World Journal of Pharmaceutical Science and Research
www.wjpsronline.com
Research Article
ISSN: 2583-6579
SJIF Impact Factor: 6.916
Year - 2026
Volume: 5; Issue: 2
Page: 670-681

STUDY OF DRUG REGULATORY APPROVAL PROCESS AND COMPARATIVE REQUIREMENT OF COMMON TECHNICAL DOCUMENTS (CTD) IN EUROPE, US AND INDIA IN COORDINATION WITH DRUG DEVELOPMENT PROCESS

Anuma Vilas More*[1], Syed Shoaib Ali[2]

[1]Second Year M. Pharmacy, Department of Regulatory Affairs, Dr. Babasaheb Ambedkar Technological University, Lonere.

[2]Assitant Professor, Dr. Vedprakash Patil Pharmacy College, Gevrai Tanda, Chh. Sambhajinagar.

Article Received: 9 January 2026 | | ***Article Revised: 30 January 2026*** | | ***Article Accepted: 19 February 2026***

***Corresponding Anuma Vilas More**
Second Year M. Pharmacy, Department of Regulatory Affairs, Dr. Babasaheb Ambedkar Technological University, Lonere.
DOI: https://doi.org/10.5281/zenodo.18767513

How to cite this Article: Anuma Vilas More, Syed Shoaib Ali (2026) STUDY OF DRUG REGULATORY APPROVAL PROCESS AND COMPARATIVE REQUIREMENT OF COMMON TECHNICAL DOCUMENTS (CTD) IN EUROPE, US AND INDIA IN COORDINATION WITH DRUG DEVELOPMENT PROCESS. World Journal of Pharmaceutical Science and Research, 5(2), 670-68. https://doi.org/10.5281/zenodo.18767513

1.0 INTRODUCTION

The pharmaceutical industry is one of the most highly regulated sectors in the world, owing to its direct impact on human health and safety. The development and commercialization of medicinal products require strict compliance with regulatory standards to ensure that drugs reaching the market are safe, effective, and of consistent quality.[1] Regulatory authorities across the globe have established comprehensive frameworks governing every stage of a drug's life cycle, from early discovery and pre-clinical testing to clinical development, marketing authorization, and post-marketing surveillance. These regulatory systems not only protect public health but also promote scientific integrity, ethical conduct of clinical trials, and transparency in pharmaceutical manufacturing and distribution. Drug development is an inherently complex, lengthy, and resource-intensive process. On average, it takes more than ten years and substantial financial investment to bring a new drug from laboratory discovery to the patient's bedside. The process typically includes target identification, lead optimization, pre- clinical pharmacology and toxicology studies, phased clinical trials, scale-up manufacturing, and regulatory submission. At each of these stages, regulatory requirements shape the design of studies, selection of endpoints, validation of analytical methods, and documentation of results. Therefore, regulatory science has become an integral component of pharmaceutical research and development, influencing decision-making and strategic planning throughout the product life cycle.[2]

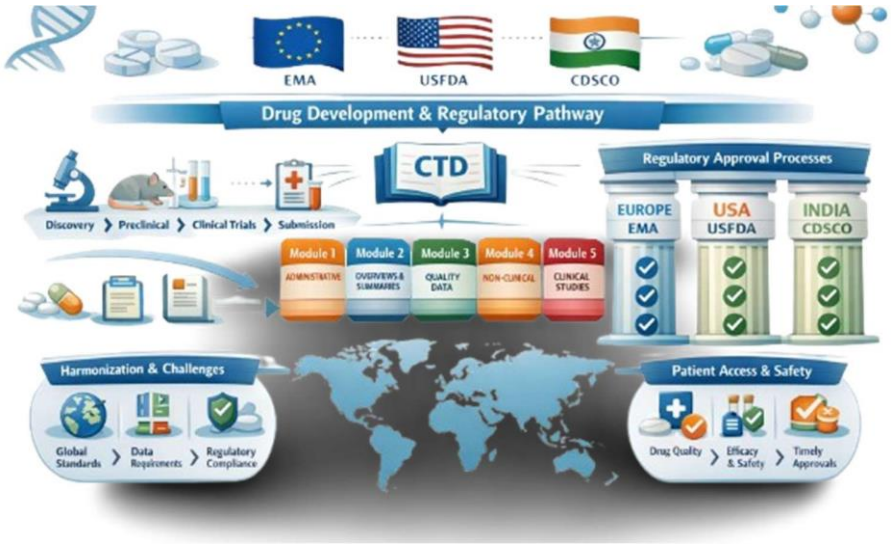

Fig. 1.1: Drug development and Regulatory Pathway.

