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REGULATORY AFFAIRS IN THE PHARMACY MODULES

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ABSTRACT

The pharmaceutical industry plays a crucial role in regulatory affairs, ensuring the safety, efficacy, and quality of drugs, protecting human health, promoting consumer trust, and supporting innovation. Key terms include Active Pharmaceutical Ingredient (API), New Drug Application (ANDA), Clinical Trials, Good Manufacturing Practice (GMP), International Council for Harmonisation (ICH), Investigational New Drug (IND), New Drug Application (NDA), Orphan Drug, Pharmacovigilance, and Post-Marketing Surveillance. Regulatory Authorities like the FDA, EMA, and MHRA regulate drugs and have standard operating procedures (SOP) for specific tasks. Intellectual Property Rights (IPR) are granted to creators and owners of intellectual property. Exploratory development (ExPD) is an essential process for companies to achieve growth and improve product development success. And also specifications that key documents Batch manufacturing record, Manufacturing formula record and other Aspects like SOP are described. The preparation of dossiers for multiple countries and the CTD format, which reduces time and resources for global registration applications. The International Conference on Harmonization of Electronic Common Technical Documents revolutionizes pharmaceutical submission procedures. Regulatory affairs personnel help pharmaceutical companies maintain accurate records, comply with regulatory requirements, and ensure product quality and safety.

KEYWORDS: Regulatory Requirements, Records, Roles, Regulatory authorities, Manufacturing Practice (GMP), Intellectual Property Rights (IPR), Exploratory development (ExPD), standard operating procedures (SOP), Manufacturing Record, CTD, eCTD, Batch manufacturing record, Manufacturing formula record.

➢ INTRODUCTION

❖ Dug Regulatory Affairs (DRA)

According to the World Health Organization (WHO), Regulatory Affairs is defined Regulatory affairs refers to the activities undertaken by governments, regulatory authorities, and the pharmaceutical industry to ensure that pharmaceutical products, including medicines, vaccines, and medical devices, are safe, effective, and of good quality for human use.

Basic terminology

1. **Active Pharmaceutical Ingredient (API):** The substance in a pharmaceutical drug that is biologically active.
2. **ANDA (Abbreviated New Drug Application):** Application for the approval of a generic drug where the safety and efficacy are proven to be similar to an already approved drug.
3. **Clinical Trials:** Research studies performed on human participants to evaluate the safety and efficacy of a medical intervention.
4. **Good Manufacturing Practice (GMP):** Regulations that ensure that products are consistently produced and controlled according to quality standards.
5. **ICH (International Council for Harmonisation):** An organization that brings together regulatory authorities and pharmaceutical industry experts to discuss scientific and technical aspects of drug registration.
6. **Investigational New Drug (IND):** Application submitted to regulatory authorities before beginning clinical trials in humans, detailing the drug's safety and efficacy data.
7. **New Drug Application (NDA):** Application submitted to a regulatory authority to request approval to market a new pharmaceutical for sale.
8. **Orphan Drug:** A drug developed for the treatment of a rare disease or condition.
9. **Pharmacovigilance:** The practice of monitoring the effects of drugs after they have been licensed for use, especially to identify and assess previously unreported adverse reactions.
10. **Post-Marketing Surveillance:** Ongoing monitoring of a drug's safety and efficacy after it has been approved and released to the market.
11. **Regulatory Authority:** A governmental body responsible for regulating drugs, such as the FDA (Food and Drug Administration) in the United States, EMA (European Medicines Agency) in Europe, and MHRA (Medicines and Healthcare products Regulatory Agency) in the UK.
12. **Standard Operating Procedure (SOP):** Documented instructions for performing specific tasks to ensure compliance with regulations and consistency in product quality.[2,3,4,5,6,7]

❖ Regulatory Affairs in the Pharmaceutical Industry

Fig no. 1: Regulatory Affairs in the Pharmaceutical Industry.[8,9]

