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A REVIEW ON: OVERVIEW OF CTD AND ECTD FOR REGISTRATION OF PHARMACEUTICALS

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Abstract: The United States has the biggest pharmaceutical market in the world. Common Technical Documents (CTDs) are required in the European Union (EU), Japan, Canada, Switzerland, and Australia, and are recommended in the United States, according to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). An electronic version known as the Electronic Common Technical Document (ECTD) was created concurrently with the CTD. Currently, the US, Europe, and Japan accept ECTD filings. The ECTD offers advantages over the CTD in terms of user-friendliness, archiving, and managing registration information throughout its lifecycle. For both clinical and nonclinical studies, the ECTD definition specifies the folder and content structures as well as the XML backbone and Study Tagging File. Considerations for ECTD documentation design include document granularity, templates, shell documents, and filing regional variations. An Integrated Summary of Safety and an Integrated Summary of Efficacy, for example, are mandated in the United States. The CTD offers a universally recognized structure that is internationally harmonized, removing the need to create distinct registration dossiers for distinct regulatory bodies. It is divided into five modules: Module 1 is peculiar to a particular region, whereas Modules 2, 3, 4, and 5 are meant to be shared by all regions. There is a regional component in Module 3. Pharmaceutical businesses can submit applications to regulatory agencies such as the FDA without changing the data by using the ECTD format. These days, the US, Japan, the EU, and Canada all make extensive use of it.

Index Terms **-** CTD, eCTD, ICH M4, ANDA, Regulatory requirement, Regulatory Affairs.

I. INTRODUCTION

Background:

The European Union (EU), the United States (USA), and Japan were the three main regulatory regions prior to the introduction of the Common Technical Document (CTD) in 2002. These regions had their own unique regulations and formats for submitting regulatory dossiers in order to receive marketing approval for new drugs or modifications to existing drug licenses. A summary of technical material has to be arranged and presented by the GAIYO in Japan. Written summaries were advised but expert reports and tabulated summaries were required throughout Europe. The Food and Drug Administration (FDA) in the United States has released guidelines about the structure and contents of the New Drug Application (NDA). Because each country and area within the EU had different criteria and forms, this made the submission procedure time-consuming and repetitious.

In 2000, in response to this problem, officials from the Ministry of Health, Labor, and Welfare in Japan, the European Medicines Agency (EMA), and the USA FDA worked together to create guidelines that would specify the format and contents of a new medicine application dossier in each of the three regions. These recommendations were created as part of the International Conference on Harmonization (ICH) and are now included in the ICH recommendations by creating a uniform framework for technical documentation, the CTD aimed to drastically cut down on the time and resources needed to assemble applications for the registration of human medicines. Additionally, it sought to improve the transmission of regulatory information across Regulatory Authorities, ease the production of electronic submissions, and facilitate regulatory assessments and communication with applicants using a standard document structure. [1]

There are now four question and answer publications and four ICH recommendations (M4, M4Q, M4S, and M4E) on the CTD. The first set of ICH CTD guidelines was published in 2002. In July 2003, the CTD format became mandatory for NDAs filed in the EU and Japan, and it was strongly recommended for NDAs submitted to the FDA. After the EU, USA, and Japan adopted the CTD format, several other countries—including Canada and Switzerland—followed suit. The paper CTD is soon to be replaced by its electronic counterpart, the eCTD, as the eCTD has been necessary for the centralized process in the EU since 2010. [2]

General principles:

Like any other document, the CTD should have an easy-to-read and straightforward information layout. It is recommended to utilize margins that allow the document to print on 8.5 × 11" (USA) and A4" (EU and Japan) paper, per the ICH M4 guidance document. For the narrative text, a Times New Roman font with a size of 12 points is advised. When referencing literature sources at the end of each module, adhere to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Furthermore, when using acronyms and abbreviations, they should be defined right away.

