee to do a post-approval study.
4. It mentions that the drug has been accepted[21].

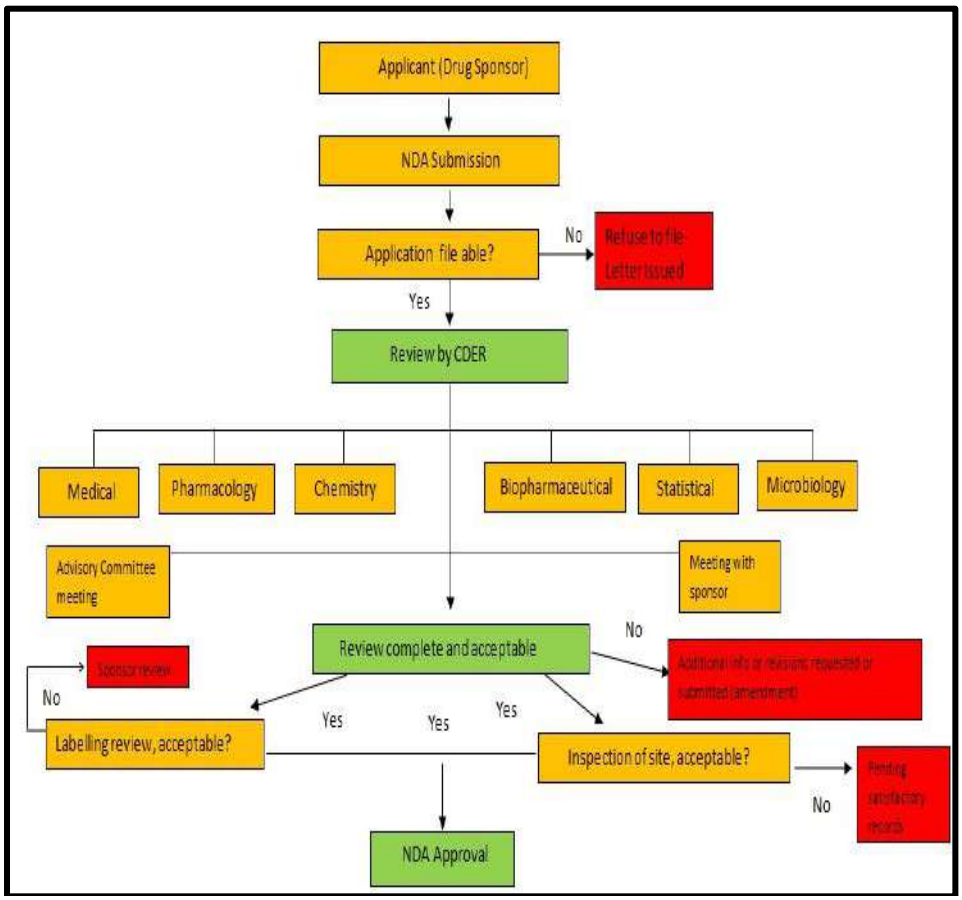

Figure 6:NDA Registration Process.

6. Clinical Trial Phases:

Figure 7 depicts a flowchart for the various phases of the FDA medication permitting process. Pre-clinical research using mice, rats, rabbits, and monkeys.

Phase I- Human pharmacology trial: assessment of tolerance and safety.

PHASE II - Exploratory trial: Estimation and assessment of efficacy and immediate side effects.

PHASE III - Confirmatory studies were conducted in phase three to evaluate the treatment's effectiveness.

Phase IV- Post-marketing trials, are those carried out following medication approval.