In an increasingly globalized pharmaceutical market, drug developers often seek approval in multiple regions to maximize patient access and commercial potential. However, regulatory systems differ widely among countries with respect to legal frameworks, review procedures, timelines, data requirements, and post-approval obligations. These differences can lead to duplication of studies, increased development costs, prolonged approval timelines, and delayed access to essential medicines. To address these challenges, international regulatory harmonization initiatives have gained importance, with the aim of aligning technical requirements and facilitating mutual recognition of data across regulatory jurisdictions.[3]

A landmark step in regulatory harmonization was the establishment of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The ICH was formed to bring together regulatory authorities and pharmaceutical industry representatives from major regions, including Europe, the United States, and Japan, with the objective of standardizing technical guidelines for drug registration. One of the most significant outcomes of the ICH initiative is the development of the Common Technical Document (CTD), a harmonized dossier format for marketing authorization applications. The CTD provides a common structure for organizing quality, non-clinical, and clinical data, thereby simplifying regulatory submissions and facilitating efficient review by regulatory agencies. The CTD is organized into five modules: Module 1 contains region-specific administrative and prescribing information; Module 2 includes high-level summaries and overviews; Module 3 presents quality data related to drug substance and drug product; Module 4 comprises non-clinical study reports; and Module 5 includes clinical study reports. This standardized format allows pharmaceutical companies to prepare a single core dossier that can be adapted to meet the specific requirements of different regulatory authorities. The adoption of the CTD has significantly improved consistency, reduced redundancy, and enhanced communication between sponsors and regulators.[4]

Despite the widespread acceptance of the CTD format, substantial variations remain in regulatory approval processes and documentation requirements among major regulatory agencies such as the European Medicines Agency (EMA), the United States Food and Drug Administration (USFDA), and the Central Drugs Standard Control Organization (CDSCO) of India. Each regulatory authority operates within a distinct legal and administrative framework, with unique procedures for application submission, scientific review, inspection, and post- approval monitoring. For

example, the EMA follows a centralized and decentralized procedure within the European Union, In India, the CDSCO regulates drug approvals under the Drugs and Cosmetics Act and Rules, with evolving guidelines and increasing alignment with international standards.[5]

Differences are also observed in the timelines for review and approval, requirements for local clinical trials, data exclusivity provisions, labeling regulations, and pharmacovigilance obligations. In some regions, bridging studies or additional stability data may be required to support approval, even when a product has been authorized elsewhere. These regulatory divergences pose significant challenges for global drug development programs, necessitating careful regulatory strategy planning and region-specific adaptation of development plans.[6]

Coordination between the drug development process and regulatory submission requirements is a critical determinant of successful product approval. Early integration of regulatory considerations into development planning can help optimize study design, ensure compliance with guidelines, and minimize the risk of deficiencies during regulatory review. Regulatory agencies increasingly encourage early scientific advice meetings, pre-IND consultations, and protocol assistance to guide sponsors in generating data that meet regulatory expectations. Such interactions facilitate alignment between sponsors and regulators and reduce the likelihood of costly delays or application rejections.[7]

Furthermore, regulatory requirements influence key aspects of pharmaceutical development, including selection of dosage forms, formulation design, manufacturing processes, validation strategies, and quality control systems. The implementation of Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP) ensures that data submitted in regulatory dossiers are reliable, reproducible, and traceable. The integration of quality-by-design (QbD) principles and risk-based approaches further strengthens regulatory compliance and product robustness.[8] In recent years, regulatory systems have continued to evolve in response to scientific advances, emerging technologies, and public health needs.