Every document in the CTD should have a page number starting on page 1, with the exception of particular literature references, where the current journal page numbering is sufficient. Page numbers do not have to be displayed as '1 of n,' where n is the total number of pages in the text, according to the ICH M4 guidelines. This is an important point to remember. A distinct header or footer that briefly describes the content of each page of a document should be included. An example of this may be an acronym for the entire section number and title (e.g., 2.7 Clinical Summary). The M4 rules provide for a reduced numbering string so that documents don't have to use fifth, sixth, etc. level subheadings. In this instance, the page header or footer should provide the document name and number (e.g., 2.6.6 Toxicology Written Summary), and the document itself should utilize an abridged section numbering system (e.g., 1, 1.1, 2, 3, 3.1, 3.2, etc.). [3]

Regulatory affairs (RA) acts as a liaison between the global drug regulatory agencies and the pharmaceutical sector. Its main responsibility is to supervise the registration of pharmaceutical goods in various nations before they are made available for purchase. The department of drug regulatory affairs is a crucial component of pharmaceutical corporations' organizational structures. The pharmaceutical sector complies with worldwide regulatory requirements that are methodical and well-organized when producing chemical and biological pharmaceuticals for human and veterinary use, medical equipment, cosmetics, and traditional herbal remedies. Regulatory affairs specialists are essential at every stage of the process, from developing regulatory plans in response to the discovery of a novel chemical entity to organizing post-marketing operations. Errors may seriously damage a company's reputation in the pharmaceutical sector, where the development of a new chemical can cost millions of rupees or dollars. Since pharmaceuticals are fundamental to human existence, laws governing their safety, quality and effectiveness must be in place.

Regulatory matters professionals bear complete responsibility for ensuring compliance and maintaining all necessary records and documents. A small mistake in any action pertaining to safety, quality, or regulations can lead to product recalls and significant financial losses.

From the very beginning to the point of commercialization, the whole process of medication development is heavily controlled. Every medication must go through clinical studies to guarantee its quality, safety, and efficacy before being approved for sale. Regulatory authorities in each respective country establish certain standards that must be met. All facets of the pharmaceutical industry are impacted by regulation, including patients, administrative and regulatory bodies, pharmaceutical firms, and independent inventors. The department of regulations functions as a conduit for information between the business, its goods, and the regulatory bodies whose views, whether favorable or unfavorable, help the latter gain insight into the sector. Therefore, a product's chances of reaching the market on schedule increase with increasing scientific precision. [4, 5, 6]

1.1 Common Technical Document (CTD) Adoption and Implementation:

Safety, quality, and efficacy were the first subjects chosen for harmonization within the International Conference on Harmonization of Technical Standards for Medicines Approved for Human Use Registration (ICH), reflecting the three standards for evaluating and approving new pharmaceuticals. Topics with notable regional variations in the requirements for regulations were prioritized. E3, or clinical study reports' format and content, was one of the early subjects, though, since it offered a standardized method for reporting the registration file's key clinical studies. [7]

Following the initial harmonization of laws and regulations, the ICH shifted its focus towards streamlining the documentation structure in registration files. The objective was to eliminate redundancy and duplication, allowing for the provision of a solitary data set to prove efficacy, quality, and safety. Reducing the expenses pharmaceutical firms incur when transferring registration data between several regional formats was another goal. In November 2000, the ICH Steering Committee released the final version of the Common Technical Document (CTD). Initially, beginning in July 2001, the EU, US, Japan, Canada, and Switzerland offered the CTD as an optional format. But as of July 2003, it was required in the EU, Japan, Canada, and Switzerland. In the US, although the CTD is not mandatory due to the Good Guidance Practices Final Rule from September 2000, it is still the recommended format. The US Food and Drug Administration (FDA) has always considered ICH documents as guidance.

Other national regulatory agencies and regional agency groups are now using the CTD format, with the required adjustments made to meet local requirements. For example, the countries that make up the Association of Southeast Asian Nations (ASEAN), which has a combined population of over 550 million, have published their own requirements for the ASEAN CTD (ACTD). These countries include Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam. [8]

1.2 Electronic CTD (eCTD) Adoption & Implementation:

Apart from the CTD, which was developed by the Working Group of ICH M4, the M2 group worked on the electronic CTD (eCTD). Version 3.0 of the eCTD Specification was approved in October 2003, and the most recent version, 3.2, was made available in February 2004 after editorial revisions. [9]

Applications for eCTD are accepted in all three ICH regions and Canada, with the exception of Module 1 in Switzerland. Nowadays, the majority of new drug applications (NDAs) are filed electronically in the US. As the official signed archival copy, the European Medicines Agency (EMEA) and a few of EU nations still demand a paper CTD application in addition to the eCTD. The need is being gradually removed from national rules.