❖ **Role for Regulatory Affairs**

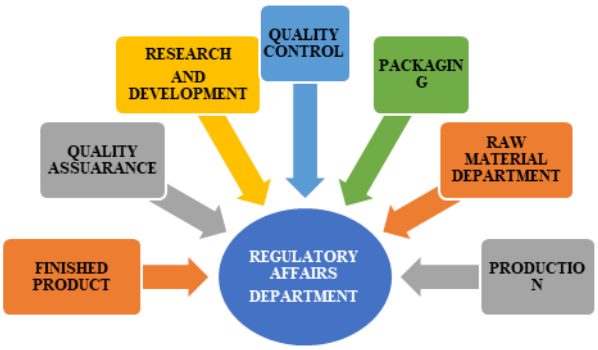

Fig. no. 2: Role for Regulatory Affairs.[10]

➢ **Healthcare Industry IPR**

IPR stands for Intellectual Property Rights. It refers to the legal rights granted to creators and owners of intellectual property, such as:

1. Patents (inventions and innovations)
2. Trademarks (brands, logos, and slogans)
3. Copyrights (literary, musical, and artistic works)
4. Trade secrets (confidential information)
5. Industrial designs[8]

Figure 3: IPR.[11]

❖ **An Exploratory Development Product**

Companies face uncertain, fast-changing, and complex environments, causing traditional phased-and-gated processes to fail. This leads to changing product requirements, unexpected problems, rework, schedule delays, budget breaks, and commercial failure, requiring efficient and effective exploratory development.

- **Goal**

Develop (ExPD), which help companies achieve growth and improve product development success through an adaptive system. The primary goal of ExPD is to reduce uncertainty and risk by reducing the unknown. When organizations adapt quickly to the changing environment (market, technology, regulations, globalization, etc.), they reduce uncertainty and risk leading to product success.[12]

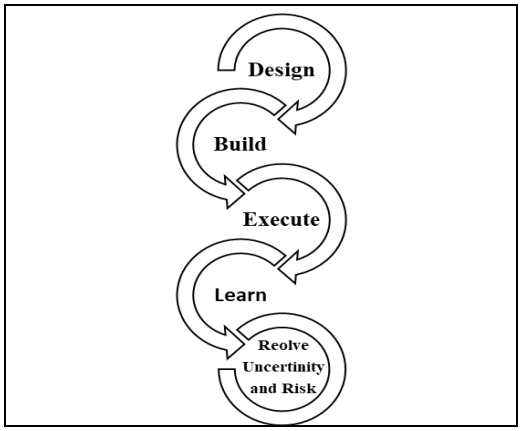

Fig. no. 4: Goal EXPD.[12]

1. Product development plan

The overall process of strategy, organization, concept generation, product and marketing plan creation and evaluation, and commercialization of a new product. Innovative new products are the fuel for the most powerful growth engine you can connect to.

Fig.no. 5: Product development plan.

2. A product development report

A product development report is a detailed document detailing the progress and outcomes of a drug development project, crucial in the pharmacy industry for ensuring compliance with regulatory requirements, providing evidence for submissions, supporting inspections, facilitating communication, ensuring transparency, mitigating risks, and supporting product registration and approval.

3. Batch Formula Record

A Batch Formula Record is a document that details the formulation, production, and control of a specific batch of a pharmaceutical product. It should include dates, times, major equipment used, batch identification, actual results for critical process parameters, sampling, signatures of those performing critical steps, in-process and laboratory test results, actual yield, packaging and label description, representative label of the intermediate or API, deviations noted, evaluation, investigation conducted, and release testing results. Written procedures should be established for investigating critical deviations or failure of a batch to meet specifications. The investigation should extend to other batches that may have been associated with the specific failure or deviation.[13,14,15,16]

Fig. no. 6: Batch Formula Record.

4. Batch Reconciliation

According to the World Health Organization (WHO), Batch Reconciliation is defined as a process to account for the quantity of starting materials, intermediates, and finished products during the manufacturing process, to ensure that the quantities are accurately recorded and reconciled. This process is critical in the pharmaceutical industry, where batch reconciliation is used to:

- Ensure accurate accounting of materials and products
- Detect and investigate discrepancies or deviations
- Verify compliance with Good Manufacturing Practices (GMP)
- Support regulatory submissions and inspections
- Ensure product quality and safety

By performing batch reconciliation, pharmaceutical companies can ensure compliance with regulatory requirements, maintain accurate records, and ensure the quality and safety of their products.

