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A REVIEW OF "REGULATORY SUBMISSION FOR PHARMACEUTICAL DEVELOPMENT"

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ABSTRACT

Regulatory submission is an important process in the pharmaceutical assiduity that ensures drugs are safe, effective, and high in quality before they're retailed. This review explains the part of nonsupervisory affairs in medicine development, clinical trials, manufacturing, quality assurance, and post-marketing conditioning. It describes different stages of clinical trials and medicine blessing processes followed in India and other countries. operations similar as IND, NDA, ANDA, and CTD are important for carrying blessing from nonsupervisory authorities. The review also highlights the significance of proper attestation, stability studies, process confirmation, and compliance with nonsupervisory guidelines. Organizations similar as USFDA, CDSCO, EMA, and ICH help maintain transnational nonsupervisory norms. Effective nonsupervisory submission systems ameliorate patient safety, product quality, and global pharmaceutical compliance throughout the product lifecycle.

KEYWORDS: - IND, NDA, ANDA, CTD and MAA etc.

INTRODUCTION

Presently different countries must follow different regulatory requirements for sanction of new drug. Marketing Authorization Application (MAA) a single regulatory approach is valid to various countries is almost a difficult task. Therefore, it is essential to have knowledge about regulatory requirement for MAA of each country.

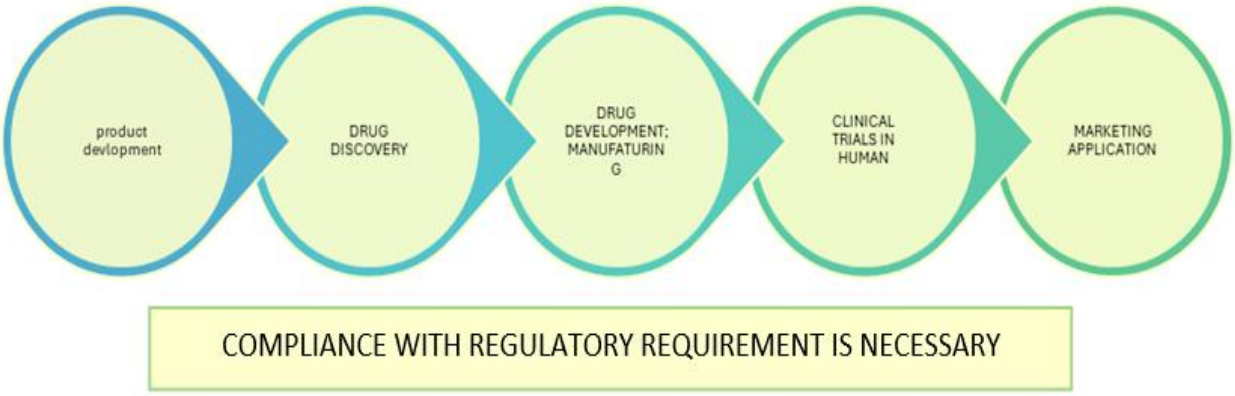

Figure 1: Drug Development and Regulatory Approval Process.

Historical Overview of Regulatory Affairs The regulatory affairs department can be established based on government desires. And for regulating the severe adverse consequences in public health. Actually, regulatory affairs can act as interphone between pharmaceutical industry and regulatory body. During 1950‘s there was many disasters were happened due to the invalid judgement of professionals. During the manufacturing and incidence of adulteration of drug substances which cause death of patients. So due to this after this incident the government was thinks to establish the regulatory bodies which give new regulations related on quality, safety, efficacy of new drug products.[6]

1.1 Disasters out of India: In 1935, a tragedy involving the oral elixir of sulphanilamide, prepared with the toxic solvent diethylene glycol, led to the deaths of over 100 people, highlighting the dangers of unregulated drug formulations. In response, the U.S. government passed the Food, Drug, and Cosmetic Act of 1938, empowering the FDA to approve drugs for safety before public distribution. A few decades later, between 1961 and 1962, the thalidomide disaster further exposed regulatory gaps when the drug, used to treat morning sickness, caused severe birth defects in over 10,000 children and led to hundreds of deaths. These two tragedies underscored the urgent need for rigorous drug testing, especially for vulnerable populations like pregnant women. They triggered major reforms in drug approval processes, establishing stringent preclinical and clinical trial requirements and shaping modern pharmaceutical regulations to prioritize patient safety[7]

1.2 Detailed Elaboration of Phases[14]

Phase I: Safety and Dosage

This is the first time a drug is tested on humans, typically a small group of healthy volunteers.

