The Brief Review Mucoadhesive Drug Delivery System

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➢ **Abstract:** Drug Regulatory Affairs is a vital unit in pharmaceutical company. It is concern about the healthcare product lifecycle, it provide strategic tactical and operational direction and support for working within regulation for expedite the development and delivery of safety and efficacy in pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, healthcare products to individuals around the world regulatory affairs (RA) professionals are employed in pharmaceutical industry, government, academic research and clinical institutions. As India is growing very in pharmaceutical sector, there is need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. A regulatory affairs is a somewhat new profession which has developed from the desire of governments to defined public health.

➢ **Keywords:** Agrochemicals, Global competition, RA, Pharmaceuticals.

➢ Introduction:

Regulatory affairs is a vast field to study. It takes a several years for a professional to comprehend a small segment of this field. Through the dynamics of RA Firms assure regulatory agencies that the products marketed meet all the regulatory expectations in regards to quality, safety and efficacy. The complexity of regulatory affairs is several folds magnified when a drug, device or biological product manufacturer exporting to several countries.

The current Pharmaceutical industry is well organized , systemic and compliant to international regulatory standards for manufacturing of chemical and biological drugs for human and veterinary consumptions as well as medical devices, traditional herbal products and cosmetics stringment GMPs are being followed for blood and its derivatives well as controlled manufacturing for traditional herbal medicines, cosmetics and food ,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.

RA involves complex dynamics-

- **Multi-dimensional**
- **Knowledge in science and technology**
- **Prolific communication skill**
- **Deal with people with diverse background ,skill culture and personalities**

➢ Role of Regulatory Affair :

Healthcare Industry of IPR

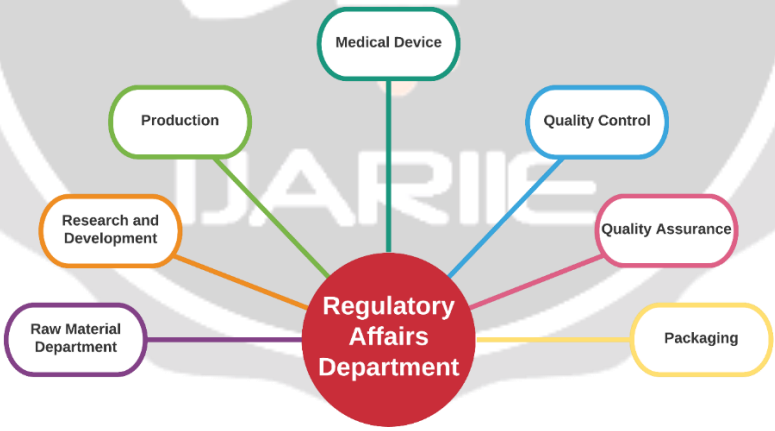
Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.[1] These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize his invention/creation for a given period of time.

Basic Understanding of drug Regulatory Affairs

- RA 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 medicines.
- RA in the pharma industry may be defined as "The interface between the pharmaceutical company and the regulatory agencies across the world."[1,2]

➢ RA Department

Figure 1:- Departments connected to RA in pharmaceutical industry



➢ Terminologies in RA:

1. Regulatory Affairs (RA): Profession that deals with the processes, practices, and regulations related to the development, approval, and post-marketing surveillance of pharmaceutical products.
2. FDA (Food and Drug Administration): The U.S. regulatory agency
3. EMA (European Medicines Agency)
4. ICH An international organization that develops guidelines and standards to ensure the safety, efficacy, quality, and interchangeability of medicinal products.
5. IND (Investigational New Drug): A regulatory submission made to the FDA before the start of clinical trials to provide information about the new drug's safety and efficacy.
6. NDA (New Drug Application): A comprehensive submission made to the FDA after the completion of clinical trials to obtain marketing approval for a new drug.
7. ANDA (Abbreviated New Drug Application):Application to the FDA for approval of generic drugs.
8. CMC (Chemistry, Manufacturing, and Controls): Part of regulatory submissions that focus on the detailed information about the drug's composition, manufacturing process, and quality controls.
9. GMP (Good Manufacturing Practice): Regulations and guidelines to define quality standards.
10. Pharmacovigilance: The science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.
11. Post-Marketing Surveillanc
12. Compliance: Adherence to regulatory requirements and standards in the development, manufacturing, and marketing of pharmaceutical products.
13. Clinical Trial Protocol: A detailed plan specifying how a clinical trial will be conducted, including the objectives, design, methodology, statistical considerations, and organization.
14. Quality by Design (QbD): An approach to product development that emphasizes understanding the product and process, identifying critical quality attributes, and designing processes to ensure consistent product quality.
15. DMF (Drug Master File)

