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AN OVERVIEW ON REGULATORY AUTHORITIES, AGENCIES & CTD MODULES

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Abstract :

Drugs are crucial for saving lives, preserving health, preventing diseases, halting epidemics, and boosting a nation's economy. As a result, the cost of pharmaceuticals is borne by the general public, government, pharmaceutical industry, and research institutions. However, for this to happen, the medicine must be high-quality, reliable, and safe. In order to ensure that medications are developed, produced, imported, exported, and distributed in accordance with established standards, there are regulations in place. Governments create powerful National Regulatory Authorities (NRAs) to ensure that pharmaceutical products are adequately regulated, thereby preserving and advancing public health. Global pharmaceutical rules are essential for ensuring the efficacy, quality, and safety of the medicines. Global pharmaceutical rules are essential for ensuring the efficacy, quality, and safety of the medicines. The responsibility for enforcing laws and issuing guidelines for medication development, licensing, registration, production, labelling, storage, marketing, distribution, drug pricing, import, and post-marketing research on pharmaceutical products falls on the shoulders of the pharmaceutical regulatory agency. Pharmaceutical businesses that are interested in the global market must adhere to the various regulatory requirements of other nations' pharmaceutical laws. It is challenging to develop a single regulatory strategy for a drug product's Marketing Authorization Application (MAA) that is relevant to numerous nations. As a result, the Common Technical Document (CTD) was created to offer a standard structure for electronic filing of applications for the registration of pharmaceuticals. An overview of the pharmaceutical regulatory bodies of three nations is provided in this review article.

Index Terms: CTD, Regulatory, Marketing, Pharmaceuticals, FDA, Clinical

Introduction :

A job in regulatory affairs (RA) involves working in regulated fields such pharmaceuticals, medical devices, veterinary medicine, cosmetics, and other related fields. Gathering, assessing, documenting, and disseminating risk assessments and benefits of healthcare goods to regulatory bodies and the general public around the world are the fundamental responsibilities of the regulatory affairs profession. All medications must be of the highest quality possible and be safe and effective. The scientific and legal components of the New Drug Application (NDA), Investigated New Drug Application (INDA), and Market Authorization processes are all included in the dynamic field of regulatory affairs. Drug marketing and development are the focus of the Drug Development to Marketing Application (MAA). Due to recent scientific and technology breakthroughs, regulatory affairs now saves data like eCTD and CTD in various regulatory software that is accessible online, like Pharma. Freyr Global's regulatory solution and service, which consists of master control registration, eCTD and eDMS submission software, is prepared. The Food and Drug Administration (FDA), Therapeutic Goods Administration (TGA), Central Drug Standard Control Organization (CDSCO), and European Medicines Agency are a few examples of well-known regulatory agencies (EMEA). Currently, the pharmaceutical industry is very organized, methodical, and in compliance with all international regulatory standards for the production of chemicals, biological drugs, medical devices, traditional herbal products, and cosmetics for both humans and animals.

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Role of Regulatory Affair Department :[2-3]

The pharmaceutical industry's regulatory affairs (RA) division is in charge of securing approval for new pharmaceutical drugs and ensuring that approval is upheld for as long as the company chooses. Regulatory affairs practitioners, also referred to as regulatory professionals, are in charge of the following areas: ensuring that their companies follow all relevant rules and laws. A regulatory affairs specialist is in charge of acting as a point of contact for regulatory bodies. Make sure all applicable CGMP, ICH, GCP, and GLP rules, laws, and regulations are followed.

Role of Regulatory Affair in Product Management :

The primary responsibility of RA professionals extends beyond the registration of products; they provide the highest degree of strategic and technical advice to businesses. Their responsibility extends from product development to production, marketing, and post-marketing tactics. Companies are able to produce products more quickly and more affordably by following their guidance at all stages about the technical and legal requirements. The World Health

Organization's guidance on health issues and the World Trade Organization's rules on international trade are adopted by governments without their own legislation.

Role of Regulatory Affair in Clinical Trails :

The RA professional serves as the company's main liaison with international regulatory organizations including the UK's Medicines and Healthcare Products Regulatory Agency and the US Food and Drug Administration's Centre for Devices and Radiological Health.

Role of Regulatory Affair in R& D :

Additionally, he conveys and interprets to the other firm divisions the seemingly unending maze of rules, regulations, and norms. The RA staff creates methods to avoid delays and communicates the results of clinical trials to the regulatory agencies in order to gain speedy clearance and shorten the time it takes for new molecules to be approved. Fundamentally, a RA professional helps regulatory authorities, healthcare systems, and the general public gather, analyze, and communicate information on the risks and benefits of health products. Operationally, RA is in charge of ensuring that diverse stakeholders understand and take into account governmental obligations, market-driven demands, and emerging scientific conventions.

Role in Gathering Information :

The team in charge of regulatory affairs collaborates closely with marketing and R&D to create cutting-edge goods that speed up time to market by using recent regulatory and technological advancements. Small reductions in time to market translate into major material increases in revenue and profit since new goods are anticipated to significantly boost the bottom lines of the organization. Utilizing flexible clinical trial methodologies, securing swift regulatory approval, and avoiding process problems can hasten the development of novel drugs and help to minimize expensive errors and time lags.

Roles in Communicating Information :

Non-critical information is the simplest type of information to exchange and discuss. The biggest challenge with such knowledge is reaching the appropriate audience without boring them to the point when they stop realising they are learning something helpful. Most businesses use email to receive internal regulatory information updates or subscribe to news updates. One approach is to make them entertaining and practical.

The information that is challenging to explain is critical information. This could refer to anything crucial to a project's success or failure, such as specific and significant FDA input. To properly comprehend the information and its ramifications, we must first thoroughly document it. Then consider those people who both "need to know" and "know who else needs to know." In a small sector, the CEO or the president should handle it, but in larger businesses, the head of clinical or a project manager should.