The increasing complexity of biologics, biosimilars, gene therapies, and personalized medicines has posed new regulatory challenges, requiring adaptive regulatory pathways and innovative review models. Accelerated approval mechanisms, conditional approvals, and reliance pathways have been introduced to expedite access to critical therapies, particularly in the context of unmet medical needs and global health emergencies. India, as a major hub for pharmaceutical manufacturing and generic drug exports, plays a crucial role in the global regulatory landscape. The Indian regulatory system has undergone significant reforms to strengthen regulatory capacity, enhance transparency, and align with international standards. The adoption of CTD and eCTD formats, implementation of revised Schedule M for GMP, and participation in ICH activities reflect India's commitment to regulatory harmonization. However, challenges remain in achieving full convergence with global regulatory practices, particularly with respect to review timelines, inspection capacity, and post-marketing surveillance.[9]

In this context, a comparative study of the drug regulatory approval processes and CTD requirements in Europe, the United States, and India is of considerable academic and practical significance. Such an analysis provides valuable insights into regulatory similarities and differences, highlights critical gaps and opportunities for harmonization, and supports the development of effective regulatory strategies for multinational drug development programs. Understanding how regulatory requirements interact with various stages of drug development enables pharmaceutical

scientists, regulatory professionals, and policymakers to design efficient development pathways and ensure timely patient access to high-quality medicines.[10]

Therefore, the present study aims to systematically examine the regulatory approval frameworks of the EMA, USFDA, and CDSCO, with a particular focus on the structure and content of the Common Technical Document and its coordination with the drug development process. By analyzing regulatory guidelines, submission procedures, review mechanisms, and integration with development activities, this research seeks to provide a comprehensive understanding of global regulatory practices and contribute to improved regulatory compliance, harmonization, and innovation in pharmaceutical development.[11]

1.2 Limitations of study

- The study is based mainly on secondary sources such as regulatory guidelines, official websites, books, and published literature, and does not include primary data from regulatory professionals or authorities.
- Regulatory guidelines and approval procedures are subject to frequent updates and revisions; therefore, the information presented may change over time and may not remain fully applicable in the future.
- The scope of the study is limited to three regulatory regions Europe (EMA), the United States (USFDA), and India (CDSCO) and does not cover other important regulatory agencies such as PMDA (Japan), Health Canada, or TGA (Australia).
- The study focuses primarily on general drug approval pathways and conventional pharmaceutical products and does not extensively address specialized products such as biologics, biosimilars, vaccines, gene therapies, or medical devices.
- Differences in internal review practices, reviewer expertise, and administrative efficiency among regulatory agencies were not evaluated, although these factors may influence approval timelines and outcomes.[12]

2. REVIEW OF LITERATURE

2.1 Wasiullah et al. (2025)

Wasiullah and colleagues conducted a comparative analysis of drug approval processes among major global regulatory agencies, including the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and selected regulatory bodies from developing countries. The study described the standard stages of drug development, such as preclinical testing, clinical trial phases (I–III), regulatory submission, and post-marketing surveillance. It emphasized that while regulatory agencies shared common goals of ensuring drug safety, efficacy, and quality, notable differences existed in review timelines, submission requirements, and approval pathways. The authors discussed harmonization initiatives like the International Council for Harmonisation (ICH), which aimed to streamline global regulatory standards. However, the study found that regulatory divergence still affected market entry and innovation. The authors concluded that greater regulatory cooperation and reliance mechanisms could reduce duplication, accelerate approvals, and improve global patient access to medicines.[13]

2.2 Madagoni et al. (2017)

Madagoni and co-authors reviewed the drug approval processes in the United States, Europe, and India, with a strong emphasis on regulatory documentation and bioavailability and bioequivalence (BA/BE) studies. The article described the structure and importance of the Common Technical Document (CTD) and electronic CTD formats used for

regulatory submissions. It explained how BA and BE studies were essential for establishing therapeutic equivalence, particularly for generic drug approvals. The authors highlighted differences in regulatory expectations among regions, such as study design, reference products, and acceptance criteria. The review demonstrated that while developed regions followed highly standardized procedures, India's regulatory framework was evolving to align with international norms. The authors concluded that understanding regional regulatory differences was crucial for pharmaceutical companies to ensure successful submissions and global product commercialization.[14]