Testing: Focuses on how the drug is absorbed, distributed, and metabolized. It involves testing multiple doses to find the highest dose humans can tolerate without serious side effects.

Goal: If the drug proves to be safe within the tested range, it receives the "green light" to move to Phase II.

Phase II: Safety and Efficacy

The drug is administered to a larger group of people (usually 100–300) who actually have the condition the drug is intended to treat.

Testing: Researchers look for initial evidence that the drug works (efficacy) while continuing to monitor safety and potential side effects in actual patients.

Goal: To determine if the therapeutic benefit outweighs the risks. If beneficial, it moves to Phase III.

Phase III: Large-Scale Confirmation

These are the most expensive and time-consuming trials, involving thousands of patients across multiple sites or countries.

Testing: The focus is on gathering statistically significant data to prove the drug's effectiveness and safety compared to current standard treatments or placebos.

Goal: This phase generates the massive volume of data required for **Regulatory Approval** (such as from the FDA or CDSCO). If successful, the drug can be marketed to the public.

Phase IV: Post-Marketing Studies

Once the drug is available at pharmacies and hospitals, the study does not end.

Testing: Researchers monitor the drug’s performance in the "real world" across a much broader and more diverse population than in previous phases.

Goal: To identify rare side effects that only appear after long-term use and to conduct cost-benefit analyses. This ensures the drug remains safe for the general public over many years.

1.3 Indian Clinical Research[14]

Table 1: Key Milestones In Indian Clinical Research.

Year	Event /act	Significance
1940	Drug & cosmetic Act	Established the central regulatory framework.
1949	Formation of ICMR	Created the apex body for biomedical research.
1988	Introduction of Schedule Y	Defined the clinical trial requirements for the first time.
2005	Schedule Y Amendment	Removed the "Phase Lag," allowing global concurrent trials
2009	CTRI Launch	Removed the "Phase Lag," allowing global concurrent trials.
2019	New Drugs & CT Rules	Comprehensive modernization of trial regulations.

HISTORY OF REGULATORY AFFAIRS IN INDIA[12]

Till 20th century the pharmaceutical products import from other countries, so after world war- 1 in 1914. Due to increased demand for the drug products, many substandard drug products enter into market, to control these products, many legislations were made from time to time (Table: 1).[8, 9]

Role of Regulatory Affairs[13]

It is a unique combination of Science and Management.

It is the first point of contact between pharmaceutical company and Regulatory Authority.

It helps in knowing legislations implementing legislations and get approval for the legislations Authorities. Laid down by Regulatory

4.1. In Production

- Role of Regulatory Affairs started from product development to marketing, marketing to post marketing surveillance.
- Regulatory Affairs give advises at all stages with respect to technical requirements.
- Regulatory Affairs should ensure the labelling and packing of drug product

4.2. In Clinical Studies

It should collect analyses and communicate the obtained data to Regulatory Authorities for approval

4.3. In Research and Development

It should work together with Research and Development and marketing to develop novel drug product by using latest technologies and Regulatory Development.

4.4 In Quality Control and Quality Assurance

In collaboration with QC and QA the Regulatory Authorities should submit the Dossier (documentation containing all details) which includes

4.4.1. Certificate of Analysis

4.4.2. Stability studies

4.4.3.Analytical Method Validation Report

4.4.4. Process Validation Report

4.4.5.Master Formula Record to Regulatory Authorities for approval.

DRUG APPROVAL PROCESS IN INDIA[27]

The Drug and Cosmetic Act 1940 and Rules 1945 were proclaimed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

The Central Drugs Standard Control Organization (CDSCO), and the office of its leader, the Drugs Controller General (DCGI) was established[17]

In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945.

Schedule Y provides the guidelines and requirements for clinical trials, which was further reviewed in 2005 to bring it at par with worldwide recognised procedures.