Worldwide Regulatory Agencies :[4,5]

Country Name	Regulatory Agencies
India	Central Drug Standard Control Organization (CDSCO)
Australia	Therapeutic Goods Administration (TGA)
Europe	European Medicines Agency (EMA)
USA	Food and Drug Administration (FDA)
Canada	Health Canada
China	National Medicines Products Administration (NPMA)
Japan	Ministry of Health ,Labor &Welfare (MHLW)
Italy	Italian Medicine Agency(IMA)
South Africa	Medicine Control Council
U.K	Medicines and Healthcare Products Regulatory Agency
Singapore	Health Sciences and Authority
Netherlands	Medicines evaluation Board
Russia	Ministry of Health and of the Russian federation
Spain	Spanish Medicine Agency
Ukraine	Ministry of Health
Uganda	National Drug Authority
Bulgaria	Bulgarian Drug Agency
United Kingdom	Medicine and Healthcare Regulatory Agency (MHRA)
Sri Lanka	State Pharmaceutical Corporation
Uganda	National Drug Authority

CDSCO : Drug regulatory agency of India[5]

The National Regulatory Authority (NRA) in India is the Central Drugs Standard Control Organization (CDSCO). This is a part of the Directorate General of Health Services of India's Ministry of Health and Family Welfare. The FDA Bhawan, Kotla Road, New Delhi 110002 serves as the organization's main office, while thirteen port offices, six zonal offices, four sub-zone offices, and seven laboratories are dispersed across the country.

In order to achieve uniformity in the application of the 1940 Drug and Cosmetic Act, CDSCO is in charge of approving drugs, conducting clinical trials, creating drug requirements, observing the quality of drugs imported into the nation, and coordinating the activities of State Drug Control Organizations.

Vision :

To protect and promote the public health in India .

Mission :

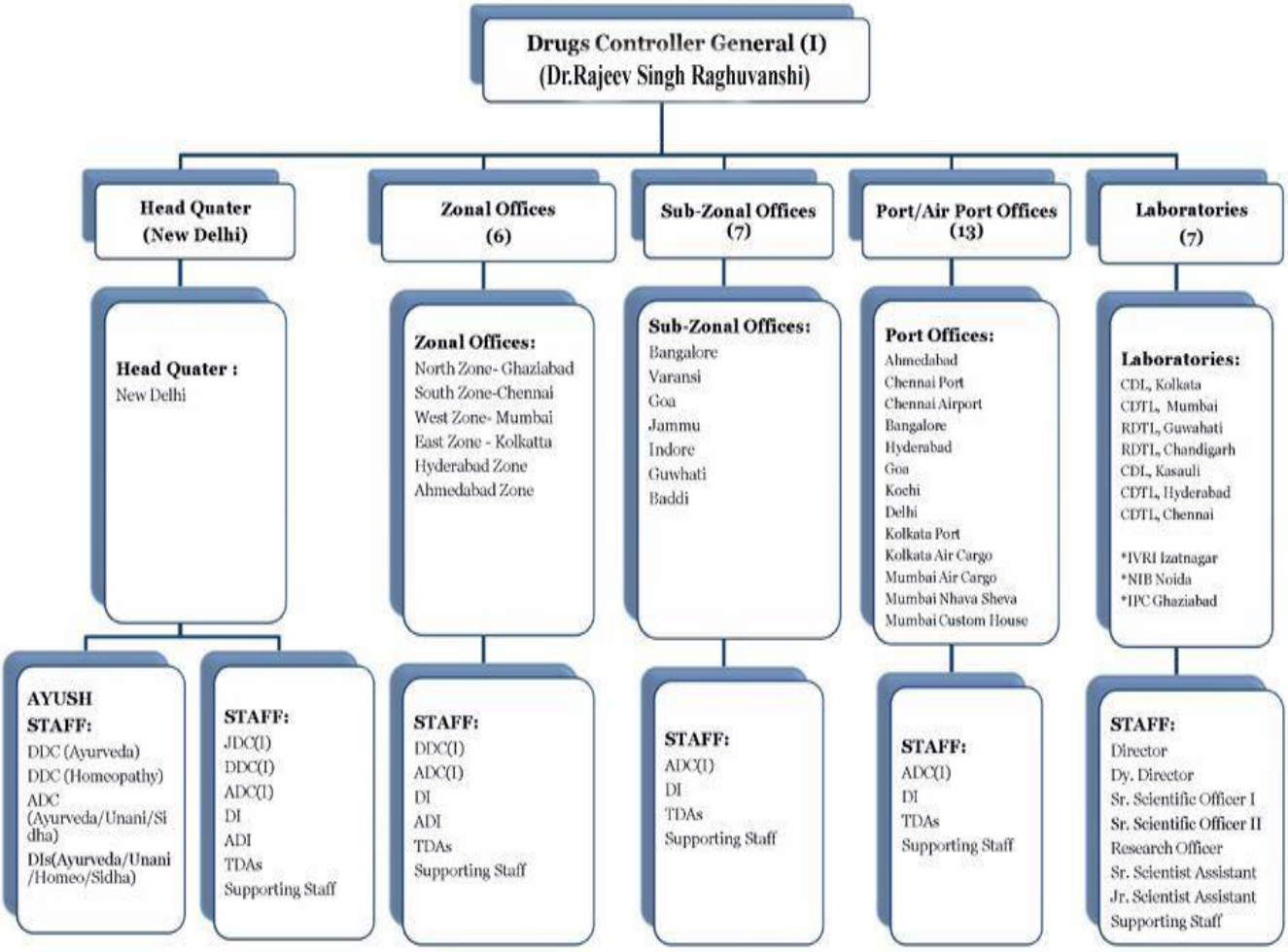
To ensure the safety ,efficiency and effectiveness of drug, medicine, cosmetics and medical devices in order to protect and improve the public health .

CDSCO's key responsibilities :

The CDSCO administrative center oversees the regulation of drug imports, the authorization of new products and clinical trials, meetings of the Drugs Consultative Committee (DCC) and Drug Technical Advisory Board (DTAB), as well as the granting of licenses by the central License Approving Authority.

Under the Drug and Cosmetics Act, state authorities are primarily in charge of regulating the production, sale, and distribution of medications, while central authorities are in charge of approving new medications, carrying out clinical trials within the nation, establishing drug standards, checking the quality of imported medications, and coordinating the efforts of State Drug Control Organizations. Licensing decisions for particular drug categories, such as blood and blood products, intravenous fluid, vaccinations, and sera, are made by the Indian Drug Controller General.