5. Batch Packaging Record

According to the World Health Organization (WHO), (BPR) is defined as: A document that provides a detailed record of the packaging operations for a specific batch of a pharmaceutical product. It shall be based on the relevant partsof the packaging instructions, and the method of preparation of such records shall be designed to avoid transcription errors. A batch packaging record shouldbe kept for each batch or part batch processed. It should be based on the relevantparts of the packaging instructions. The information should be recorded at the time each action is taken and, after completion, the date and the person responsible should be clearly identified by signature or electronic password.[14]

6. Master Production Instructions (Master Production and Control Records)

According to the World Health Organization (WHO), (MPR) is defined as: A document that contains information on the production of a pharmaceutical product, including the formula, manufacturing process, equipment, and controls. To ensure uniformity from batch to batch, master production instructions for each intermediate and API should be prepared, dated, and signed by one person and independently checked, dated, and signed by a person in the quality unit(s).[15,16]

7. Documentation System and Specifications

The World Health Organization (WHO) emphasizes the importance of a document system specification for managing electronic records related to intermediates or APIs. This includes hardware, software, and procedural controls to ensure authenticity, integrity, and confidentiality. All documents related to these processes should be prepared, reviewed, approved, and distributed according to written procedures. Retention periods for these documents should be specified,

with production, control, and distribution records retaining for at least one year after batch expiry, and APIs with retest dates for at least three years.[15]

7. Certificates of Analysis

A certificate of analysis is a document issued by regulatory or quality assurance entities to verify product adherence to specifications and standards, such as food and drugs. It includes test results, authentication for each batch, and lists each test performed in accordance with compendial or customer requirements. It should be dated, signed, and include the manufacturer's name.

- **Dossier preparation in CTD format, eCTD submissions**

CTD (Common Technical Document) format dossier preparation involves compiling and organizing the necessary documents and information to support the approval of pharmaceutical product. Here's a general outline of the steps involved.

1. Module 1: Administrative and Product Information
2. Module 2: Summaries
3. Module 3: Quality
4. Module 4: Nonclinical Study Reports
5. Module 5: Clinical Study Reports