The transition to regulatory bodies' use of electronic review has necessitated significant investments in software and hardware at a national level, resulting in varying timelines for implementation across different countries. [10]

It is possible to file electronically or on paper with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. But since the agency's review process is now all computerized, paper files that are submitted are scanned and turned into electronic ones. Currently, 95% of files in Belgium are submitted electronically, thanks to the country's aggressive promotion of electronic filings. 2009 is the goal date by which all 25 EU members will accept files in the eCTD format. In 2007, Belgium said that it will start requiring the usage of eCTD. [11-14]

COMMON TECHNICAL DOCUMENT (CTD):

A standardized set of requirements for the application dossier used to register medicines is known as the Common Technical Document (CTD). It is intended for use in the United States, Europe, and Japan. For the purpose of preparing new drug applications to be submitted to regional authorities in these countries, the CTD format is widely recognized. The Food and Drug Administration (FDA) in the US, the Ministry of Health, Labor, and Welfare in Japan, and the European Medicines Agency (EMA) in Europe worked together to generate this paper. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is in charge of maintaining the CTD. [15]

The CTD dossier is structured in to five primary sections (refer to figure 1):

1. Module 1: Administrative details and prescription data
2. Module 2: Common Technical Document Synopses
3. Module 3: Quality documentation related to pharmaceutical aspects
4. Module 4: Reports that are not clinical include toxicology and pharmacology
5. Module 5: reports on clinical studies using clinical trials

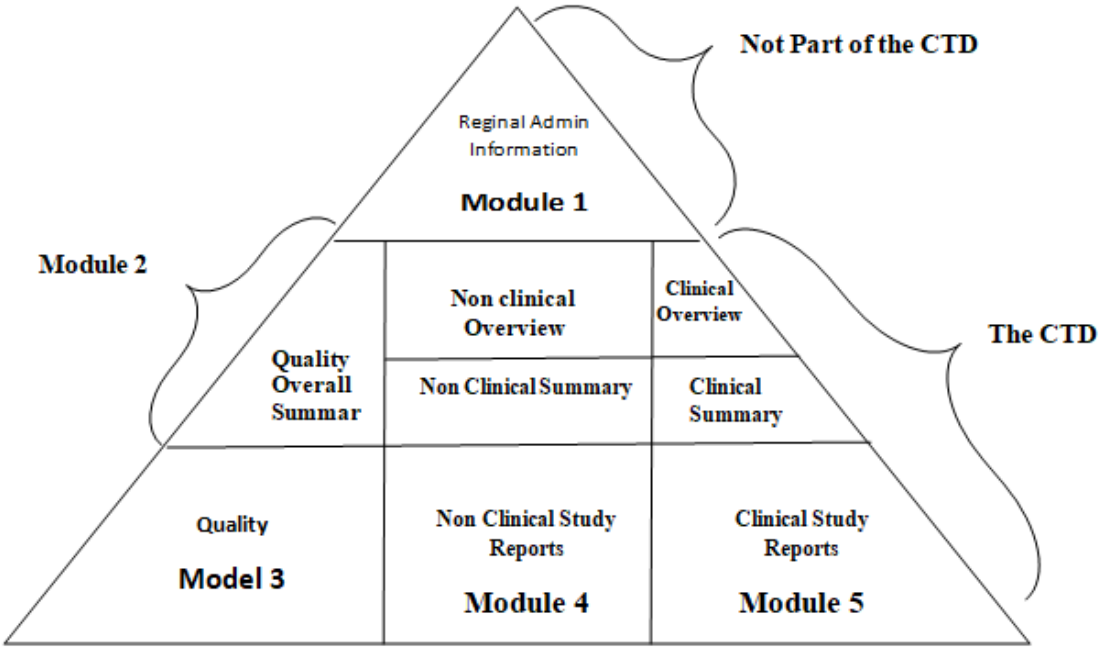

figure 1 triangle of ctd

Generally Regarding the Preparation of Dossiers [16]