When a company in India wants to manufacture/ import a new drug, it must apply to seek permission from the licensing authority (DCGI) by filing in Form 44, also submitting the data as given in Schedule Y of the Drugs and Cosmetics Act 1940 and Rules 1945. To demonstrate its efficacy and safety in Indian population, must conduct clinical trials in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in specified format.[18]

Rule- 122A of the Drug and Cosmetics Act says that the clinical trials may be waived in the case of new drugs which are approved and being used for several years in other countries. Section 2.4 (a) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says for

those drug substances which are discovered in India all phases of clinical trials are compulsory.[27]

Section 2.4 (b) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says that for those drug substances which are discovered in countries other than India; the applicant should submit the data presented from other countries and the licensing authority may necessitate to replication all the studies or permit him to proceed from Phase III clinical trials.

Demonstration of safety and efficacy of the drug product for use in humans is essential before the drug product can be approved for import or manufacturing of new drug by the applicant by Central Drugs Standard Control Organization (CDSCO). The regulations under Drugs and Cosmetics Act 1940 and its rules 1945, 122A, 122B and 122D and further Appendix I, IA and VI of Schedule Y, describe the information required for approval of an application to import or manufacture of new drug for marketing.

The changes in the Drugs and Cosmetics Act includes, launching definitions for Phase I-IV trials and clear responsibilities for investigators and sponsors. The clinical trials were further divided into two categories in 2006.In one category clinical trials can be conducted in other markets with competent and established regulatory systems whereas the remaining ones fall in to another category other first category.

An application to conduct clinical trials in India should be submitted along with the data of chemistry, manufacturing, control and animal studies to DCGI. The date regarding the trial protocol, investigator's brochures, and informed consent documents should also be attached.

A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only after approval of DCGI and ethical committee.

To regulate the maximum tolerated dose in humans, adverse reactions, on healthy human volunteers, Phase I clinical trials are conducted. The therapeutic uses and effective dose ranges are determined in Phase II trials in 10-12 patients at each dose level. The confirmatory trials (Phase III) are conducted to generate data regarding the efficacy and safety of the drug in approximate 100 patients (in 3-4 centers) to confirm efficacy and safety claims. Phase III trials should be conducted on a minimum of 500 patients spread across 10-15 centers, If the new drug substance is not marketed in any other country.[19,20]

After the NDA approval, when an Organization can distribute and market the product, it is considered to be in Phase IV trials, in which new uses or new populations, long-term effects, etc. are explored.

Through the International Conference on Harmonization (ICH) process, the Common Technical Document (CTD) guidance has been developed for United States, European Union, Canada, Japan and other countries.

Most countries have adopted the CTD format. Hence, CDSCO has also decided to adopt CTD format for technical requirements for registration of pharmaceutical products for human use.

Stages of approval

Submission of Clinical Trial application for evaluating safety and efficacy.
Requirements for authorization of new drugs approval.
Post approval changes in biological products: quality, safety and efficacy documents.
Preparation of the quality information for drug submission for new drug approval.

The drug approval process varies from one country to another. In some countries, only a single body regulates the drugs and responsible for all regulatory task such as approval of new drugs, providing license for manufacturing and inspection of manufacturing plants e.g. in USA, FDA performs all the functions. However, in some counties all tasks are not performed by a single regulatory authority, such as in India, this responsibility is divided on Centralized and State authorities. Some counties have two review processes as normal review process and accelerated review process as in USA and some countries have only a single review process as in India. Similarly, the format used for the demonstration of dossier submitted for approval of drug is also dissimilar. In some countries like as in USA, EU, Canada and Japan, it is mandatory that the dossier should be represented in eCTD format only.[21,23]