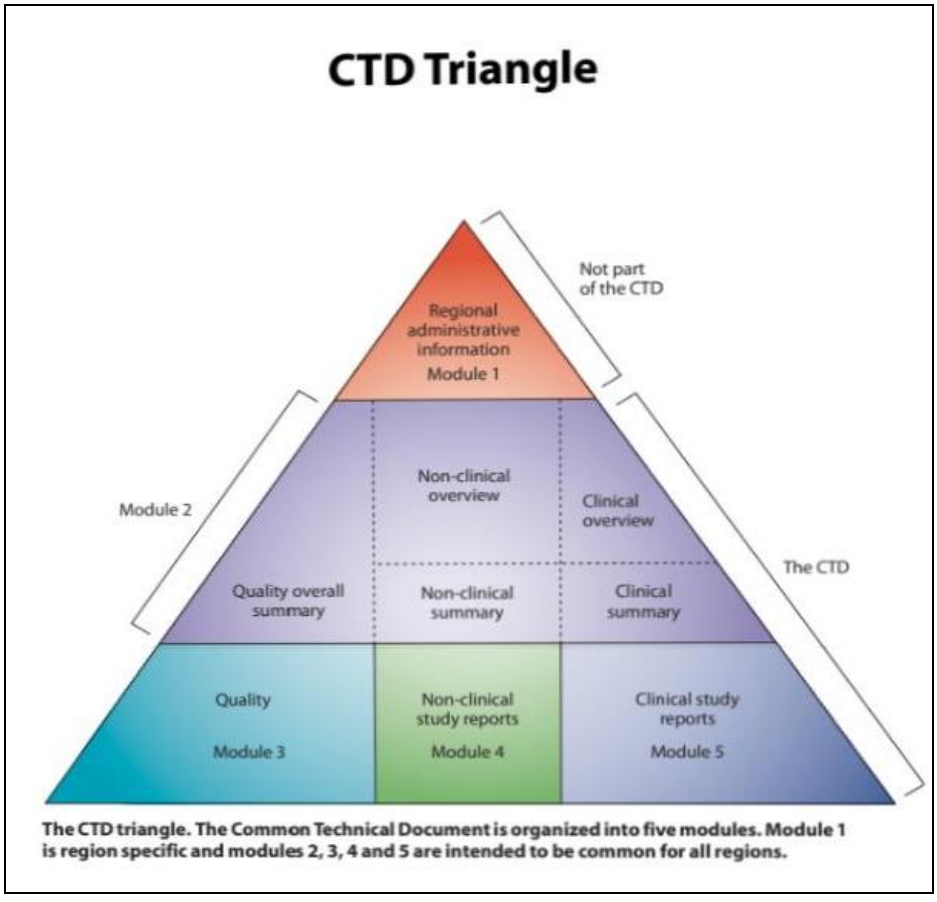

Fig No.7: CTD Triangle.[17,18]

CTD format dossier preparation requires expertise in regulatory affairs, quality assurance, and project management. It's essential to work with experienced professionals to ensure a high-,quality dossier that meets regulatory requirements[17,18]

eCTD dossier preparation

eCTD (Electronic Common Technical Document) format dossier preparation involves compiling and organizing the necessary documents and information to support the approval of a pharmaceutical product in an electronic format. Here's a general outline of the steps involved:

1. Module 1: Administrative and Product Information
2. Module 2: Summaries
3. Module 3: Quality
4. Module 4: Nonclinical Study Reports
5. Module 5: Clinical Study Reports
6. Appendices and Supporting Documents
7. XML File Creation

- Create an XML file to link and organize the electronic documents.
- Ensure compliance with ICH eCTD guidelines and regulatory requirements.

8. Validation and Quality Control

- Validate the XML file and electronic documents for accuracy and completeness.
- Ensure compliance with regulatory requirements and eCTD format guidelines.

9. Finalization and Submission

- Finalize the eCTD dossier and prepare it for electronic submission to regulatory authorities.
- Ensure timely submission and follow up with regulatory agencies as needed.

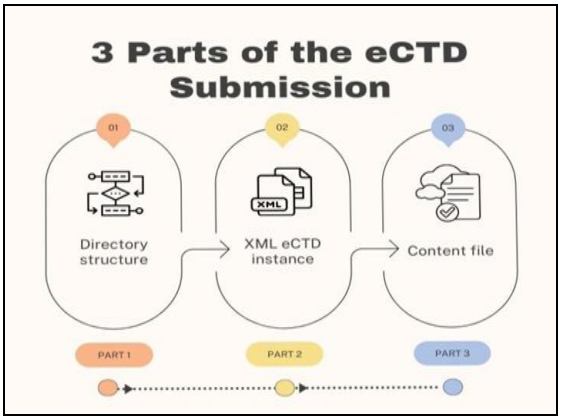

Fig. no.8: eCTD parts of submission.[17,18]

eCTD format dossier preparation requires expertise in regulatory affairs, quality assurance, and electronic publishing. It's essential to work with experienced professionals to ensure a high-quality dossier that meets regulatory requirement.[17,18]

Regulatory Compliance

Compliance Guidelines are documents outlining regulatory requirements, laws, and international standards for the quality, safety, and efficacy of pharmaceutical products, medical devices, and other health-related products.[24]

Fig no. 9: Regulatory compliance.

❖ **Government Audit**

A systematic examination and evaluation of a country's regulatory system, policies, procedures, and practices to ensure that they are functioning effectively and efficiently to protect and promote public health.