Organization of CDSCO :



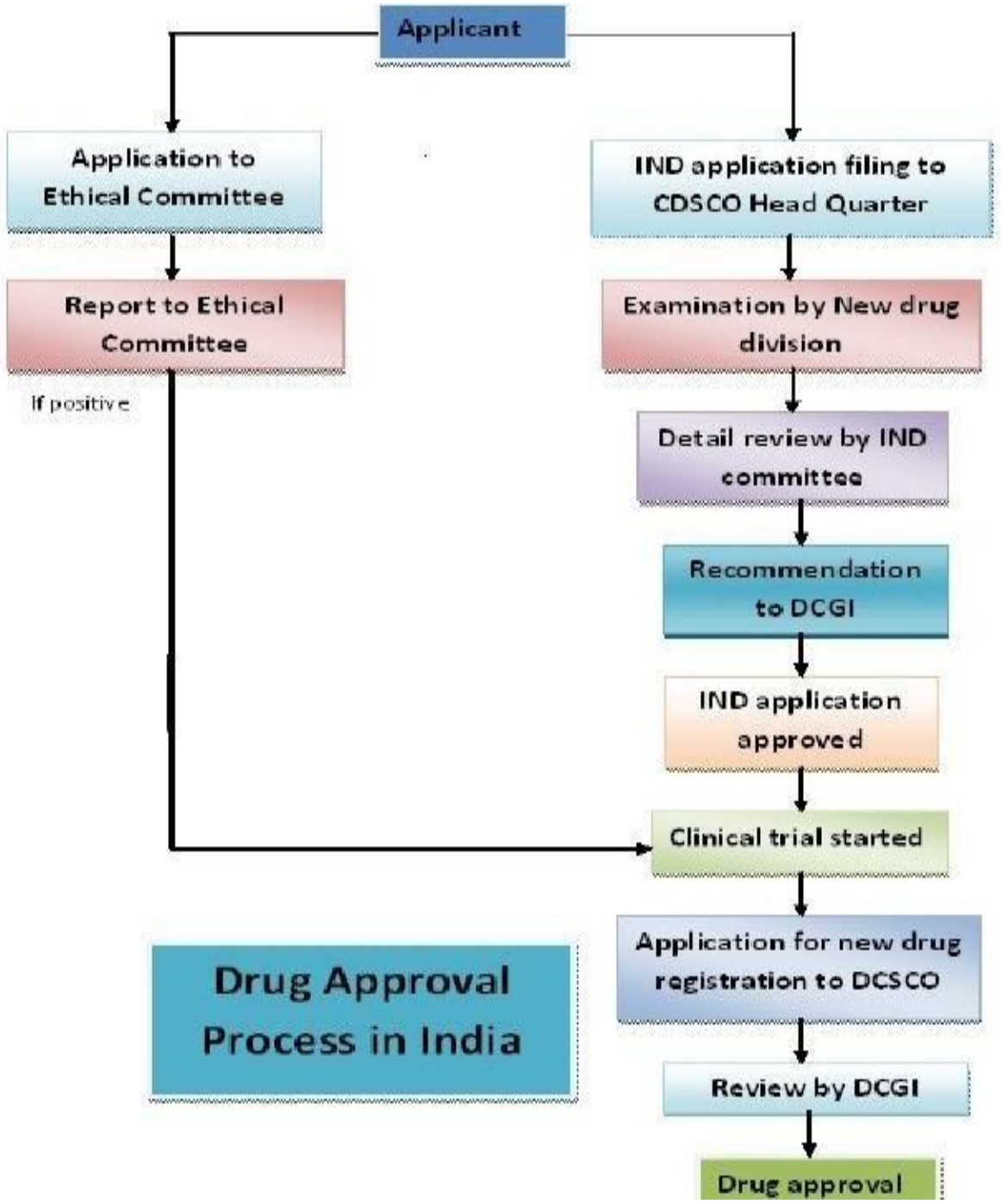
Function of CDSCO :[6]

- Approval of new drugs and clinical trials .
- Amendment of D&C Act and Rules.
- Import Registration and Licensing .
- Banning of drugs and cosmetics .
- Grant of test license ,Personal License , License for export of drugs.
- Testing of new drugs comes to the market.
- Oversight and market surveillance through inspectorate of center and state authority.
- License approving for blood product and medical devices .

Drug approval process in India

The company must fill out Form 44 and submit the required information in accordance with Schedule Y of the D&C Act 1940 in order to get approval from the licensing authority (DCGI) for the manufacture or import of a new medicine. The Indian medication approval procedure is depicted in Fig. 1. Clinical trials are carried out in accordance with the Schedule Y requirements, and the report is submitted in the designated format, to demonstrate the efficacy and safety of an imported medicine in the Indian population. When the application is deemed appropriate, DCGI authorizes.[7]

Flow chart of drug approval process in India [7]



Schedule Y of D &C Act 1940 and Rules 1945 :

- According to section 2.4(a) of Schedule Y All phases of clinical trials must be conducted for drug compounds identified in India.
- According to section 2.4 (b) of Schedule Y, if a drug substance is identified in a foreign country, the applicant is required to present the data that is available from that country. The licensing authority may then ask him to repeat all of the studies or may allow him to move on to Phase III.
- According to Schedule Y's Section 2.8 The licensing authority may need Pharmacokinetic studies (Bioequivalence studies) in order to verify that the data generated in the Indian population is equivalent to the data generated abroad before requiring him to move on to Phase III.

Drug approval process in USA

Individual vaccines, including those using blood and blood derivatives, cellular and gene therapy products, and tissues and organ allergies The world's tightest rules for drug approval are found in the United States. American drug approval standards are very strict. Many people believe that certain countries are the most challenging in the world. A new era in American drug regulation began with the passage of the United States Drug Act in 1820. The creation of the US Pharmacopoeia was decided. In 1906, the first Food and Drug Act was passed by Congress, requiring that medicines meet set standards for strength and purity.