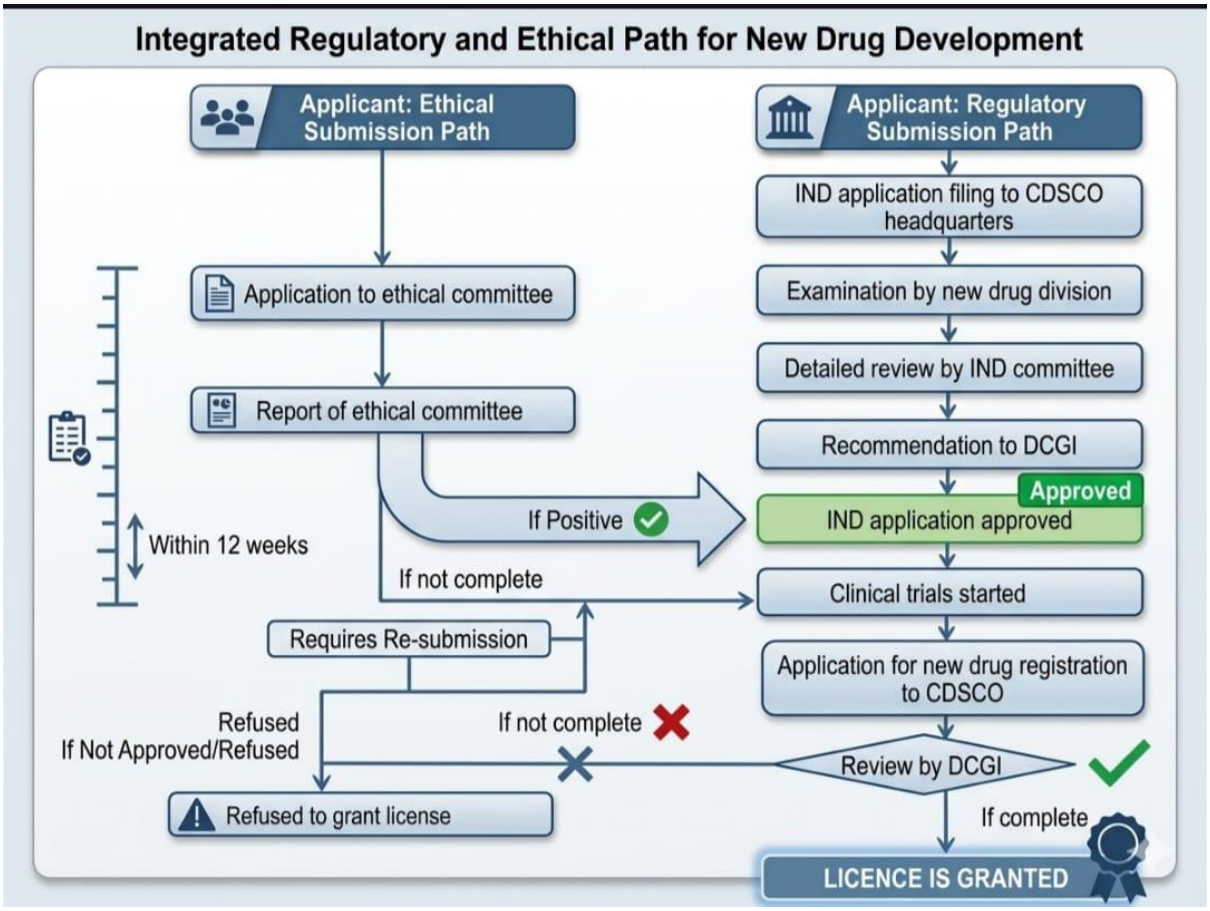

Figure 2: Drug Approval Process In India.[42]

INVESTIGATIONAL NEW DRUG APPLICATION

Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), having screened the new molecule for pharmacological

activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

There are three IND types:

- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.23 or Sec. 312.20. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