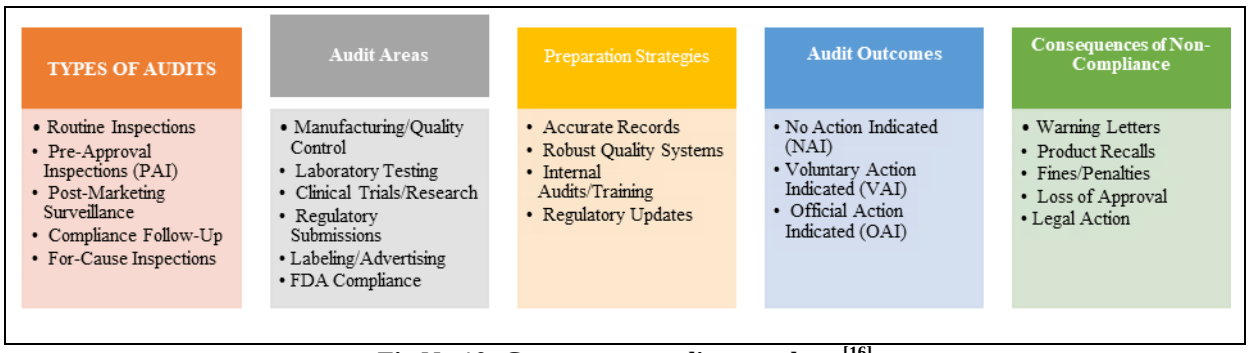

Fig.No.10: Government audit procedure.[16]

1. Government Audit in FDA

FDA pharm conducts government audits to assess pharmaceutical companies' compliance with FDA regulations, while the MHRA conducts similar audits to ensure UK and other regulatory requirements are met.

2. PMBA Government Audit

The PMBA government audit is a process that evaluates a pharmaceutical company's compliance with Japanese regulations, ensuring they adhere to Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and other regulatory requirements.

3. DCGI Government Audit

The DCGI government audit evaluates pharmaceutical companies' adherence to Indian regulations, including Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), to ensure compliance.

4. TGA Guidelines

The Therapeutic Goods Administration (TGA) guidelines are Australian regulations for the registration, manufacture, and marketing of therapeutic goods, ensuring safety, quality, and efficacy.[16]

❖ **Regulatory Requirements for biologics, Licensing and Registration, Regulation on Labeling of Biologics in India, USA and Europe**

Biologics: Biological products derived from living organisms (e.g., vaccines, blood products, monoclonal antibodies)

Table No.1: Regulatory Requirements for Biologics.[19]

Biologics	Licensing	Registration	Labeling
1. Preclinical	1. Marketing Authorization Application	1. Product Registration with regulatory agencies	1.Product name and strength
2. Clinical	2. Biologics license application	2. Establishment registration	2.Indication and usage
3. Post marketing	3. New drug Submission	3. Labeling compliance	3.Batch number and expiration date
4. Regulatory Submission	4.Clinical Trial Application	4. Brech report	4. Precaution
5. Regulatory agencies	5. IND Application	5. Certification	5. Storage

❖ **Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO**

Table no. 2: Regulatory Requirements for Registration of drugs.[20,21,22,23,24]

Drug registration	Medical device	Post approval
1. Preclinical data	1. Device classification	1. PV
2. Clinical data	2. Clinical evaluation	2. Field safety corrective action
3. Quality control/ assurance	3. Quality management system	3. Periodic performance evaluation
4. Labelling and packaging	4. Labelling and packaging	

➢ **Study of various committees across the globe**

Countries group	ASEAN	APEC	EAC	GCC	PANDRH	SADC
Regulatory Authority	Philippines – FDA Vietnam - MOH Myanmar -FDA Board of Authority	**Australia-**(TGA) **Canada-** Health Canada **Chile-** Institute of Public Health	**East African Community** Medic ines **Regulatory** H armonization	Saudi Arabia - SFDA Oman – MOH UAE –DHA	Cuba –CECMED United States- FDA Mexico- COFEPRIS	Tanzania- TMDA South Africa- SAHPRA Zambia- ZMRA
Regulatory authority Logo		APEC Asia-Pacific Economic Cooperation			PAHO	
Dossier Format	ACTD	CTD	EAC CTD	CTD/eCTD	CTD/ eCTD	CTD
Dossier language	English/ Official Native language	English	English	Arabic and English	English	English and Portuguese
COPP	Legalized	Legalized	Legalized	Legalized	Legalized	Legalized
Manufacturing license	Required	Required	Required	Required	Required	Required
Registration Validity	3 to 5 years	1-2 years	5 years	5 years	3-5 Years	2 years
Registration Time	12 months	12 months	181 working days	24 to 36 months	6 -12 months	12 – 24 months

Fig. no.11: Study of various committees across the globe.[25]