16. Bioavailability and Bioequivalence.

➢ Need of RA professional in pharma industry:

RA professionals play a crucial role in the pharmaceutical industry for several reasons:

1. Compliance with Regulations

2. Drug Approval

3. Quality Assurance

4. Product Lifecycle Management

5. Global Market Access

6. Risk Management

7. Interdisciplinary Collaboratio

8. Pharmacovigilance

9. Innovation Support

Essential qualities of regulatory Affair (RA) Professional

RA professionals play a crucial role in the pharmaceutical industry by ensuring compliance with regulations and guiding the development, approval and marketing of pharmaceutical products. To be effective in this role, RA professionals need a combination of education, skills and qualities. Here are some essential qualities and skills for RA professionals in the pharma industry:

1. **Scientific and Technical Understanding**
2. **Attention to Detail**
3. **Communication Skills**
4. **Regulatory Knowledge**
5. **Project Management**
6. **Adaptability**
7. **Problem-Solving Skills**
8. **Ethical Conduct**
9. **Collaboration**

- **Healthcare Industry IPR**

Types of intellectual property rights :-

1. Trademark
2. Patent
3. Copyright
4. Design
5. Trade secrets

Patents :

A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.

Stage - Filling for grant of patent

1. **Filling of application**
2. **Publication of application**
3. **Request for examination**
4. **Examination issue of FER**
5. **Grant of patent**

What is Copyright:

Copyright is the legal right given to an intellectual property owner. As the term suggests, it is the right to copy. Thus, copyright meaning is that when a person creates a product, they own

What is trademark:

Trademark is defined in the Trademark Act, 1999 as, "trademark means a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include the shape of goods, their packaging and combination of colours.

Types of Trademark:

1. Generic marks
2. suggestive mark
3. Descriptive mark
4. Arbitrary mark
5. Fanciful mark

What is geographical indication:

A geographical indication (GI) is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin.

What is industrial design:

Industrial Design is the professional practice of designing products, devices, objects, and services used by millions of people around the world ever.

Dossier preparation in CTD Format:

The Common Technical Document (CTD) is a set of specifications for a dossier for the registration of medicines. The CTD was developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and adopted by the Therapeutic Goods Administration (TGA) in 2004.

The CTD dossier is divided into five main modules:

Module 1: Administrative information and prescribing information

Module 2: Overviews and summaries of Modules 3-5

Module 3: Quality (pharmaceutical documentation)

Module 4: Non-clinical reports (pharmacology/toxicology

eCTD Submission:

eCTD (electronic Common Technical Document) is a standard format of submitting Regulatory information (such as applications, supplements, and reports) to the concerned Health Authorities (HAs). It provides a harmonized solution to implement the Common Technical Document (CTD) electronically. All life science companies require approval from Regulatory Health Authorities to place their human, medical device, or veterinary medicinal products on the market. For approval to be granted, the drug application data needs to be submitted in an electronic format, which uses specific software and is structured in the format of an "electronic common technical document" (eCTD).

Structure of submission:

The structure and organisation of an eCTD submission is defined by the following

Standards- ICH M2 eCTD Specification • EU Module 1 Specification • Relevant ICH and EU Q&A docs Annex 1 contains links to the currently approved version of these documents.