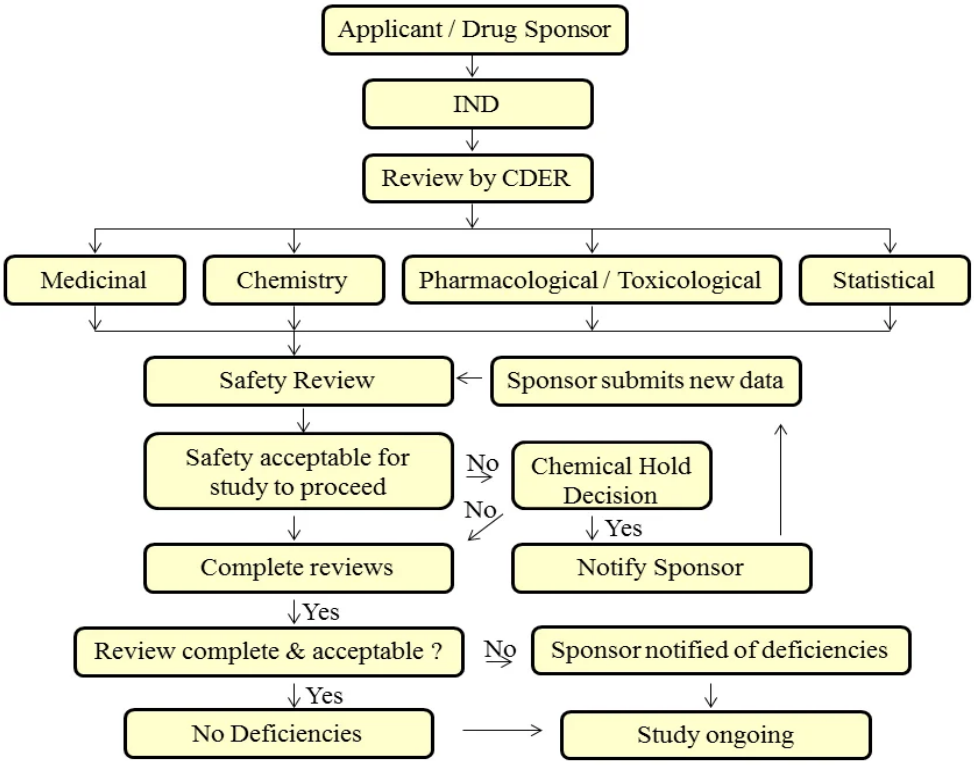

Figure 3: Ind Review & Process.

NEW DRUG APPLICATION (NDA)[26]

A New Drug Application (NDA) is a formal submission to the U.S. Food and Drug Administration (FDA) seeking approval to market a new drug. It compiles all data from the drug's development, including preclinical studies,clinical trial results, manufacturing processes, and proposed labelling. The NDA provides a full profile of the drug's safety, efficacy, pharmacokinetics, and pharmacodynamics. After submission, the FDA has 60 days to determine if the application is complete before proceeding with a detailed review. If the benefits outweigh the risks, the FDA grants approval, allowing the drug to be marketed in the U.S.[40]

Contents and Format of NDA Two copies of the application are:

(a) Archival copy &

(B) Review Copy.

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

1) Application form FDA 356
2) Index
3) Summary
4) Technical sections: further typed to
5) Chemistry, manufacturing and controls section
6) Non-clinical pharmacology and toxicology section
7) Human pharmacokinetics and bioavailability section
8) Microbiology section
9) Clinical data section
10) Statistical section
11) Pediatric use section
12) Samples and labeling
13) Case report forms

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

1) Index
2) Copy of FDA Form 356 h

3) Copy of cover letter
4) Letters of authorization
5) Copy of application summary

The FDA can conduct meetings with the sponsor at least two times; once at the end of Phase 2 clinical trials and another before an NDA is submitted i.e., a pre- NDA meeting. The review team shall study the study results and make a decision whether or not to approve the application[41]