❖ GMP & Current Good Manufacturing Practices

cGMP and GMP are guidelines for manufacturing, testing, and quality assurance in pharmaceuticals, biologics, and medical devices. They emphasize risk-based approach, quality by design, and continuous improvement. Benefits include product quality, safety, and innovation, while challenges include compliance and resource management.[25]

cGMP vs GMP Table no.3[,26,27]

cGMP vs GMP		
CHARCTERISTICS	**cGMP**	**GMP**
1. COST	More expensive to implement.	Cost-friendly to implement
2. APPILCATION	Applicable in selected scenarios directly related to the manufacturing processes only.	Much broader and it goes deeper into complaints, book keeping, personnel and labeling practices and so much more.
3. USAGE	Applied to less countries as compared to GMP.	More than 100 countries have set manufacturing regulations based on GMP
4. QA	More reliable in quality assurance when compared to GMP, due to the additional use of innovative technology.	Lower quality assurance rate due to the lack of automation and use of technology in the processes, systems employed.
5. ACQUISITION	Requirements are less acquirable than GMP	GMP guidelines and requirements makes their acquisition easier.

❖ Good Automated Laboratory Practice (GALP)

Good Automated Laboratory Practice (GALP) guidelines ensure reliable and reproducible results from automated laboratory systems. GALP builds upon Good Laboratory Practice (GLP) principles, focusing on automation-specific considerations. Set of guidelines and recommendations for the automation of laboratory systems, ensuring data integrity, security, and compliance with regulatory requirements.

➢ GALP Principles

1. Data integrity: Ensure accuracy, completeness, and security of automated data.

2. System validation: Verify automated systems' performance and reliability.

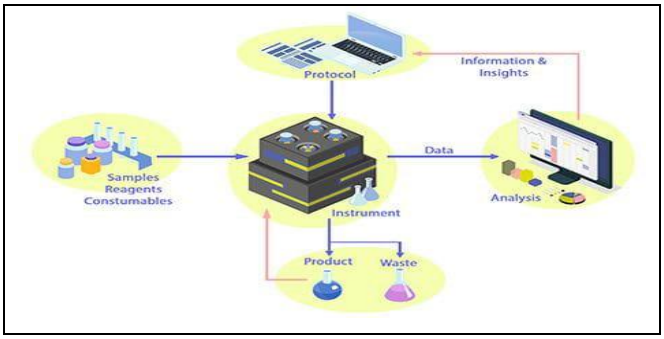

Fig.no. 12: GALP Procedure.

3. Standard operating procedures (SOP): Document and follow procedures for automated systems**.**

4. Training and competency: Ensure personnel understand automated systems and procedures.

5. Maintenance and calibration: Regularly maintain and calibrate automated equipment.

6. Data backup and recovery: Ensure data availability and recovery in case of failures.

7. Audit trails: Maintain records of system changes, errors, and user activities.

8. Compliance with regulations: Adhere to relevant regulations and standards (e.g., FDA, EPA, ISO). By adopting GALP guidelines, laboratories can ensure the reliability, efficiency, and compliance of their automated systems, ultimately supporting high-quality research and decision-making.

➢ **Objectives**

1. Understand GALP principles and procedures
2. Operate automated laboratory systems correctly
3. Maintain data integrity and security
4. Identify and report system errors
5. Implement corrective actions

➢ **General requirements for Good Automated Laboratory Practice (GALP)**

(SOP) GALP

- Security
- Raw Data
- Data Entry
- Data Verification
- Error Codes
- Data Change Control
- Data Archiving
- Backup and Recovery

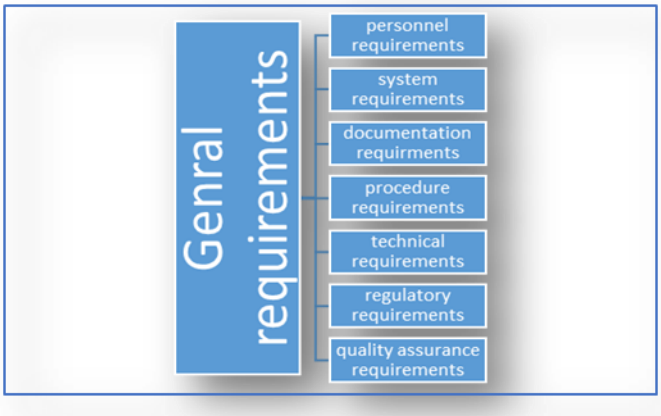

Fig. No.13: General requirements for GALP.