Compliance guidelines:

Corporate and regulatory, both corporate and regulatory compliance consist of framework of rules, regulations and practices to follow. Compliance means acting and making decision in accordance with relevant laws, regulations, and internal guidelines

Compliance is essential in the pharmaceutical industry for several reasons:

- **Protecting Public Health**
- **Maintaining Industry Integrity**
- **Meeting Ethical and Legal Standards**
- **Avoiding Legal Penalties**
- **Ensuring Product Quality**

Compliance with quality control regulations is essential to ensure that pharmaceutical products are of the highest quality, safe, and effective for use by patients. Quality control measures include good manufacturing practices (GMP), good laboratory practices (GLP) and good clinical practices (GCP)Another crucial area of compliance in the pharma

industry is RA

GOVERNMENT AUDITS:

FDA & USFDA	**Food &Drug Administration**	**The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and over-thecounter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feedand veterinary products.**
MHRA (UK)	**Medicines and Healthcare products Regulatory Agency**	**The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.**
TGA	**Therapeutic**	
Part of Australian govt.	**Goods Administration**	

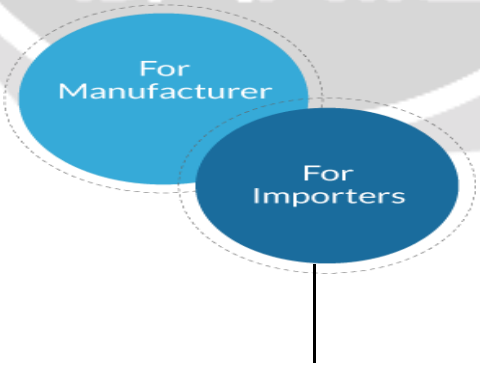
Regulatory Requirement For Biologics:

Biologics are the medicinal therapeutics/diagnostic/ preventive preparation composed or derived from living organism and their spin off for human use. They include serum, vaccine, antitoxins, blood antigens and blood components, gene therapy tissues etc.

The regulatory authority for mfg. and import of biological product in India. Regulatory Requirement Biotechnology is used as unique approaches in mfg. such as medicinal agents. The central drug standards control organization (CDSCO)

- NOC for form 29
- Test License
- Post Approval Changes
- Marketing Authorization
- Clinical
- Trial
- Permission

(Phase 1, 2 & 3) & GCT



- Registration
- Import License
- Marketing Authorization
- Clinical Trial Permission
- (Phase 1, 2 & 3) & GCT

LICENSING AND REGISTRATION OF BIOLOGICS:

Introduction

FDA is a federal agency in US supervising various food products& drug used for humans and veterinary use. The FDA has seven product and research centres, including the Centre for Biologics Evaluation Research (CBER), which ensures the safety, purity, potency, and effectiveness of biologics and related products. CBER regulates a number of biologics-related products, including blood tests, computer software, and blood transfusion devices

Registration

A biological product must be licensed pursuant to a BLAshowing it is “safe, pure, and potent”, the sponsor of a non-biological drug must submit a NDA showing the drug is safe and effective. The new biological products will receive 12 years of data protection, whereas the new drugs receive up to 5 years of protection. Before a biologic may be approved and marketed, the biologic must undergo extensive testing and regulatory review in order to determine that the biologic is safe and effective.

BLA & Regulatory requirements for registration of Biologics in U.S

• Biological license application.

• Checklists of required elements for Biological license application.

• Examination of biologics license application by USFDA.

• Agency review process.

• Complete response letter to the applicant.

- Approval process.
- Post-approval changes.

• Reference product exclusivity for biological products filed under 351(a) of the PHS act.

• Regulatory requirements for registration of biologics according to USFDA.

1. Biologics license application:

The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680.

