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REVIEW ON DRUG REGULATORY AFFAIRS (DRA) AND NEW DRUG APPROVAL PROCESS

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ABSTRACT

Regulatory affairs are a new profession that can be developed for the controlling the safety, quality and efficacy of the drug products by submitting the investigational new drug application (IND) and new drug application (NDA) to regulatory authority. The whole process may be done in conscious manner in order to release a safe drug product to protect the public from non-toxic effects of drugs during and after the usage of drugs. The main intention of this article was too aware the peoples towards the role of regulatory affairs department, requirements for new drug approval and the involvement of the regulatory professionals in this process access as well as how crucial it is to perform and monitor the clinical and nonclinical trials of the drug before marketing the drug.

KEYWORDS: *Drug regulatory affairs, MAA, USFDA, CDSCO, EMA, Notice of Compliance (NOC), Notice of Deficiency (NOD), RMS, CMS, ANDA*

INTRODUCTION

1. Regulatory affairs (RA) is a career opportunity for regulating industries including such as pharmaceutical medicinal device, Veterinary medicine Cosmetics and other so on. Regulatory affairs is a bridge between pharmaceutical companies and government authorities for controlling efficacy and safety of medicinal products and also include its registration process so also known as government affairs. Regulatory affairs is a profession in the drug development world where one false move can bring years of research data to an unwelcome end Therefore, an RA Professionals needs to understand all the information and to be hands on both the hardware and the software of the function most of companies, they are major multinationals pharmaceutical corporations or small Biotechnology companies have specialist departments of regulatory affairs (RA) professionals.

2. For any new pharmaceutical product coming into the market, it will be required about 10-15 years, spending much time and many monies, but take a current example of covid-19 Disease (Corona virus disease) is an infectious disease caused by a newly discovered corona virus (SARS-CoV-2 -2), which has spread rapidly throughout the world. In march 2020.the World Health Organization (WHO) was declared the Covid -19 outbreak a pandemic. The Pandemic has destroyed health system, economic and social progress globally. For in that Emergency condition developing of a Corona virus vaccine WHO, ICH guidance Regulatory authorities and the Government of respective countries have taken strong action under the regulation to make vaccine. Developed Corona Virus Vaccine and its authorization is country by country.

3.e.g. Covishield, Covaxin (CDSCO, India), covid moderna -19 (USFDA) is an incredible and amazing surprise in the pharmaceutical business market with vaccine created in small time over a year. The Regulatory affairs system has a huge influence on the world. In Product management, clinical trials, and research and development, drug regulatory affairs is a research field. The global market is separated into two categories: Regulated and Semi-controlled markets

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods) most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals [1-4]. The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. Stringent GMPs are being followed for blood and its derivative as well as controlled manufacturing for Traditional Herbal Medicines, Cosmetics, Food and Dietary products which was otherwise differently a century before. Each regulatory system had faced certain circumstances which led to current well- defined controlled regulatory framework. This has resulted into systematic manufacturing and marketing of safe, efficacious and qualitative drugs. With the growth of industry, the legislations from each region have become more and more complex and created a need for regulatory professionals. 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

NEW DRUG APPLICATION (NDA):

A New Drug Application is filed to get approval for marketing a new drug in the USA. An NDA contains information included in the IND, as well as the results of clinical studies proving safety and efficacy. The FDA shall start the review process within 60 days from the submission of an NDA. Contents and Format of NDA

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Two copies of the application are: (a) Archival copy and (b) Review copy.

a) Archival Copy: It serves as a reference source for FDA reviewers to locate information not contained in the review copy; and it contains copies of tabulations and clinical study case report forms. It contains the following elements:

b) Application form FDA 356
c) Index
d) Summary
e) technical sections: further typed to
f) Chemistry, manufacturing and controls section
g) Non-clinical pharmacology and toxicology section
h) Human pharmacokinetics and bioavailability section
I) Microbiology section
j) Chemistry, manufacturing and controls section
k) Non-clinical pharmacology and toxicology section

b.) Review Copy: Each technical section is separately bound in each folder. Each technical section should contain

1. Index
2. Copy of FDA Form 356 h
3. Copy of cover letter
4. Letters of authorization
5. Copy of application summary.

The FDA can conduct meetings with the sponsor at least two times; once at the end of Phase 2 clinical trials and another before an NDA is submitted i.e., a pre- NDA meeting. The review team shall analyze the study results and make a decision whether or not to approve the application