1. Training for Good Automated Laboratory Practice (GALP)

It ensures personnel understand and follow procedures for reliable results, including operating automated systems correctly, maintaining data integrity and security, identifying and reporting system errors, and implementing corrective actions.

2. Documentation

Documentation is a critical aspect of Good Automated Laboratory Practice (GALP). Here's an overview of the documentation requirements.

Types of Documentation:

1. Standard Operating Procedures (SOPs)
2. System documentation (user manuals, guides)

3. Validation and verification reports
4. Maintenance and calibration records
5. Audit trails and logging records
6. Change control and configuration records
7. Training records
8. User manuals
9. System architecture and design documents
10. Data management and backup procedures.[28,29,30]

Fig. No.14: 21CFR Part 11.

➢ **21 CFR Part 11**

21 CFR Part 11 is a regulation enforced by the US Food and Drug Administration (FDA) that sets standards for electronic records, electronic signatures, and system validation in industries regulated by the FDA.[24,25]

➢ **Software Evaluation Checklist**

Fig.No.15: Software Evaluation Checklist.

❖ Good Distribution Practice (GDP)

Good Distribution Practice (GDP) refers to the guidelines and standards for the proper distribution of pharmaceutical products, medical devices, and other healthcare products. GDP ensures that products are stored, transported, and delivered safely and efficiently, maintaining their quality and integrity. A set of guidelines and standards for the distribution of pharmaceutical products, ensuring their quality, safety, and integrity throughout the supply chain.

1. General Principles

The Drugs & Cosmetics Act 1940 and Drugs & Cosmetic Rules 1945 outline conditions for drug sales, distribution, and stocking. All parties involved in pharmaceutical distribution must maintain product quality and integrity. GDP principles apply to both forward and backward distribution chains. Collaboration between government, custom agencies, law enforcement, regulatory authorities, manufacturers, distributors, and patient supply entities is crucial for ensuring product safety and preventing patient exposure to spurious products. Agreements must be established with all agencies involved in storage, transportation, and distribution.

Personnel

Distribution personnel must be trained in GDP requirements and SOPs, covering product handling, safety, security, identification, and preventing spurious pharmaceutical products from entering the supply chain. Proper storage and distribution, wearing protective garments, and following hygiene procedures are essential to maintain product quality.

Documentation

Pharmaceutical distribution documentation includes written procedures, instructions, contracts, records, and data. It includes receipts, invoices, and supplier information. Clear, unambiguous documents and instructions are crucial for maintaining product quality.

Premises (Good Distribution Practice)

Premises are the physical facilities where pharmaceutical products, medical devices, or healthcare products are stored, handled, and distributed. GDP requirements include location, cleanliness, sanitation, temperature control, lighting, ventilation, secure storage, pest control, waste management, maintenance, calibration, and validation of equipment. US FDA GDP Guidelines include CGMP regulations and Guidance for Industry. Best practices include regular maintenance, monitoring, audits, and quality management systems.[29]

❖ Regulatory Intelligence (RI)

As per the World Health Organization (WHO), Regulatory Intelligence (RI) is defined as it refers to the systematic collection, analysis, and dissemination of information on regulatory requirements, policies, and practices, to support informed decision-making and compliance in the pharmaceutical, biotechnology, and medical device industries.

1. Role of Regulatory Intelligence

Regulatory Intelligence plays a crucial role in pharmacovigilance, identifying and interpreting information on medicines that may pose public health risks. It aids regulators in understanding risks, monitoring safety, making informed decisions, and protecting patients from potentially harmful medicines. Regulatory Intelligence for Pharmacovigilance (RI) supports pharmacovigilance by providing early warnings of regulatory changes, identifying knowledge gaps, and developing strategies to prevent adverse drug reactions, a significant global health concern.