2. Checklist of required elements for biologics license application:

- Cover letter and application form
- Table of Contents (Index)
- Labelling
- Summary
- Chemistry, Manufacturing and Controls (CMC)
- Nonclinical Pharmacology and Toxicology
- Clinical Microbiology
- Clinical data section
- Safety Update reports
- Statistical section
- Case Report Tabulations (CRTs)
- Case Report Forms
- Patent Information.

Vaccine regulations in India USA and Europe:

INTRODUCTION:

1. Vaccines are one of the most significant achievements of science and public health. Many diseases that can be prevented by vaccination are now rare in the United States due to successful immunization programmes. Drugs are described as substances that are employed in the treatment, mitigation, medicine, or prevention of disease.

2. Typically, disease-causing microorganisms, their toxins, or a denatured or dead version of one of their surface proteins are used to create Vaccines belong to a brand- new category of pharmaceutical medicines that can be classified as both medications and biological products. 4.A vaccination is a prescription medication used to increase immunity to a particular disease.

1. Vaccine regulations in India.

Various regulatory agencies for vaccine registration are the Ministry of Health and Family

Welfare, National Technical Advisory Group on Immunization, Indian Council for Medical Research, Central Drugs Standard Control Organization.

2. Vaccine regulations in USA.

Various regulatory bodies for vaccine registration in the US include Centre for Biologics Evaluation and Research, Vaccines and Related Biological Products Advisory Committee,
Biologics License Application.

Step:

1. Sponsor
2. Submit IND to FDA
3. IND describes the vaccines ,its method of mfg and Qc tests for relase
4. Conduct clinical test
5. Phase I ,II & III
7. Biological license application is submitted

8. Reviwed by reviews team medical officer chemists

9. Technical advice is given by VRBPAC include scientist physican

10.Labelling examination to understand use potenital risk and benefit

11. Conduct phase IV cliniocal trials

12. During phase IV vaccine adverse event reporting system is carry out by government

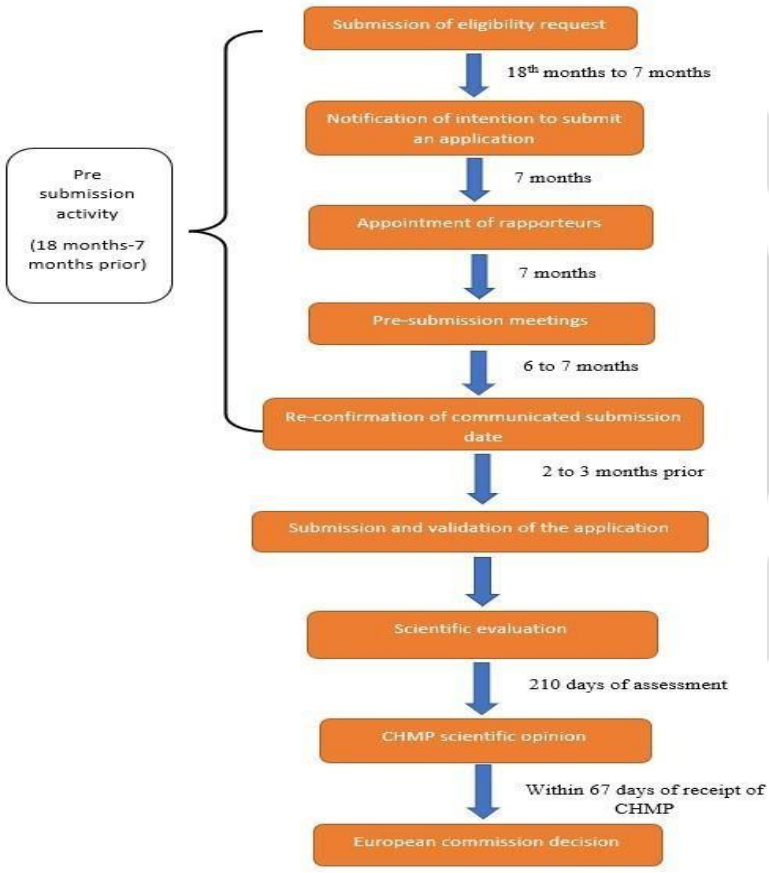


Figure 4 Marketing authorisation application (MAA) of EU

Marketing authorization is the process of reviewing and assessing the evidence to support a medicinal product, such as a drug, in relation to its marketing, finalised by granting of a licence to be sold.