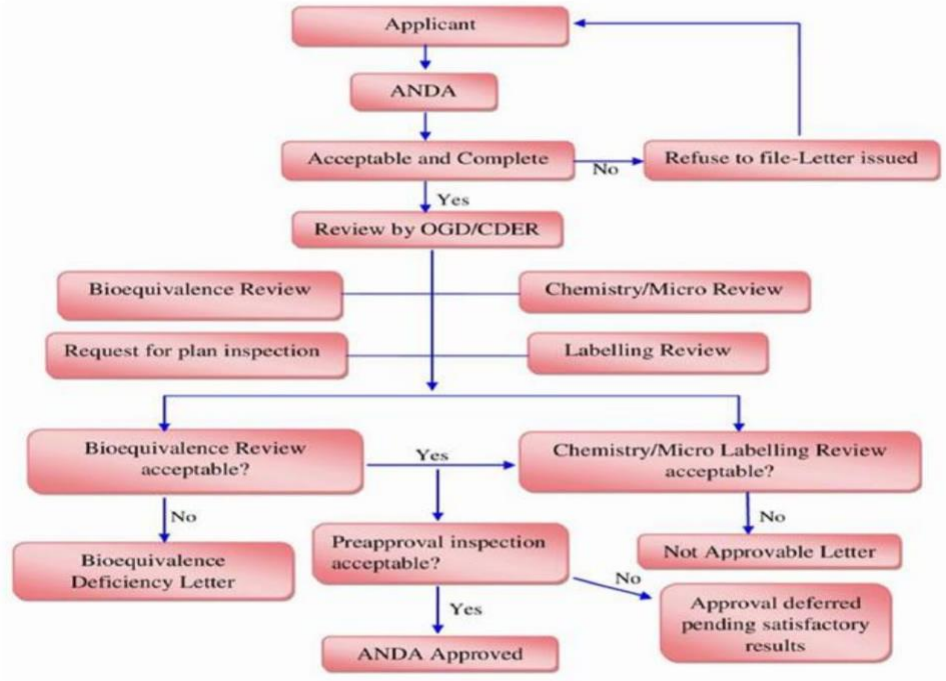

Figure 4: NDA Review Process.

ABBREVIATED NEW DRUG APPLICATION (ANDA)

ANDA is applied for products with same or closely related active ingredients, dosage form, and strength, route of administration, use and labelling as product already shown to be safe and effective. It is used when the patent has expired for a product, and a company wants to market its copy. Such drugs are called generic drugs, which should meet bio and pharmaceutical equivalent standards.[16]

An ANDA is submitted to Center for Drug Evaluation and Research, Office of Generic Drugs, where it is reviewed and approved. Content and Format of ANDA

1) Application form
2) Table of contents

3) Basis for ANDA submission
4) Conditions of use
5) Active ingredients
6) Route of administration, dosage from, strength Bioequivalence
7) Labelling
8) Chemistry, manufacturing and control
9) Human pharmacokinetics and bioavailability
10) Samples
11) Analytical methods
12) Case report forms and tabulations.

The Division of Bioequivalence's Office of Generic Drugs issued guidance in 1992 on valid statistical analysis for bioequivalence studies. Later, the FDA released draft guidance for studies comparing pharmacokinetic metrics in INDs, NDAs, and ANDAs. Approved branded and generic drugs are listed in the FDA's "Orange Book," which evaluates safety, effectiveness, and therapeutic equivalence.