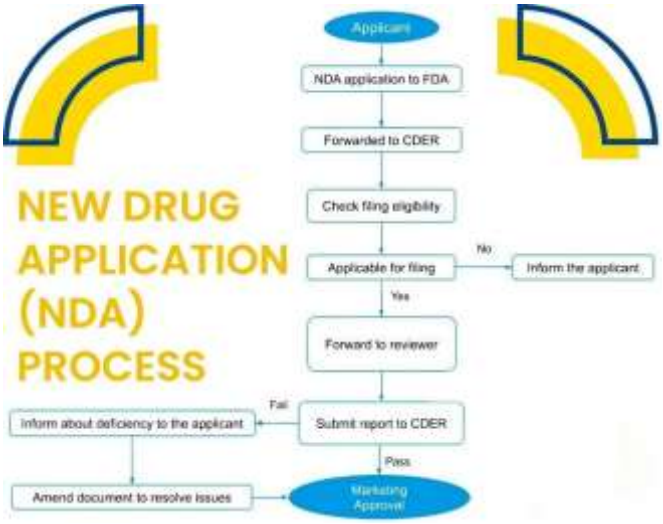


Figure:1 Structure of {NDA} Process

OBJECTIVES

Role of Regulatory Affairs (RA)Department: -

- Regulatory Affairs plays a key role in the pharmaceutical industry: from drug development to commercialization, especially during drug development: a lengthy, complex, and extremely costly but necessary process.
- The regulatory department is responsible for a lot. First, they have to ensure manufacturers are in compliance with any applicable global legislative and regulatory requirements. And these steps need to be followed at each stage of the development process, so all the way from research and development to the pre-clinical phase through the clinical phase, and then followed by marketing and post-marketing.
- Along with the drug development process, there are many times where regulatory submissions are required to move on to the next phase of the drug development process. Next, regulatory affairs professional is also responsible for keeping track of all the different updated legislative not only in the countries that the company might be in but globally which means, basically, anywhere that company is looking to distribute its products.
- The Regulatory Affairs department provides strategic and technical advice at the highest level in such companies. In this way, they make a significant contribution, both commercially and scientifically, to the success of a development program and the company as a whole.
- Early in the development process, at the research stage, it is critical to get regulatory affairs involved to ensure that an appropriate Clinical Development Strategy is developed with the goal of a carefully planned series of clinical trials, ranging from first-in-human Phase I to Phase II "proof of concept" and crucial Phase III trials for registration purposes.
- Once the drug discovery phase, during which potentially interesting compounds are tested for their non-clinical characteristics, the clinical phases (early to late phase) are initiated to further test the safety and efficacy of the drug candidate.

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MATERIAL & METHODOLOGY

MATERIAL

1. Regulatory Documents and Guidelines:
   - CDSCO guidelines and notifications.
   - EMA guidelines and directives.
   - FDA regulations and guidance documents.



Figure:2 Role of FDA, EMA And CDSCO IN Clinical Research

2. *Primary Data*
   - *Interviews with regulatory experts.*
   - *Case studies of recent approvals in each region.*
3. *Secondary Data*
   - *Academic papers on regulatory science.*
   - Industry reports and regulatory submission experiences.
   - Government and agency websites for latest updates.

METHODOLOGY

1. Document Analysis:
   - Data Collection: Gather official regulatory guidelines from CDSCO, EMA, and FDA websites.
   - Content Analysis: Analyze the structure, key stages, and specific requirements for the approval process in each region.
   - Comparative Analysis: Identify similarities and differences in regulatory approaches.

2. Expert Interviews
   - Selection of Experts: Identify and approach regulatory affairs professionals with experience in India, Europe, and the US.
   - Interview Process: Conduct semi-structured interviews to gain insights into practical challenges and nuances of each regulatory system.
   - Data Coding: Transcribe and code interviews to identify common themes and unique perspectives.



Figure:3 Document Analysis

RESULTS

1. The Regulatory Affairs (RA) department of the pharmaceutical industry is in responsibility or functioning of obtaining permission for new pharmaceutical medicine or drug that ensuring the approval maintenance process for as desiring firm or for as long.
2. Right from the start of a product development, regulatory affairs experts provide technology and strategic guidance to quality control, R &D, production department, among other contributing significantly both financially and scientifically to the advancement of a development initiative & the enterprise.
3. Keep in touch with customer practices, guidelines and international legislation.
4. Ensure that a company's product comply with the current regulation.
5. Keep up to the date with a company's product range.
6. Manage review audit reports and compliance, regulatory and customer inspections.
7. The Regulatory Affairs professional role is to keep track of the ever-changing legislation in all the region in which company wishes to distribute to its product with the advice on the legal and scientific restrains and requirements, and collect also evaluate the scientific data that their research and colleagues are generating.
8. Regulation is a binding instruction issued by an agency that tells how to clarify and comply with the law, failures to follow regulation many, end up into the "issued warning letter "sections of the FDA website, which is a fair for pharma industry.
9. Maintain approved application and the record of registration fees paid against submission of DMF's (Drug Master File) and other documents.

- Regulatory affairs professional help company that avoids problem caused by badly kept records and inappropriate scientific thinking or poor presentation of data.
- A good Regulatory Affairs professional will have 'right first time' approaches and will play a very major and

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important part in coordinating scientific end with regulatory demand throughout the life of the products, helping to maximize effective use of the company resources.

- Also, in the role to provide physician and other healthcare professionals with accurate and complete information about the safety, quality and effectiveness of the products.