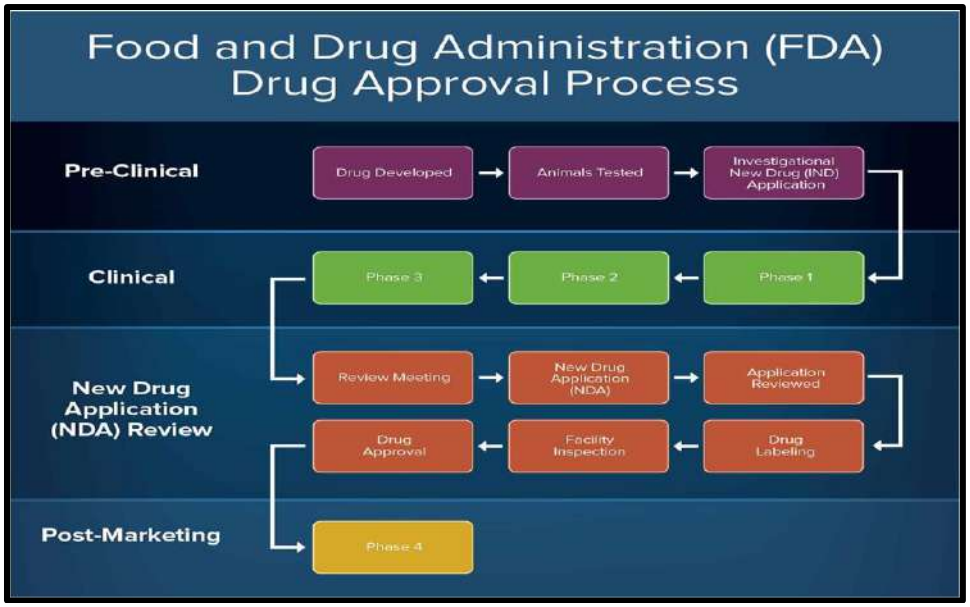

Figure 7: Flowchart for the many stages of the FDA medication approval process.

6.1. Some of the regulations and recommendations regarding drug use in India that should be followed include:

- 1940 Drugs and Cosmetics Act and its 1945 regulations
- Psychotropic Substances and Narcotic Drugs, 1985
- 1995 Drugs Price Control Order
- 1986 Consumer Protection Act
- 1948 Factories Act
- Legal Contracts (Indian contract Act-1872)
- Act of 1969 against Monopolistic and Restrictive Trade Practices
- ICH GCP Recommendations
- Schedule Y Recommendations
- ICMR Recommendations
- Registration of Trials

7. Multiple-source (generic) drugs:

When a patent or other exclusive right expires, multisource (generic) medications are created. Since they are well-known in the medical community and typically cost less because of competition, these medications have a major effect on people's well-being. The therapeutic interchangeability of generic medications with original drugs is crucial. Generic drugs must be pharmaceutically comparable (contain the same quantity of the active ingredient and have the same dose form) and bioequivalent to the brand-name drug in order to assure therapeutic interchangeability. Comparative in vivo pharmacokinetic studies with originator products are typically used to establish bioequivalence. The relevant WHO paper and country regulatory guidelines both provide a full description of how it is carried out. A multisource (generic) drug must satisfy specific regulatory requirements in order to be approved by well-resourced regulatory agencies.

7.1.Regulations governing multisource (generic) medications

Consists of the same active components as the brand-name medication.Have the same dose, potency, and mode of administration.Share the same usage guidelines.possess bioequivalence (as a marker for therapeutic interchangeability).Comply with the same batch's identity, strength, purity, and quality criteria.Be produced in accordance with the exact same high GMP standards demanded by the innovative item. Pharmacopoeia monographs are especially

significant when it comes to multisource (generic) medications since they allow producers to create goods that adhere to pharmacopoeia standards rather than creating their own specifications once patents and other exclusive rights expire (both for APIs and finished dosage forms). Not all pharmacopoeias have monographs (quality criteria) for completed dosage forms, it should be mentioned. Pharmacopoeia standards include some restrictions as well. For instance, testing according to pharmacopoeia procedures may not always detect all potentially harmful contaminants.

8. DEVELOPMENT OF REGULATORY AFFAIRS IN THE FUTURE:

Many within the regulatory affairs industry think the new regulatory strategy will eventually be used to all healthcare goods since it is the most effective way to bring new medical advancements to market in a timely manner while maintaining acceptable safety. Companies are expanding their regulatory affairs sections. Several businesses also opt to outsource or delegate regulatory matters to outside service providers due to the shifting resources required to satisfy regulatory standards. The regulatory affairs department is the one that is least affected by mergers and acquisitions as well as economic downturns since it is continually changing and expanding. Global standardisation has resulted in a uniform approach to regulatory filings and, consequently, to theirassessment

9. CONCLUSION:

Since the New Approach is the ideal model for bringing new medical breakthroughs to market in anadequate amount of time while retaining adequate security, many regulatory affairs specialists believe that it will be used for all healthcare products in the future. The department that is least impacted by mergers and acquisitions, as well as the recession, is Regulatory Affairs, which is always growing and increasing. The regulatory affairs divisions of businesses are expanding. In light of the variable assets needed to satisfy statutory standards, several businesses opt to outsource regulatory affairs to outside service providers. The success of a product and, by extension, the firm in today's competitive market depends on how quickly it can reach the market. The successful execution of the company's Regulatory Affairs activities is consequently crucial to its financial health. From the analysis above, it can be inferred that the FDA should get the relevant information on the approval of new drugs in India along with the NDA. The Schedule Y, the Drug and Cosmetics Guidelines of 1945 rules provided by the CDSCO must be adhered to while submitting the clinical studies report and relevant information for the procedure for certifying new medications in India, with a focus on clinical trials. The approval of pharmaceutical products should be a crucial step in ensuring that people have access to safe and effective medications[22]. The shortening of a product's time to market is essential for its success and that of the company in the highly competitive climate of today[23].Therefore, this job's objective is to get deeper understanding of the criteria for various technical documents and to research numerous policies that assist the medication approval process.