The Federal Food, Drug, and Cosmetics Act (of 1938) and the Sulfanilamide Tragedy, which included additional requirements for the approval of new pharmaceuticals (medicines), were however passed as a result of the Great Depression in 1937.Prior to marketing, safety has to be proven.

vaccines for people, including those using blood and blood derivatives, cellular and gene therapy products, and allergens found in tissues and organs. The two stages of the FDA's new medicine approval process are as follows: Clinical Trials (CT) and New Drug Application (NDA) approval from the United States. The new drug product is controlled by a new drug application. NDA (National Defense Authorization Act), an agreement prohibiting disclosure. Such applications are now accepted for analysis in eCTD. Once an application for an investigational new drug (IND) has been submitted to the FDA, the approval process can begin. The United States has strict drug laws and regulations. To establish a standard for drug strength and purity, the United States Pharmacopoeia (USP) was established in 1820.

An important turning point in the development of US drug policy is the Food and Drugs Act (1906). It says that medications must meet specific requirements. The 1938 Food, Drug, and Cosmetic Acts It was then put into effect. The sulfanilamide disaster happened to show the safety of a medicine before it is licenced.It's been promoted.

The Kefauver-Harris Amendment was adopted in 1962. It was relocated after the catastrophe with thalidomide. Manufacturers of pharmaceuticals must demonstrate that their product is reliable and safe. Every business ought to convey a negative message. The communication has been delivered to the FDA. Tax deductions are permitted under the 1973 Orphan Drug Act for drugs deemed to be rare. Orphan drug development is being worked on by businesses.

Arrests made in accordance with the 1992 Generic Drug Enforcement Act are at issue. Convictions connected to the ANDA authorization (1902) are covered by the generic drug control Act. The FDA Modernization Act of 1997 (FDAMA) has undergone a number of modifications. The production and distribution of food, drugs, and cosmetics are regulated under the Food, Drug, and Cosmetics Act.

Food and Drug Administration :[8]

A division of the U.S. Department of Health and Human Services is the Food and Drug Administration (FDA). It has six product centers, one center for research, and two offices. The Centre for Drug Evaluation and Research (CDER) makes ensuring that medicines that improve peoples' health are accessible and safe. The FDA has 3 duties according to the Food and Drug Modernization Act.

- To ensure that foods and medications are safe and appropriately marked;
- To enhance health by examining research and new product approval;
- To collaborate with other nations to lighten the regulatory burden

Investigational New Drug (IND) Application :[9-11]

Preclinical studies are conducted once a medicine is discovered, and the results are presented. If the medicine is deemed safe, the drug developer (or sponsor) submits an IND application to the FDA to start human volunteer clinical trials. Applications for INDs must include details about the toxicological tests and animals used for pre-clinical research, as well as information about the trial's composition, manufacturer, stability, and clinical protocols. The clinical trial investigators can deliver a medicine to numerous study locations across the US after their IND application has been approved. The underlaying figure illustrates the procedure for approving an IND application. To discuss topics including the design of animal research, the expected study methodology for carrying out the trials, and chemistry, manufacturing & control of the IND, a pre-IND meeting can be scheduled with the FDA. Such a conference will assist the pharmaceutical company in planning animal testing, gathering data, and developing the study protocol in accordance with FDA guidelines. Applications for investigational new drugs (INDs) can be divided into three categories: investigator, emergency, and treatment.

The Investigator IND : A doctor will occasionally submit an investigator IND application on behalf of an institution or sponsor. Before beginning any clinical studies, the investigator must wait at least one month after submitting an IND application. Phase-I clinical trials may begin within that time frame if the FDA has no objections.

Treatment IND : Treatment Prior to the end of the study, FDA evaluation, and ultimate approval, IND applications are submitted to get authorization to use an experimental novel drug that has shown promise in clinical studies. These are also known as INDs with expanded uses .

The Emergency IND : This application request for FDA approval to utilize a experimental drug in an emergency when there is no sufficient time for following a standard IND process .

Flow chart of IND Application[11]

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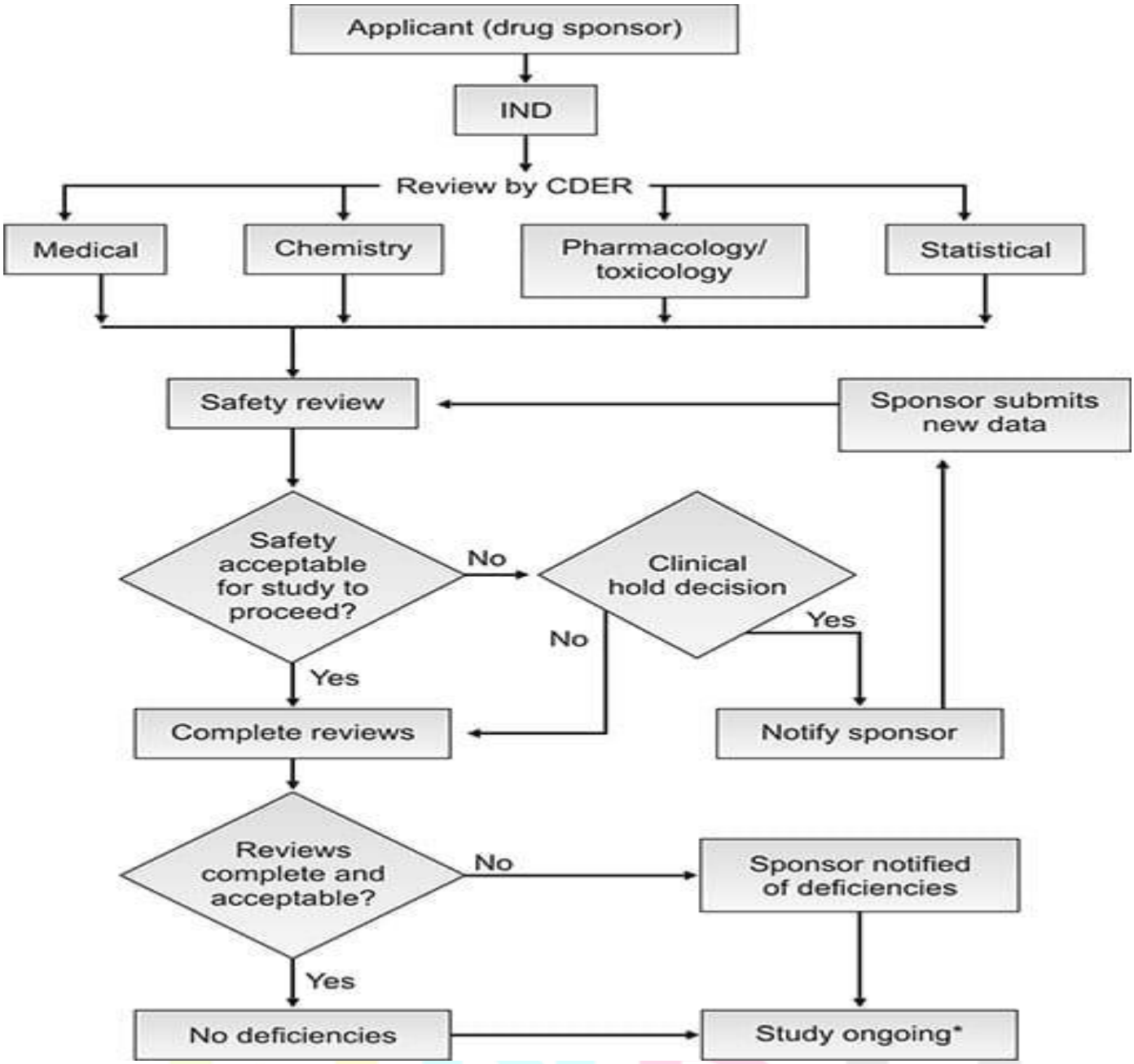