table 1 ctd's modular organization

The Common Technical Document
Module 1: Administrative Details and Prescription Data
1.1 Submission Table of Contents, Including Module 1
1.2 Documents Specific to Each Region
Module 2: Common Technical Document Synopses
2.1 Table of Contents for Ctd
2.2 Introduction of Ctd
2.3 Overall Quality Synopsis
2.4 Overview of Nonclinical Practices
2.5 Overview of Clinical Practice
2.6 Written and Tabulated Nonclinical Summary • Toxicology; • Pharmacokinetics; • Pharmacology
2.7 Clinical Summary • Analytical Methods Associated with Biopharmaceutics • Clinical Safety; • Clinical Efficacy; • Clinical Pharmacology Studies; • Individual Study Synopses
Module 3: Quality Documentation Related to Pharmaceutical Aspects
3.1 Table of Contents for Module 3
3.2 Collection of Data
3.3 Literature Citations

Module 4: Reports That Are Not Clinical Include Toxicology and Pharmacology
4.1 Table of Contents for Module 4
4.2 Research Reports
4.3 Literature Citations
Module 5: Reports On Clinical Studies Using Clinical Trials
5.1 Table of Contents for Module 5
5.2 A Tabular List of Every Clinical Research
5.3 Reports on Clinical Studies
5.4 Literature Citations

The CTD is mainly separated into five modules, each of which has a distinct function. While Modules 2, 3, 4, and 5 are intended to be relevant to all regions, Module 1 is specialized to one particular location.
Module 1, known as Documents unique to each region are included in the administrative information. This might be the suggested label for usage in that specific area or the application forms.

Module 2: CTD summaries start with an overview of the pharmaceutical product, which is the Quality Overall Summary. Its pharmacological class, mechanism of action, and suggested clinical usage are all covered in this introduction.

Module 3: Emphasizes quality and offers a standard method and structure for presenting information on Chemistry, Manufacturing, and Controls (CMC) in a registration dossier. Tables 2 and 3 illustrate the sections on Drug Substance and Drug Product that are included in the table of contents. There are also several appendices and sections with information relevant to certain regions.
3.1 Module 3's table of contents
3.2 collection of information
3.2. S Drug Substance
3.2. P+ Drug Product
3.3 References to literature utilized in Module 3

table 2 contents of drug substance module 3 [19]

Sr. No	**Contents**
3.2.S	**Drug Substance**
3.2.S.1	**Overall Details**
	3.2.S. 1.1 Nomenclature
	3.2.S. 1.2 Structure
	3.2.S. 1.3 Overall Characteristics
3.2.S. 2	**Making Of Drugs Supplements**
	3.2.S. 2.1 Manufacturer
	3.2.S. 2.2 An Explanation of Manufacturing and Process Control
	3.2.S. 2.3 Materials Controls
	3.2.S. 2.4 Management of Crucial Phases and Intermediaries
	3.2.S. 2.5 Validation And/or Process Evaluation
	3.2.S. 2.6 Creation of Production Methodologies
3.2. S.3	**Details Of the Drug Substance**
	3.2.S.3.1 Clarification of Structures and Additional Features
	3.2.S.3.2 Impurities
3.2. S.4	**Control Of Drug Substance Quality**
	3.2.S.4.1 Description and Rationale for The Specification

	3.2.S.4.2 Methods of Analysis
	3.2.S.4.3 Validation of Analytical Procedures
	3.2.S.4.4 Analyses in Batch
3.2.5.5	**Resources Or Standards of Reference**
3.2. S.6	**System For Closing Containers**
3.2.8.7	**Drug Substance Stability**
	3.2.S.7.1 A Synopsis of Stability and Conclusions
	3.2.S.7.2 Protocols for Stability and Obligations After Approval
	3.2.S.7.3 Data on Stability