10. REFERENCES:

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory Affairs.
2. International regulatory affair updates, 2005. available at http,//www.iraup.com/about.php.
3. Douglas J Pisano and David S. Mantus. Textbook of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.

4. Regulatory Affairs brought by learning plus, inc. available at http,//www.cgmp.com/ra.htm.
5. Training Needs in Regulatory Science for the Biopharmaceutical Industry, Nature Jobs Biotechnology, 19(12), 2001, 1187-1188.
6. Careers in Regulatory Affairs from Practitioner to professional, Nature Jobs Biotechnology,20(4), 2002, 409-410.
7. Praneeth P. Regulatory Affairs and its role in Pharmaceutical Industry. International Journal of Pharmacy and Biomedical Engineering (SSRG-IJPBE). Jan-Feb, 2016; 3(1): 1-2.
8. Dolita Shah, Mayur Mistry. Pharma tutor. https://www.pharmatutor.org/articles/an-overview-of-regulatory-affairs-and-its-importance-in-pharmaceuticals-other-industries.
9. Shivam Lale, Amol Kendre, Mayur Gandhi, and Shreyas Dani. Role of drug regulatory affairs in Pharma Industry. World Journal of Pharmaceutical Research SJIF., 2015: 4(6): 615-625.
10. www.centerwatch.com.
11. NaishiKirtikumar, Dilip Maheshwari. Documentation requirements for generic drug application to be marketed in India- a Review. Journal of Pharmaceutical Science and Bioscientific Research (JPSBR)., 2014; 4(4): 237-242.
12. www.regulatoryone.com.
13. Sachin C Itkar, Ns Vyawahare, "Drug Regulatory Affairs", Third edition (2015).
14. "Need For the Introduction of Regulatory Affairs in the Pharmacy Curriculum" Health Administrator Vol: XIX Number 1: 51-52.
15. Sai Hanuja G, Sai Kumari B, Nagabhushanam MV,Nagarjuna Reddy D, BrahmaiahBonthagarala, Regulatory Requirements for Registration of Generic Drugs in "BRICS" Countries, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6 , November-December 2016, 20-40.
16. Sai Kumari B, Sai Hanuja G, Nagabhushanam MV, Nagarjuna Reddy D, BrahmaiahBonthagarala, Current Regulatory Requirements for Registration of Medicines, Compilation and Submission of Dossier in Australian Therapeutic Goods Administration, International Journal of Advanced Scientific and Technical Research, ISSN 2249-9954, Issue 6 volume 6, November- December 2016, 144-157.
17. Shaik Salman Basha, Shakeel SM, Nagabhushanam MV, Nagarjuna Reddy D, BrahmaiahBonthagarala, The Assessment of Current Regulatory Guidelines for Biosimilars- A Global Scenario, World Journal of Pharmaceutical Research, ISSN 2277– 7105, volume 6, Issue 1, 351- 369.
18. Shakeel SM, Shaik Salman Basha, Nagabhushanam MV, Nagarjuna Reddy D, BrahmaiahBonthagarala, Comparison of Regulatory Requirements for Generic Drugs Dossier Submission in United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6 , November-December 2016, 1-19.
19. Mounica NVN, Sharmila Reddy V, Anusha S, Evangeline L, Nagabhushanam MV, Nagarjunareddy D, Brahmaiah B. Scale up and Post Approval Changes (SUPAC) Guidance for Industry: A Regulatory Note, ISSN: 2321–6794, DOI:https://doi.org/10.22270/ijdra.v5i1.192, International Journal of Drug Regulatory Affairs; 2017, 5(1), 13-19.
20. Sharmila Reddy V, Mounica NVN, Anusha S, Evangeline L, Nagabhushanam MV, Nagarjunareddy D, Brahmaiah B. Regulatory Requirements of Similar Biologics for Marketing Authorization in India, ISSN: 2321 – 6794,

DOI:https://doi.org/10.22270/ijdra.v5i1.193, International Journal of Drug Regulatory Affairs; 2017, 5(1), 20-24.

21. Vishal Gupta N, Mohan Reddy C,Pradeep Reddy K, Ajay Kulkarni R, Shivakumar HG. Process of approval of new drug in India with emphasis on clinical trials. International Journal of Pharmaceutical Sciences Review and Research (IJPSRR). Mar–April: 2012; 13(2): 17-23.
22. Suresh S, Puranik SB, Phatru Patel. Regulatory Requirements for Registration of Pharmaceutical to Gain Market Access in India. RRJPPS. Oct–Dec: 2014; 3(4): 49-54.
23. Sumit Kumar, Rishabh Panwar, Upendra Singh. Regulatory Affairs in the Pharmacy Curriculum. International Journal of Research and Development in Pharmacy and Life Sciences. Oct– Nov: 2013; 2(6): 690-698.