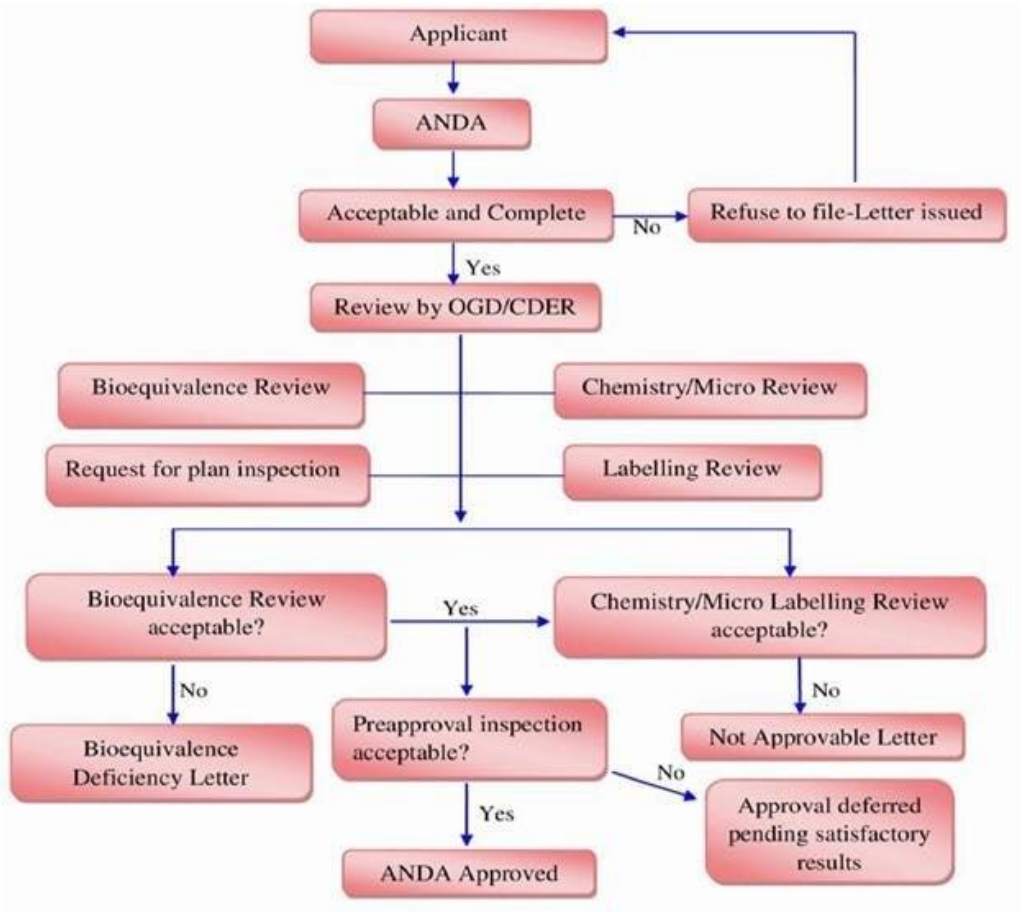

Figure 5:Anda Review Process

Supplemental New Drug Application (SNDA)[37]

After approval of NDA or ANDA, all significant changes in the conditions described in the applications must be approved, by filing a supplemental NDA or ANDA. Such changes like those in packing or ingredients should be approved by the CDER.[39] New-uses approvals of already approved drugs coming under this category are a better innovation as they need lesser resources to review than that needed for original-use approvals.[38]

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICAL PRODUCTS[35,36]