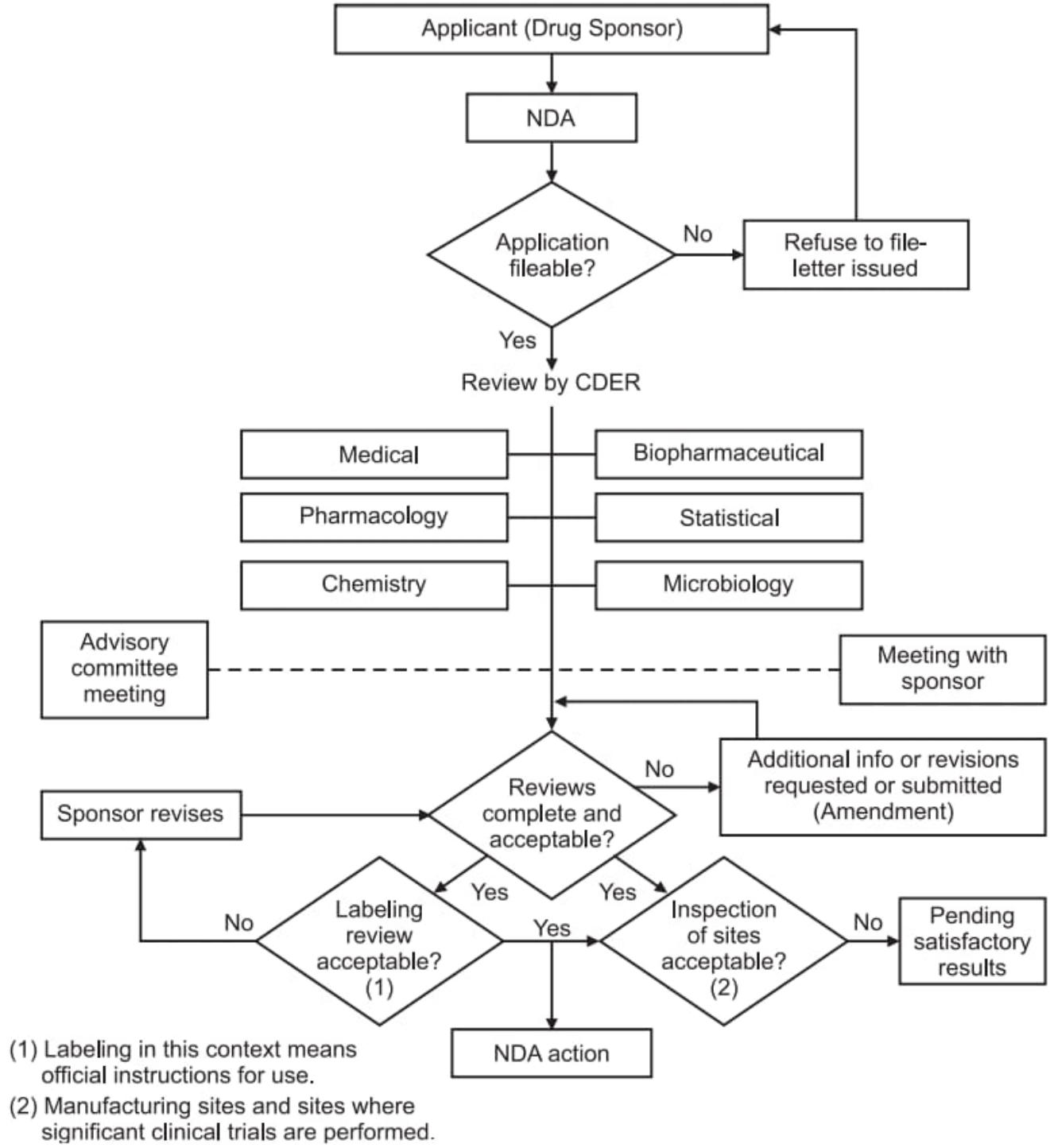
New Drug Application (NDA) :[11]

If the clinical tests show that a new drug is both effective and safe (with no side effects that are harmful or unintended), the manufacturer files an NDA. The request itself is to manufacture and market the medicine in the US. NDA is presented in accordance with FD&C Act 505(b). NDA requests are made for:

- New molecular entity (NME)
- New formulation of previously existing approved drug .
- New combination of multiple drugs .
- New indication for existing drug .