2. Benefits of RI in Drug Development

1. Reduced Time-to-Market
2. Improved Regulatory Submissions
3. KiEnhanced Risk Management
4. Streamlined Clinical Trials
5. Improved Communication with Regulatory Agencies
6. Cost Saving

Regulatory Intelligence Applications

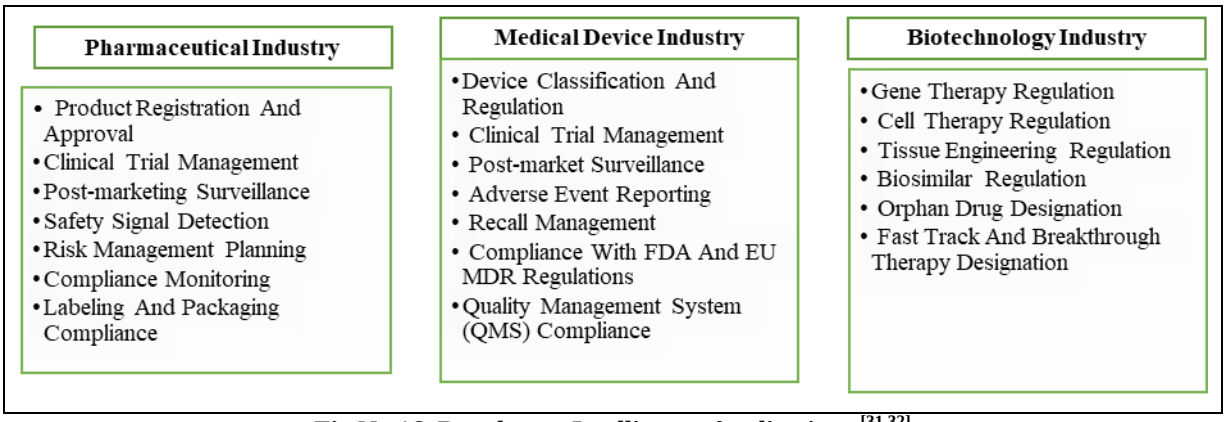

Fig.No.16: Regulatory Intelligence Applications.[31,32]

❖ **Data Integrity**

Definition: Data integrity refers to the accuracy, completeness, and consistency of data throughout its lifecycle, ensuring it remains reliable, trustworthy, and secure.

Principles

1. Accuracy: Data is accurate and free from errors.
2. Completeness: Data is complete and includes all required information.
3. Consistency: Data is consistent across different sources and systems.
4. Reliability: Data is reliable and trustworthy.
5. Security: Data is protected from unauthorized access, modification, or deletion.

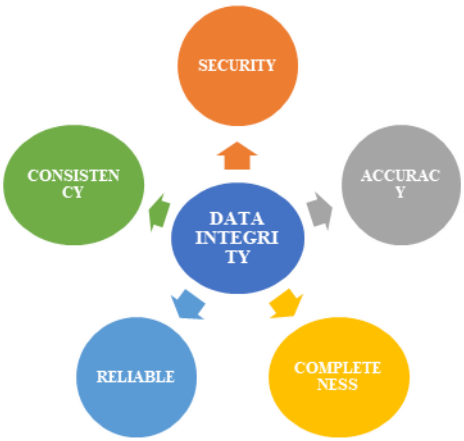

Fig.No.17: Data Integrity.

- **Tools and Technologies**

1. Data management systems
2. Electronic data capture (EDC) systems
3. Clinical trial management systems (CTMS)
4. Data analytics software
5. Data integrity monitoring tools.[38]

➢ CONCLUSION

Drug regulatory affairs crucial for safeguarding public health. By ensuring the safety and efficacy of drugs, regulatory agencies play a vital role in protecting patients and promoting access to life-saving medicines. Continuous evolution and adaptation to emerging trends will be key to maintaining the effective regulation in the future. The regulatory affairs is branch is an essential part of the organisation which shape of pharmaceutical group. However the need of the hour is more centralized procedures in drug regulation, Harmonization of regulatory norms, Strengthening the regulatory authorities. Regulatory affairs is not only the registration of drug product but they gives the practical as well as tactical knowledge to company to stand in this developing globe. Regulatory professionals works as they give proper knowledge of record keeping, data management, inappropriate scientific background to company for there growth.[40]

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