Module 1: Administrative Information and Prescribing Information

1.1 Table of Contents of the Submission Including Module

1.2 Documents Specific to Each Region (for example, application forms, prescribing information)

Module 2: Common Technical Document Summaries

2.1. Common Technical Document Table of Contents (Modules 2-5)

2.2.CTD Introduction

2.3. Quality Overall Summary

2.4. Nonclinical Overview

2.5. Clinical Overview

2.6. Nonclinical Written and Tabulated Summaries Pharmacology Pharmacokinetics Toxicology

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

Module 3: Quality

3.1. Table of Contents of Module

3.2. Body of Data

3.3 Literature References

Module 4: Nonclinical Study Reports

4.1 Table of Contents of Module

4.2 Study Reports

4.3 Literature References

Module 5: Clinical Study Reports

5.1 Table of Contents of Module

5.2 Tabular Listing of All Clinical Studies

5.3 Clinical Study Reports

5.4 Literature References

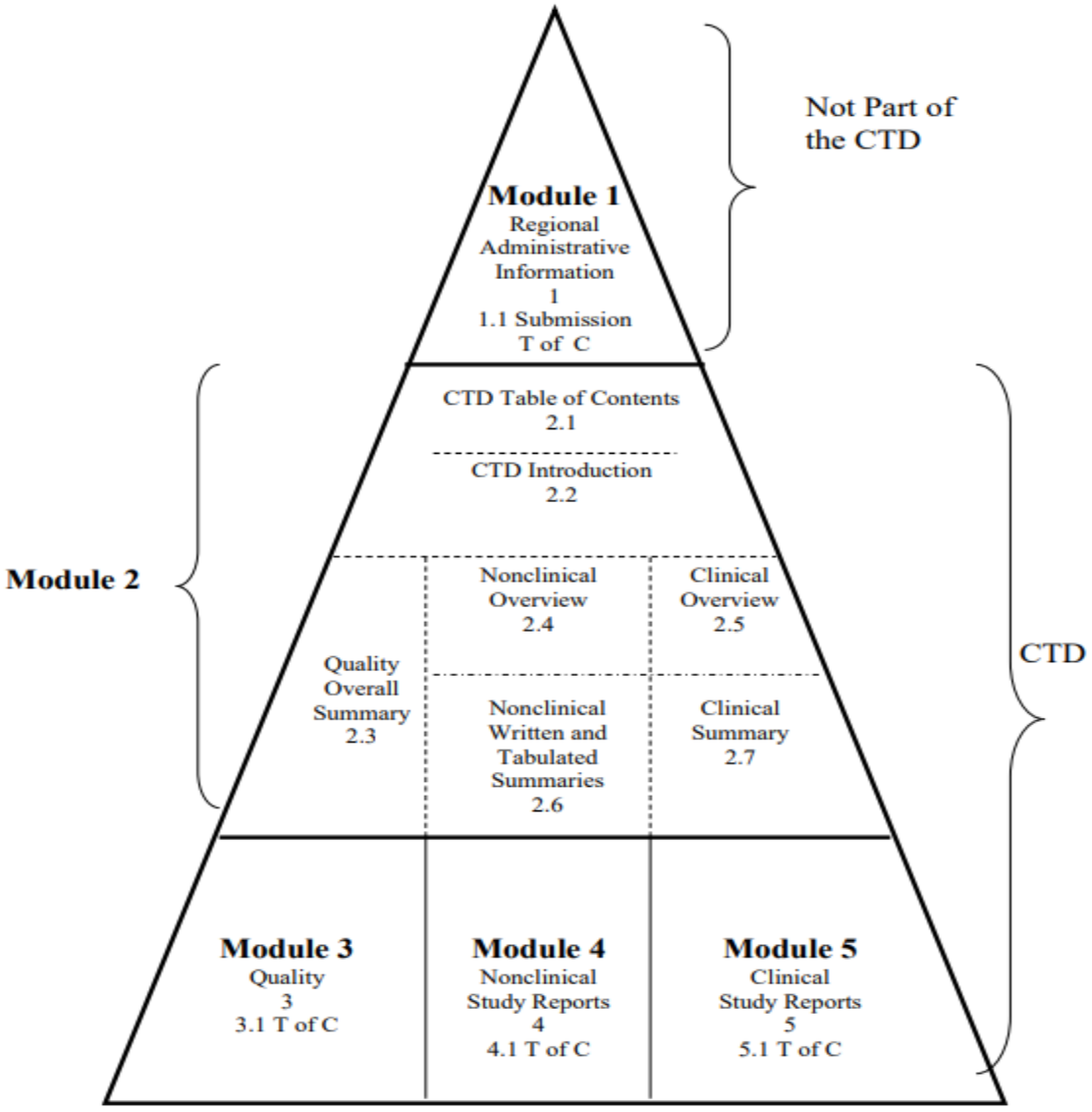

Figure 6: CTD: Module Hiarchy[30,31]

Table 2: Comparative Overview Of Drug Regulatory Requirements In The Us, Eu And India.

Sr. No.	Requirements	US[1,4,8]	EU [1,4,8]	India [1,4,8]
1	Agency	One agency USFDA	Multiple agencies • EMEA • CHMP • National health agencies	One agency DCGI
2	Registration process	One registration process	Multiple registration process • Centralised (European community) • Decentralised (at least 2 member states) • Mutual recognition (at least 2 member states) • National (1 member state)	One registration process
3	TSE/BSE study data	Not required	Required	Required
4	Braille code	Not required	Braille code is not required on labelling	Braille code is required on labelling
5	Post approval changes	Post approval changes in the approved drug: • Minor • Moderate • major	Post variation in the approved drug: • Type IA • Type IB • Type II	Post approval changes: • Major • Moderate
6	Application	ANDA/NDA	MAA	MAA
7	Debarment classification	Required	Not required	Not required
8	No. of copies	3	1	1
9	Approval timeline	18 MONTHS	12 MONTHS	2-18 MONTHS
10	Presentation	eCTD and paper	eCTD	Paper
11	No. of batch	1	3	1
12	Packaging	A minimum of 1,00,0000	Not addressed	Not addressed
13	Process validation	Not required at the time of submission	Required	Required
14	Batch size	1 pilot scale or minimum of 1 lakh units whichever is higher.	2 pilot scales plus 1 lab batch or minimum of 1 lakh units whichever is higher	Pilot scale batch

CONCLUSION

Ultra-modern pharmaceutical nonsupervisory affairs serve as a vital link between the assiduity and government bodies to insure that new drugs are safe and effective. Historically, major medical tragedies led to the creation of rigorous clinical trial phases and oversight associations like the FDA and CDSCO. Developing a medicine involves a complex series of way, ranging from preclinical testing to mortal trials that cover lozenge and long- term side goods. Companies must navigate specific submission pathways, similar as Investigational New Drug(IND) or New Drug Applications(NDA), to gain marketing blessing. While different nations, like India and the United States, maintain unique legislative fabrics and timelines, numerous have espoused the Common Technical Document(CTD) to regularize

global data formatting. Eventually, these nonsupervisory systems aim to help public detriment by administering strict norms for quality control and manufacturing throughout a product's lifecycle.

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