Role of CDSCO

1. For approval of new drug.
2. Processing and conducting the clinical trials. 3. Licensing and import registration.
4. Also approving license for blood banks, r-DNA Vaccine, LVPs vaccine, and some medicinal device and products.
5. New drug testing.
6. Drug and cosmetics banning.
7. Market surveillance through inspectorate center and state Authority

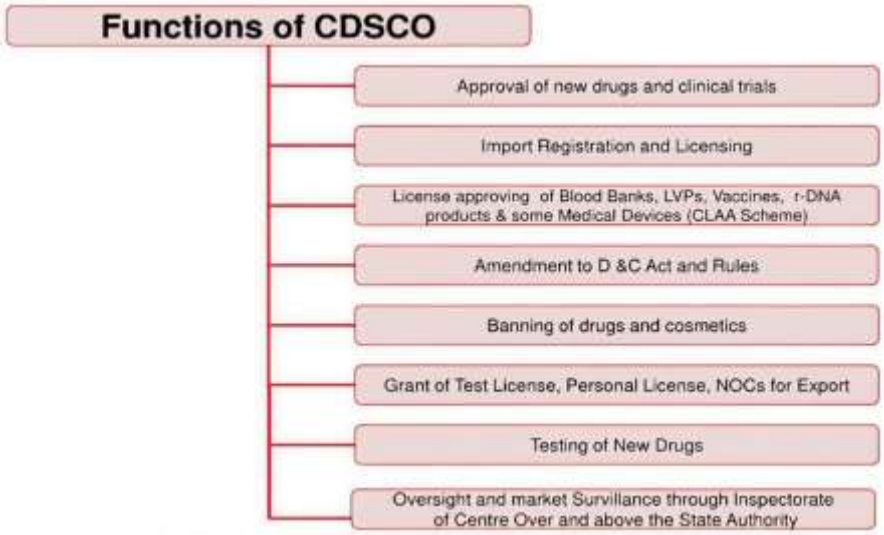


Figure: 4 Functions of CDSCO

DISCUSSION

Regulatory affairs (RA) is a critical function within the pharmaceutical industry that ensures compliance with laws, regulations, and standards governing the development, manufacturing, and marketing of pharmaceutical products. It outlines the importance of regulatory guidance documents, rules, and regulations in guiding regulatory compliance efforts within the industry. Additionally, the article discusses recent amendments in pharmaceutical regulations, highlighting the evolving nature of regulatory requirements and the need for industry adaptation.

Regulatory authorities play a pivotal role in overseeing and enforcing regulatory requirements to safeguard public health and ensure the quality, safety, and efficacy of pharmaceutical products. It provides an overview of regulatory authorities in key regions such as India, the USA, the EU, Canada, Japan, and Australia. It outlines the organizational structure of these regulatory agencies, including their roles, responsibilities, and key functions in regulating pharmaceutical products.

The regulatory approval process involves the submission and review of applications for marketing authorization of pharmaceutical products. In this section, we discussed the approval process and timelines associated with key regulatory submissions, including Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), and Biological License Application (BLA). It outlines the requirements and milestones involved in each stage of the approval process, highlighting the importance of timely and compliant submissions to expedite market access for pharmaceutical products.

CONCLUSION

Regulatory Affairs department is continually evolving and growing and is the one which is least impacted during the acquisition and merger, and also during the recession. Regulatory Affairs departments growing within companies. Due to the changing necessary to fulfil the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers. In today's competitive environment, the reduction of the time taken to reach the market is critical to a product and hence a company's success. The proper implementation of regulatory guidelines and laws will improve the economic growth of the company and also improves the safety of the people.

REFERNCES

1. *Bandarapalle K, Kumarachari RK, Sri KT, Neeraja B, Chaitanya K, Bhargavi CY. A Review on regulatory affairs and regulatory requirements for drug approval. Future Journal of Pharmaceuticals and Health Sciences. 2024;4:26-38.*
2. *Patil A, Thakre A. Overview of drug regulatory affairs and drug approval process in US, Europe, India and Canada: A review. International Journal of Drug Regulatory Affairs. 2020;8(2):36-43.*
3. *Roy A, Folbre N. Massachusetts Amherst.*
4. *Sawant AM, Mali DP, Bhagwat DA. Regulatory requirements and drug approval process in India, Europe and US. Pharmaceut Reg Affairs.2018;7(210):2.*
5. *Afreen HU, Aashritha B. A Review on Essentials of Regulatory*

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Affairs: Drug Approvals, Compliance, and Global Regulations.

6. *Sawant AM, Mali DP, Bhagwat DA. Regulatory requirements and drug approval process in India, Europe and US. Pharmaceut Reg Affairs. 2018;7(210):2.*
7. *Afreen HU, Aashritha B. A Review on Essentials of Regulatory Affairs: Drug Approvals, Compliance, and Global Regulations.*
8. *Varikkodan MM, Kunnathodi F, Azmi S, Wu TY. An overview of Indian biomedical research on the chikungunya virus with particular reference to its vaccine, an unmet medical need. Vaccines. 2023 Jun 15;11(6):1102.*
9. *Praneeth P. Regulatory affairs and its role in pharmaceutical industry. Int J Pharm Biomed Eng. 2016 Jan;3(1):1-2.*