All information on the drug, the manufacturing process, the facilities, quality control & assurance, the product description, packing, and labelling must be included in the NDA application. Clinical data will be evaluated, drug samples tested, manufacturing facilities audited, and labelling will be reviewed by FDA officials. Within 180 days of receiving an application, the FDA reviews it. The approval process for NDA applications is shown in Fig. 3. In the event that the FDA rejects the NDA, it responds with a letter outlining particular shortcomings and suggestions for the applicant to improve the application. Applicants who are rejected may ask for a hearing. The applicant may manufacture and market the medicine upon NDA clearance.22

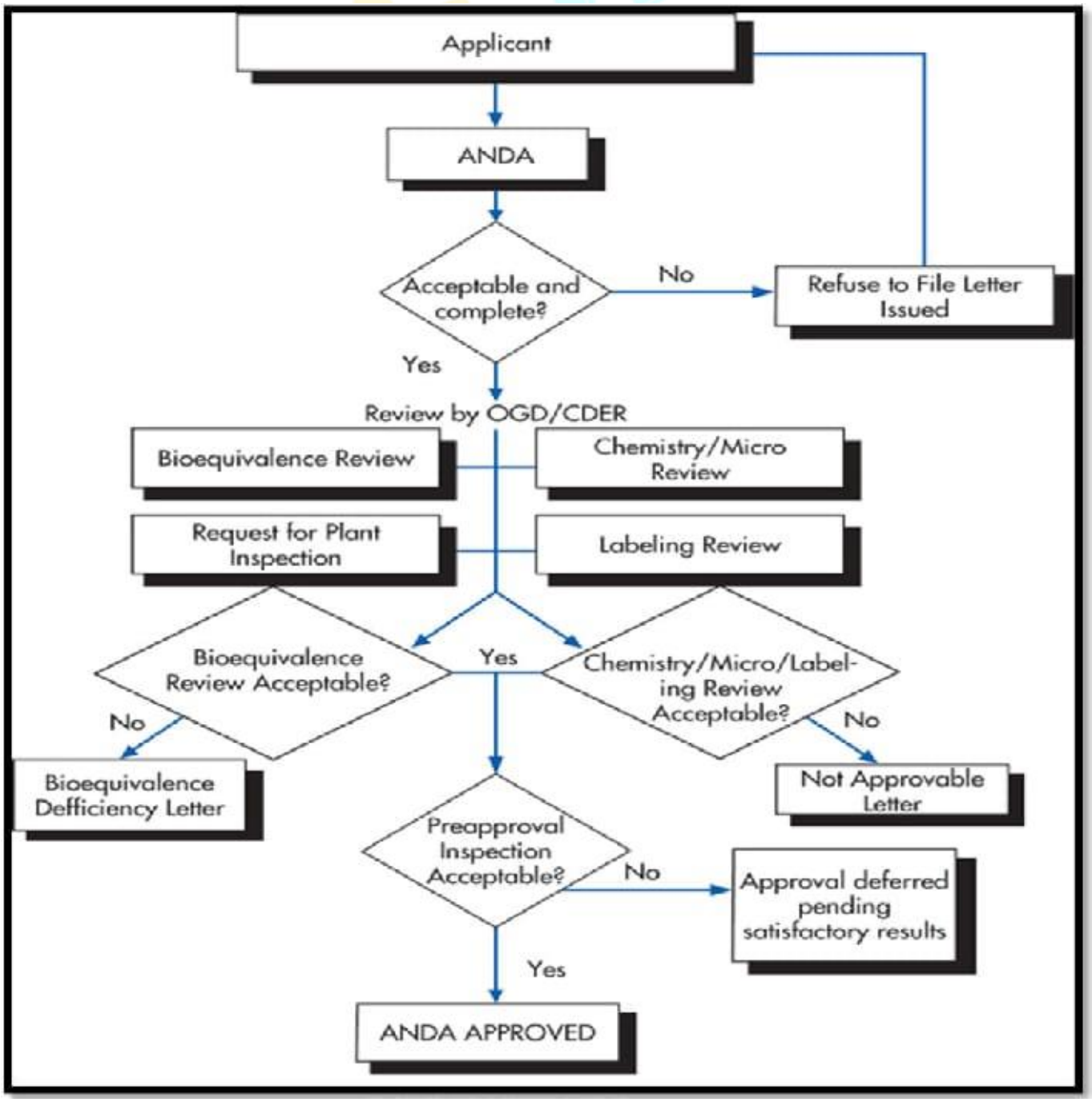
Flow chart of new drug application[11]



Abbreviated New Drug Application (ANDA) :[11-12]

An ANDA is an application submitted for a generic medicine product's approval. The original/brand-name drug product's clinical trials did not have to be repeated by the sponsor. Instead of doing this, generic medicine producers must demonstrate that their product is bioequivalent to a brand-name product that has already received approval. The generic drug applications are therefore known as "abbreviated" applications. ANDA is submitted in accordance with FD&C Act 505(j). Generic pharmaceuticals that require an authorised and listed NDA (often referred to as the Reference Listed Drug) are subject to ANDA submissions. Five years after the NME's approval date, an ANDA cannot be submitted. In order to offer the public a safe, efficient, and more affordable alternative medicine after receiving approval, an applicant may create and market the generic drug product.

Flow chart of ANDA



Supplemental New Drug Application (SNDA) :

Any significant changes to the terms outlined in the applications must be acknowledged by filing a new NDA or ANDA after the NDA or ANDA has been approved. A supplemental NDA or ANDA that incorporates revisions like new packaging or ingredients requires CDER approval. Since they need less resources to analyse, new-uses approvals of previously approved treatments fall under this category. These approvals represent a better breakthrough than new-uses approvals of previously approved drugs. The requirement for permissions is new.