Marketing authorization Application: A Marketing Authorization Application provides comprehensive information about a drug, enabling regulatory agencies to assess Quality, Safety and Efficacy, and evaluate the ability of the future Marketing Authorization Holder (MAH) to ensure and monitor a sustainable benefit/risk ratio .

Registration

The EU uses Centralized, Decentralized, Mutual recognition, and Nationalised echanisms to approve vaccines. When requesting a marketing authorization for a vaccination product, the manufacturer typically favours the centralized process, since a centralised process is used to approve a single marketing authorization for a vaccination product across the EU. Patients, as well as the healthcare system may easily get vaccines.

Quality Assessment

Quality assessment is the data collection and analysis through which the degree of conformity to predetermined standards and criteria are exemplified. If the quality, through this process is found to be unsatisfactory, attempts are made to discover the reason for this. Quality assessment generally involves evaluating the characteristics and attribute Here are some key aspects of quality assessment:

1. Accuracy: Check if the information is accurate and free from errors. This involves verifying facts, data, and details provided.
2. Relevance: Assess how pertinent and applicable the information is to the context or topic at hand. Relevant information adds value.
3. Completeness: Ensure that all necessary details and components are present. Incomplete information can lead to misunderstandings or gaps in understanding.
4. Clarity: Evaluate how clearly the information is presented. Ambiguity or confusion can hinder comprehension.
5. Currency: Determine how up-to-date the information is. Timeliness is crucial, especially in fields that undergo rapid changes.
6. Consistency: Check for uniformity and coherence in the information. Inconsistencies can create confusion and reduce credibility.

7. Objectivity: Assess whether the information is presented in an unbiased and impartial manner. Objectivity is vital for trustworthiness.

8. Reliability: Consider the source of the information and its credibility. Reliable sources enhance the trustworthiness of the information.

9. Usability: Evaluate how easily the information can be used or applied. User-friendly information is more likely to be effective.

10. Efficiency: In some contexts, efficiency matters. For example, in a process, efficiency can be assessed by how quickly and accurately a task is completed

Pharmacovigilance

V is defined as a set of scientific activities related to detecting, assessing, understanding, and preventing adverse effects and any other drug-related problems. Following is a figurative explanation of how PV works and the process therein.

Complete safety data (especially for unexpected and serious adverse events) can only be captured through pharmacovigilance

- It cannot be captured through clinical trials which are conducted in an "artificial environment."
- In clinical trials patients are not taking any other medications
- do not have concomitant diseases
- sare taking the drug short-term (during the duration of the trials only) and are not part of vulnerable groups (e.g., children, pregnant women, elderly, etc

Regulatory Requirements for Registration of Drugs

New Drug Application (NDA) is an application submitted to the individual's regulatory authority for authority for authorization to market a new drug i.e. innovative product. To gain this permission a sponsor submits preclinical and clinical test data for analysing the drug information , description of mfg. Trials

Different phase of clinical trial:

Pre-clinical study

◊ Phase I - Clinical trial

◊ Phase II – Exploratory trial

◊ Phase III- Confirmatory trial

◊ Phase IV- Post Marketing trial

Drug Approval Process in India:

The Drug and Cosmetic Act 1940 and Rules 1945 were proclaimed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its leader, the Drugs Controller General (DCGI) was established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure. When a company in India wants to manufacture/ import a new drug it has to apply to seek permission from the licensing authority (DCGI) by filing in Form 44 also submitting the data as given in Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 . In order to prove its efficacy and safety in Indian population it has to conduct clinical trials in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in specified format

Figure 5:-Documents for medical device registration

Introduction to current GMP:

Good manufacturing practice (GMP also referred to as "cGMP" or current good manufacturing practice) is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standard appropriate to their intended use and as required by the product specification

. Principles of GMP :

1. Create Standard Operating Procedures (SOPs)
2. Enforce / Implement SOPs and work instructions
3. Document procedures and processes
4. Validate the effectiveness of SOPs
5. Design and use working systems
6. Maintain systems, facilities, and equipment
7. Develop job competence of workers
8. Prevent contamination through cleanliness
9. Prioritize quality and integrate into workflow

Good laboratory practice:

The principles of Good Laboratory Practice (GLP) promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices.The principles have been developed in accordance with the Organisation for Economic Cooperation and Development (OECD) and the EU has adopted these principles and the revised OECD Guides for Compliance Monitoring Procedures for GLP as annexes to its two GLP Directives.GLP underpins the mutual acceptance of test data between countries, which avoids duplicative testing, is beneficial to animal welfare, and reduces costs for industry and governments

Good Automated laboratory practice:

Principle: The GALPs are directed to most configurations that are involved with entering, cording, manipulating, modifying, and retrieving data. Not all automated laboratory systems are LIMS. Automated laboratory systems that record data but do not allow changes to the data are not

Basic Requirements of GDP:

Always record the entries at the time of activity simultaneously.

Always record date with the signature in GMP records.

Always use an indelible ballpoint pen to record data in GMP records.

Always enter the data directly into the GMP records in the English language.

Principles: A key requirement of good distribution practice is a self-inspection programme. The scope of self-inspections can vary. The wholesaler may decide that a comprehensive selfinspection performed less often is better than smaller, more specific self-inspections performed regularly.

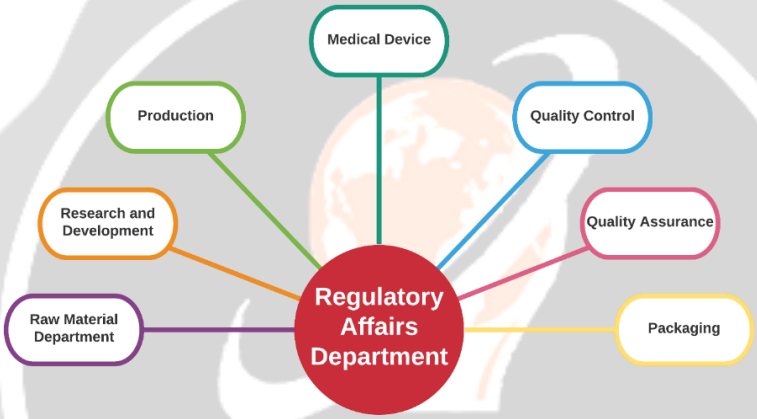
Self Inspection: Self-inspections shall be included in the quality system. These shall be conducted to monitor implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures. A designated, competent person shall conduct self-inspection in an independent and detailed way. There shall be records of self-inspection results which shall contain all observations made during the inspection and if required proposal for corrective measures. There shall be an effective follow-up programme and evaluation of inspection report and corrective action taken by the management.

Application of Regulatory Intelligence:

- Determining requirements for global clinical trials
- Developing compliance procedures
- Developing manufacturing requirements
- Advising personnel
- Answering strategic regulatory questions
- Developing a global marketing application
- Creating detailed reports on current, changing, and new regulations
- Developing strategies for company-wide regulatory compliance
- Developing and executing compliance training

Role of Regulatory intelligence in drug development:

The role of regulatory Intelligence in development is to identify, collect, and interpret information on medicines that may pose a risk to public health. This information helps regulators make informed decisions on the safety of medicines and how to best protect patients. helps regulators make informed decisions on the safety of medicines and how to best protect patients.It helps companies to understand the changing landscape of regulations and make informed decisions about their products.Regulatory Intelligence is a critical tool for pharmacovigilance, as it can help identify new safety concerns and keep track of emerging trends. It can also help assess the impact of regulatory changes on a company's product portfolio.