table 3 module 3's contents for drug products

Sr.No.	Contents
3.2 P	**Drug Product**
3.2. P.1	**Summary And Composition**
3.2. P.2	**Pharmaceutical Programmed**
	3.2.P.2.1 Elements Contained in The Drug
	3.2.P.2.1.1 Drug Substance
	3.2.P.2.1.2 Excipients
	3.2.P.2.2 Medication Item
	3.2.P.2.2.1 Creation and Formulation
	3.2.P.2.2.2 Overruns
	3.2.P.2.2.3 Biological and Physicochemical Characteristics
	3.2.P.2.3 Development of Manufacturing Processes
	3.2.P.2.4 Container Closure System
	3.2.P.2.5 Microbiological Attributes
	3.2.P.2.6 Compatibility
3.2. P.3	**Product Manufacture of Drug**
	3.2.P.3.1 Manufacturer
	3.2.P.3.2 Batch Formula
	3.2.P.3.3 An Explanation of Process Controls and The Manufacturing Process
	3.2.P.3.4 Management of Crucial Phases and Intermediaries
	3.2.P.3.5 Validation And/or Process Evaluation
3.2. P.4	**Control Of Excipients**
	3.2.P.4.1 Details and The Rationale for The Details
	3.2.P.4.2 Methods of Analysis
	3.2.P.4.3 Validation of Analytical Methods
	3.2.P.4.4 Ingredients Derived from Humans or Animals
	3.2.P.4.5 First-Time Use of Excipients
3.2. P.5	**Drug Product Control**
	3.2.P.5.1 Details and The Rationale for The Details
	3.2.P.5.2 Methods of Analysis
	3.2.P.5.3 Analytical Method Validation
	3.2.P.5.4 Batch Analyses
	3.2.P.5.5 Description of Contaminants and Impurities
3.2. P.6	**Research Methods or Supplies**
3.2. P.7	**Container Closure System**
3.2. P.8	**Drug Substance Stability**
	3.2.P.8.1 Conclusions and Summary of Stability
	3.2.P.8.2 Stability Process Following Approval and Commitment
	3.2.P.8.3 Stability Data

Module 4: Reports that are not clinical include toxicology and pharmacology:
The structure and content of the nonclinical summaries in Module 2 of the Common Technical Document are described in the CTD Safety (M4S) Guideline. The framework for Module 4, which includes the Nonclinical Study Reports, is also provided by it. The Nonclinical Overview, which should normally not be longer than 30 pages, should provide a thorough and critical examination of the pharmaceutical's pharmacologic, pharmacokinetic, and toxicological evaluation. On the other hand, it is advised that the Nonclinical Written Summaries be longer—between 100 and 150 pages—and include thorough summaries and discussions of the nonclinical data related to toxicity, pharmacology, and pharmacokinetics.

4.1 Module 4's contents
4.2 Studies Reports
- 4.2.1 Research on Pharmacology
- 4.2.2 Investigation of Pharmacokinetics
- 4.2.3 Research on Toxicology

4.3 Citations from Works Cite in Module 4.

Module 5: Clinical Study Reports
CTD-Efficacy (M4E) describes the format and organization of the clinical data that is part of an application; this includes both detailed study reports and summaries. The Clinical Overview, a brief document that evaluates the clinical data critically, and the Clinical Summary, a longer document that concentrates on summarizing and integrating the data, are the two main clinical summaries included in Module 2 of the CTD. The raw data and the clinical study reports are also included in Module 5.

5.1 Table of Contents for Module 5
5.2 Comprehensive List of Clinical Studies
5.3 Documentation of Clinical Study Findings
- 5.3.1 Results of Biopharmaceutic Research
- 5.3.2 Results of Research on Pharmacokinetics Employing Human Biomaterials
- 5.3.3 Results of Research on Human Pharmacokinetics (PK)
- 5.3.4 Results of Studies on Human Pharmacodynamics (PD)
- 5.3.5 Results of Safety and Efficacy Research
- 5.3.6 Conclusions from Experience with Post-Marketing
- 5.3.7 Forms for Case Reports and Listings of Specific Patients

5.4 Citations from Related Literature

Benefits of CTD [16]

1. The principal aim of instituting a uniform submission format is to optimize the application review procedure and forestall the exclusion of vital data or analyses. If such details are left out, approvals might be unnecessarily delayed.
2. The time and resources needed to put together applications for the registration of human medicines will be significantly reduced by the adoption of a standard format for technical material. It will also make the process of preparing electronic submissions easier.
3. The utilization of a standardized document containing common elements will enhance regulatory reviews and facilitate communication between the regulatory authorities and the applicant.
4. It is projected that the industry will save a great deal of time and money by using the Common Technical Document (CTD) instead of assembling applications for worldwide registration.
5. In addition to raising the bar for Indian norms, the CTD gives the application process as a whole a methodical framework.