Common Technical Document (CTD) :

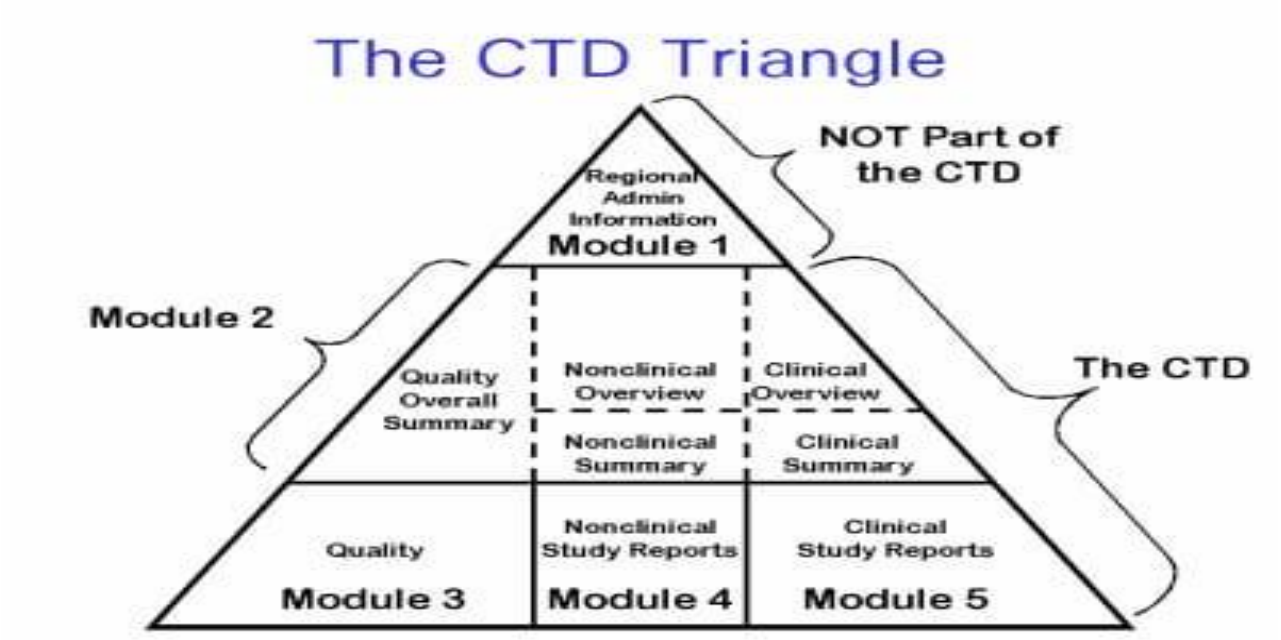
A set of application specifications for the registration of medications and designs that may be used in Europe, the US, and Japan are known as the common technical documents (CTD). It is a widely used method for creating applications for new medications that are submitted to local regulatory agencies in the participating nation.

The European Medicines Agency (EMA), the Food and Drug Administration (FDA), and the Ministry of Health, Labor, and Welfare in the United States (MHLW, Japan) have joined forces to create CTD. The International Council on Harmonization (ICH) keeps the CTD informed of any changes to the technical specifications for pharmacological authorization for human use. The CTD format is often used to arrange technical requirements before submitting them to regulatory bodies.[13]

Objective of CTD :

- Reducing the time required and resources used to compose application .
- It help in producing electronic submission of application.
- Facilitation of regulatory information exchange .

Overall organization of CTD :



Modules of CTD it can be organized into 5 Modules:

- **Module 1** : Administrative and prescribing information
- **Module 2** : The overall CTD summaries
- **Module 3** : Quality Data
- **Module 4** : Nonclinical study reports
- **Module 5** : Clinical study reports

The format should be easily visible and intelligible, for example, the font size should be 12, the font style should be Times New Roman, and the page layout should be A4 for the EU and Japan and 8.5 x 11 for the US. The left hand margin ought to be sufficiently wide, and the information shouldn't be obscured or ambiguous after binding.

- The common technical document are must be acceptable by the regulatory authority.
- The reviewer can be easily review the document.
- The submitted document should be properly signed with dated.
- As per regulatory guidelines of the country document should be labelled.
- To avoid the application being rejected or receiving questions, which would slow down the review process and delay approval, all necessary documents should be submitted in accordance with the checklist.
- It is important to appropriately mention and include supporting documentation when justifying certain tests.
- Before shipping, the prepared dossier must be examined and validated for errors.
- All study reports must be included in the clinical study report according to module 5 of the CRF.
- Some of the approved nations want validation certificates.
- If there are any modifications in any batch, these should be explained.

Module 1 : Administrative and Prescribing information

It is not a part of CTD; rather, it is region-specific. It provides both administrative and prescription information. This document has information relevant to each location, such as an application form and suggested label usage. information in general about module 1.

- It give general information about covering letter and content.
- provides administrative details, such as a summary of the application company. presents the properly filled-out and signed application on Form 44 along with the Treasury Challan. In addition to the previously mentioned documents, it also provides legal and crucial documents such as copies of clinical trial/BE, no objection letters from the CDSCO, and batch release certificates that can be issued by national regulatory authorities, for example, for the production and marketing of finished goods. For instance, a copy of the manufacturing licence that is currently in effect in Forms 25 and/or 28, a copy of Form-29, a certificate of analysis, and coordinates linked to the application.
- gives broad information about completed pharmaceutical items.
- The regulatory status in various nations is provided, as well as the internal pricing of the final drug product in each nation.
- It may also offer a succinct description of the manufacturer's research endeavors.
- It can also give a brief overview of a manufacturer's commercial operations in the domestic and foreign markets.

- It also gives information on the experts' contributions. It provides details on advertising materials and drug product samples.

Module 2 : CTD Summaries

Content of Module :-

Module 2 contains seven sections that should be maintained in the following order -

- Table of content
- Introduction of pharmaceuticals with pharmacological class ,mode of action ,clinical used.
- Overall Quality Summary
- Non clinical overview
- Clinical overview
- Non clinical Summaries
- Clinical summaries

Non clinical Overview :

This is the imputation of non clinical findings for protective use of pharmaceuticals.