- Department of RA [25,26,27]

Role of Regulatory intelligence in pharmacovigilance:

The role of regulatory Intelligence in pharmacovigilance is to identify, collect, and interpret information on medicines that may pose a risk to public health. This information helps regulators make informed decisions on the safety of medicines and how to best protect patients.

Regulatory Intelligence plays an important role in ensuring the safety of medicines by helping regulators:

- Understand the risks associated with medicines;
- Monitor the safety of medicines;
- Make informed decisions on the regulation of medicines;

Regulatory Guidelines on Data Integrity	
ALCOA by FDA **<u>Attributable</u>** **1 Data should clearly demonstrate who observed and recorded it, when it was observed and recorded, and who it is about.**	**21 CFR Part 11** **1.Ensure Validation of Systems** **2. Ensure Protection of Records** **3. Ensure Time Stamped Audit Trails** **4. Ensure Authorized use of Password** **5.Ensure Limited System Access** **6.Ensure Limited Document Access** **7.Ensure Employee Training**
2.<u>Legible</u> **Data should be easy to understand, recorded permanently and original entries should be preserved.**	**MHRA Data Integrity** **1.Ethical Behavior of all Professionals**

3.<u>Contemporaneous</u> **Data should be recorded as it was observed, and at the time it was executed.**	**2.Create Strong Passwords** **3.Ensure Authorized System Access**
4. <u>Original</u> **Source data should be accessible and preserved in its original form.**	

Table 3 :-Regulatory Guidelines on Data Integrity

LITERATURE REVIEW:

1)Pankaj Nerkar 2023 et.al

The purpose of the research is to assess the requirements for generic medicine marketing approval procedures in developed nations such as Zimbabwe and Myanmar.

2) Krishnasis Chakraborty 2022

This review article helps to study the practical aspects of different phases of life cycle of pharmaceutical products including sterile and non sterile dosage forms in regulated market of Europe.

3) Prajval Birajdar 2022 et.al

The primary consideration when developing a herbal hand sanitizer is hand cleanlines.

4)Md. Faysal Fardin 2021

Getting pregnant is gift that covers a large part of life of most women or others.

5) Khushboo Vaghela 2022 et.al

Drug repurposing is a phenomenon that aims at utilizing an established and approved drug product or drug substance for an additional clinical indications apart from one that it was intended for.

6) Vaibhav Subhash Janjal 2021

Regulatory affairs also known as government affairs is a relatively new profession that arose from governments desire to protect public health by regulating the safety and efficacy of products such as pharmaceuticals and medical devices.

7) Shivali Singla 2021 et.al

In digestive system of human beings the colon and rectum are two important parts.

8) Sukanya Paricharak 2021

A pharmaceutical drug regulatory affairs is mainly involved in registration process parameters of different pharmaceutical products.

9)Mohan Gupta 2021 et.al

The purple book is an informative database of all FDA licensed biological products regulated by the center for drug evaluation and research.

AIM

The main objective of regulatory affairs is to provide the basis for the assurance of high quality of food products which can increase consumers interest for ensuring the efficacy, quality, and safety. Regulatory frameworks vary from region to region as detailed in the chapter on regulation in this book.

OBJECTIVE

1) Production

2) Finished product

3) Quality control

4)Packaging

5) Research and development

RESULT

Regulatory affairs establish common principle and responsibilities that provide a strong scientific database, efficient organizational arrangements, and procedure to underpin decision making for nutraceuticals preparations .

CONCLUSION

The students introduce the legal and regulatory aspects pertaining to biological in the united state and European union. The drug approvals in the US, Europe are most demanding in the world. The main objective of the rules governing medicinal products in US, Europe is to safe guard the public health the drug approval in the US, Europe and India are the most demanding in the world. The primary purpose of the rules governing medicinal products in the US, Europe and India is to safe guard public health. It is the role of public regulatory authorities to ensure that pharmaceutical companies complies with regulation.

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