The CTD's adoption will also make it easier for regulatory authorities to communicate information about regulations with one another.

Silent benefits of CTD

1. Achieving worldwide consistency in application processes.
2. Provides instructions for drafting papers that are ready for submission throughout the IND phases.
3. Project and information management benefit from uniformity.
4. Simplifies the whole life cycle's administration.
5. Enhances the efficiency of drug development planning.

Issues:

All dossiers now use the Clinical Trial Document (CTD) format, while certain areas still have some pre-CTD criteria. For example, even though a clinical summary is intended to take their place, for applications submitted in the United States, the FDA continues to require an integrated statement of safety and an integrated summary of effectiveness. According to the guidelines, they should be incorporated into Module 5 and summarized for Module 2.7 papers. Although the CTD has been effective in offering a standard format for submission dossier data, it is still up for question whether or not this has resulted in a decrease in how much time and money it takes to put together applications. [22]

ECTDS, OR ELECTRONIC COMMON TECHNICAL DOCUMENTS:

The pharmaceutical sector uses the electronic Common Technical Document (eCTD) to provide regulatory data to regulatory bodies. It was created by the Multidisciplinary Group 2 Expert Working Group of the International Conference on Harmonization (ICH) and is based on the Common Technical Document (CTD) format (ICH M2 EWG). Electronic submissions are made possible by the eCTD's transport format, which is intended to be readily transferred into an agency's review environment. It serves as a conduit for the industry to provide regulatory data to the agency and makes electronic submission production, review, life-cycle management, and archiving easier. The eCTD specifications outline the criteria for ensuring the technical validity of electronic submissions. This advancement in information submission greatly supports the process of applying for approval of new drugs. In the future, companies may even have the ability to simultaneously submit their applications to multiple regulatory authorities with just a single keystroke. [16, 17]

Advantages of eCTD [17]

1. Improved submission handling and storage Benefits of electronic prescription drugs
2. Enhanced data organization
3. Assistance in managing the life cycle
4. Instant access to comprehensive and current details
5. Reviewers' enhanced search tools and tracking skills
6. Streamlined evaluation process and improved process visibility
7. Decreased effort and information use for evaluation reports
8. controlled interaction with outside specialists
9. Best possible use of available resources
10. streamlined operations of the company
11. Improved correspondence with the sector.

DRUG APPROVAL METHOD

A firm must submit a completed Form 44 together with the appropriate data listed in Schedule Y of the Drugs and Cosmetics Act 1940 and Rules 1945 to the licensing authority (DCGI) in order to request approval to make or import a new drug. The firm must undertake clinical trials in compliance with the requirements outlined in Schedule Y and submit the final report in the prescribed format in order to prove its efficacy and safety among the Indian population. Any nation's approval process for a new medicine is a very complex process that requires not only filing an NDA to the FDA but also fulfilling all prerequisites. The aim of this research is to comprehensively investigate and record the prerequisites for the approval procedure of novel pharmaceuticals in India, specifically concentrating on clinical trials as required by the Drugs Control department of the Indian government. [18]

NEW DRUG APPLICATION

Before a novel drug may be marketed, an NDA application needs to be filed to the FDA. The sponsor gives the NDA preclinical and clinical test results for the analysis of drug information and a description of manufacturing processes in order to acquire this authorization. Following receipt by the agency, the NDA is subjected to a technical screening and assessment. This assessment and accompanying documents guarantee that adequate data and information have been provided in every domain to support the FDA's formal review. Following an FDA assessment of an NDA, the sponsor may be informed of three potential courses of action:

1. Not Approvable - This letter outlines the reasons for the decision and includes a list of faults.
2. Approvable: This indicates that although the medication may be allowed, there might be a few small issues that need to be fixed, such labelling modifications or a potential requirement for a promise to carry out post-approval research.
3. Approval: This indicates that the medication has received approval. [18]

Clinical studies are conducted in many phases: [18]

- Pre-clinical research: In this study, mice, rats, rabbits, and monkeys are used to evaluate the medication.
- Phase I: This is a human pharmacology trial that focuses on estimating the safety and tolerability of the drug.
- Phase II: This is an exploratory trial designed to assess the drug's short-term side effects and effectiveness.
- Phase III - Confirmatory trials: These studies are carried out to verify the therapeutic advantages of a certain intervention
- Phase IV - post-marketing trial: These studies were carried out after the approval of a drug to gather further detail6s.

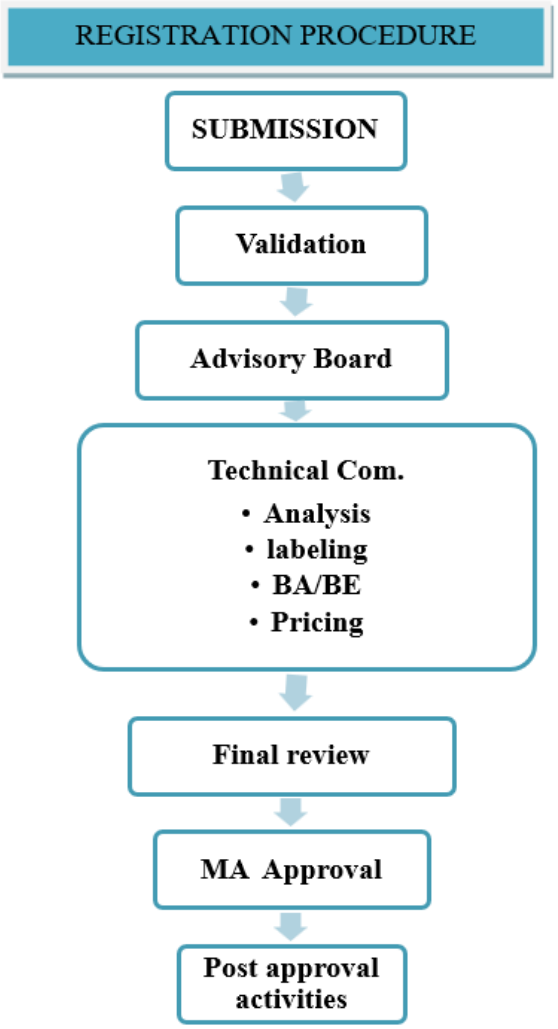

figure 2 NDA registration procedure

There are several regulations and guidelines that must be adhered to for the regulation of drugs in India. These include:

1. The Drugs and Cosmetics Act of 1940 and its accompanying rules from 1945.
2. The Narcotic Drugs and Psychotropic Substances Act of 1985.
3. The Drugs Price Control Order of 1995.
4. The Consumer Protection Act of 1986.
5. The Factories Act of 1948.
6. The Law of Contracts, specifically the Indian Contract Act of 1872.
7. The Monopolistic and Restrictive Trade Practices Act of 1969.
8. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines.
9. The Schedule Y Guidelines.
10. The Indian Council of Medical Research (ICMR) Guidelines.
11. The Registry of Trial.

Please note that these regulations and guidelines play a vital part in guaranteeing the effectiveness, safety, and caliber of medications in India.

CONCUSION:

The Drug Regulatory Affairs department in India is growing and adapting to the New Approach to regulation for healthcare products. This approach ensures timely and safe healthcare advancements. Proper implementation of regulatory guidelines improves the pharmaceutical industry's economic growth and public safety. The CDSCO adopted the CTD format for pharmaceutical product registration in 2009-2010, but some companies still lack knowledge about the primary requirements. It is essential to know how to put together a dossier using the CTD format. The use of CTD and eCTD reduces time and a resource required for registration and simplifies electronic submissions. Reducing the time, it takes for a product to reach the market is essential for its success and the growth of the firm. The approval procedure for pharmaceutical items is essential for access to safe and effective treatments. [10, 11]

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