- GLP statement about the pharmaceuticals.
- Overview of non clinical testing strategy.
- Pharmacology
- Pharmacokinetics
- Toxicology
- Conclusion
- List of literature References

Clinical Overview :

An summary of the clinical data that were analyzed can be found in the clinical overview. It also offers a succinct summary of the most recent clinical discoveries. analyses the advantages and disadvantages of the medication when used as intended.[14]

- Product Development Rationale.
- Overview of Biopharmaceutics.
- Overview of Clinical Pharmacology
- Overview of Efficacy
- Overview of Safety
- Benefits and Risks Conclusions
- Literature References

Non clinical Summaries :

It is possible to write and tabulate the non-clinical summary. It provides a summary of the pharmacokinetic, pharmacological, and toxicity investigations with in-vivo and in-vitro, species, route, and duration, as well as effects related to the right age and gender.

Clinical Summaries :

This section aims to give a thorough, factual summary of all the clinical information in the CTD, including information from clinical study reports, data from any analyses for which full reports have been included in Module 5, and post-marketing information for goods that have been marketed in other areas.[15]

The clinical summaries includes –

- Biopharmaceutic Studies and Associated Analytical Methods.
- Clinical Pharmacology Studies
- Clinical Efficacy
- Clinical Safety
- Literature References
- Synopses of Individual Studies

Module 3 – Quality Data

A comparable structure and format for presenting the chemical, manufacturing, and control (CMC) information in the registration dossier are provided by this module's quality part of common technical papers (M4Q).

This includes –

- Table of content
- Body of data
- Literature references
- Body of data
- Drug Substance
- General Information
- Nomenclature
- Structure
- General Properties
- Manufacture
- Manufacturer Details
- Description of Manufacturing Process and Process Controls
- Control of Materials Control of Materials
- Controls of Critical Steps and Intermediates

- Process Validation and/ or Evaluation
- Manufacturing Process Development
- Characterization
- Elucidation of structure and other Characteristics
- Impurities
- Control of Drug Substance
- Specification of Drug Substance
- Analytical Procedures
- Validation of Analytical Procedures
- Batch Analyses
- Justification of Specification
- Reference Stand Reference Standards or Materials or Materials
- Container Closure System
- Stability
- Stability Summary and Conclusions
- Post-approval Stability Protocol and Stability Commitment
- Stability Data
- Drug Product
- Description and Composition of the Drug Product
- Pharmaceutical Development
- Components of Drug Product
- Drug Product Drug Product
- Manufacturing Process Development
- Container Closure System
- Microbiological Attributes
- Compatibility
- Manufacture
- Manufacturer
- Batch Formula Batch Formula
- Description of Manufacturing Process and Process Controls
- Controls of Critical Steps and Intermediates
- Process Validation Process Validation and /or Evaluation
- Control of Excipients
- Specifications
- Analytical Procedures Analytical Procedures
- Validation of Analytical Procedures
- Justification of Specifications
- Excipients of Human or Animal Excipients of Human or Animal Origin
- Novel Excipients

- Control of Drug Product
- Specification of Drug Product
- Analytical Procedures Analytical Procedures
- Validation of Analytical Procedures
- Batch Analyses
- Characterization of Impurities
- Justification of Specification
- Reference Standards or Materials
- Container Closure System
- Stability
- Stability Summary and conclusion
- Post-approval Stability Protocol and Stability Commitment
- Stability Data

Module 4 : Non clinical Study Repots

Module 4 presents the non clinical reports (pharmaco-toxicological data) relevant to the application . The structure and content of module 4 is specified in ICH M4S guideline. This contains –

- Table of contents
- Study Reports
- Pharmacology
- Primary Pharmacodynamic
- Secondary Pharmacodynamic
- Safety pharmacology
- Pharmacodynamic drug interaction
- Pharmacokinetics
- Analytical Methods and validation Reports
- Absorption
- Distribution
- Metabolism
- Excretion
- Pharmacokinetic Drug Interactions
- Other Pharmacokinetic studies
- Toxicology
- Single-dose toxicity dose toxicity
- Repeat-dose toxicity
- Genotoxicity
- Carcinogenicity
- Reproductive and developmental

- Local tolerance
- Other toxicity studies other toxicity studies
- Literature References

Module 5 : Clinical study report

Module 5 describes the clinical report about the pharmaceuticals .The structure and content of module 5 is specified in the ICH M4E guidelines .

- Tabular Listings of All Clinical Studies
- Clinical Study Reports
- Bioavailability (BA) study Reports
- Comparative BA and Bioequivalence study reports
- In-vitro In-vivo Correlation study reports
- Reports of Bioanalytical and Analytical methods
- Plasma Protein Binding Study
- Reports of Hepatic metabolism and Drug Interaction Studies
- Reports of Studies Using human Biomaterials
- Healthy Subject PK and Initial Tolerability study reports
- Patient PK and Initial Tolerability study reports.
- Intrinsic Factor PK study reports
- Extrinsic Factor PK study reports
- Population PK study reports
- Healthy subject PD and PK/PD study reports
- Patient PD and PK/PD study reports
- Study reports of controlled clinical studies
- Study reports of uncontrolled clinical studies
- Reports of Analyses of data from more than one study
- Other clinical study reports
- Reports of Post-Marketing Experience
- Case report forms and Individual patient listings
- List of Key Literature References

Conclusion :

One of the sectors with the most regulation is the pharmaceutical industry. Around the world, regulatory governing bodies (authorities) have been established to guarantee that drugs intended for human use meet the highest standards of quality, efficacy, and safety. FDA, TGA, CDSCO, EMEA, and others are a few examples. In order to ensure that the joint efforts of the drug development team result in a product that is accepted by regulatory bodies, regulatory affairs' responsibility is to establish and implement regulatory strategies. Drug regulatory issues, such as NDA, INDA, and ANDA, are a dynamic field that include both the scientific and legal aspects of drug development.

Regulatory affairs professionals help the company avoid issues like sloppy record keeping, poor quality control, and other issues by enforcing SOPs, ICH standards, and WHO-GMP recommendations.

Presentation of the evidence and flawed scientific reasoning. Since the effective acceptance of any new pharmaceutical product, new molecular entity, takes between 10 and 15 years and entails a sizeable amount of time and money, regulatory affairs plays a crucial part in all aspects of drug regulations.

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