2.3 Lipsky & Sharp et al. (2001)

Lipsky and Sharp provided a detailed overview of the drug approval process, primarily focusing on the United States regulatory system. The article traced the historical development of drug regulation, highlighting key legislative milestones that strengthened safety and efficacy requirements. The authors described the stepwise drug development process, beginning with laboratory and animal studies, followed by phased clinical trials in humans. They explained the role of Investigational New Drug (IND) applications and New Drug Applications (NDAs) in regulatory review. The article emphasized the ethical and scientific rigor required during clinical testing to protect patient safety. The authors also discussed the challenges faced by regulatory authorities in balancing rapid access to innovative therapies with thorough evaluation. The review concluded that the structured approval process had significantly improved drug safety and public trust in pharmaceuticals.[15]

2.4 Hornecker et al. (2009)

Hornecker reviewed the history, approval process, and challenges associated with generic drugs. The article explained how generic drugs emerged as cost-effective alternatives to branded medicines following patent expiration. The author described the abbreviated approval pathway for generics, which relied primarily on bioequivalence studies rather than extensive clinical trials. The article discussed regulatory mechanisms such as the Abbreviated New Drug Application (ANDA) in the United States. It also highlighted challenges faced by the generic drug industry, including patent litigation, quality concerns, manufacturing compliance, and market competition. The author emphasized the role of generics in improving medication accessibility and reducing healthcare costs. The review concluded that despite regulatory and commercial challenges, generic drugs remained a vital component of modern healthcare systems.[16]

2.5 Gupta PK et al. (2018)

Gupta provided a comprehensive overview of drug regulatory affairs with a focus on regulatory systems governing pharmaceutical development and commercialization. The book explained national and international regulatory frameworks, including requirements for drug approval, clinical trials, quality assurance, and post-marketing surveillance.

It detailed regulatory submissions such as IND, NDA, ANDA, and CTD formats. The author emphasized the role of regulatory professionals in ensuring compliance with evolving laws and guidelines. The text also discussed regulatory challenges in emerging markets and the importance of harmonization through organizations like ICH. The book concluded that effective regulatory strategies were essential for timely drug approvals and global market access.[17]

2.6 Berry & Martin et al. (2008)

Berry and Martin examined the pharmaceutical regulatory process from drug discovery to post- approval monitoring. The book described regulatory decision-making, risk–benefit assessment, and the role of agencies such as the FDA and

EMA. It highlighted regulatory science principles, including quality, safety, and efficacy evaluation. The authors discussed regulatory policy development, inspection systems, and lifecycle management of medicines. The text emphasized the growing complexity of global regulation and the need for science-based regulatory frameworks. The book concluded that transparent and consistent regulatory processes were vital for protecting public health.[18]

2.7 Shah & Patel et al. (2017)

Shah and Patel conducted a comparative study of drug approval processes in the United States, Europe, and India. The article described regulatory authorities such as the FDA, EMA, and CDSCO, and compared submission requirements, review timelines, and approval pathways. It highlighted differences in clinical trial approval, documentation, and generic drug regulations. The study showed that while the US and Europe followed highly structured systems, India's regulatory framework was developing toward global harmonization. The authors concluded that understanding regional regulatory differences was critical for global pharmaceutical development.[19]

2.8 Bhatt et al. (2010)

Bhatt reviewed the historical evolution of clinical research from early experimentation to modern evidence-based practices. The article traced the origins of clinical trials to James Lind's scurvy study and described the progression toward ethical and scientific standards. It highlighted key developments such as randomization, informed consent, and regulatory oversight. The author emphasized the impact of historical milestones on modern clinical research practices. The review concluded that the evolution of clinical research had significantly improved the reliability and ethical conduct of drug development.[20]

2.9 Pisano & Mantus et al. (2015)

Pisano and Mantus presented an in-depth examination of pharmaceutical regulatory science and its application in drug development and approval. The book integrated scientific, legal, and policy perspectives on regulation. It discussed regulatory decision-making, benefit–risk evaluation, and lifecycle management of pharmaceutical products. The authors emphasized the role of innovation, emerging technologies, and global harmonization in regulatory science. The text concluded that regulatory science was essential for advancing public health while supporting pharmaceutical innovation.[21]

2.10 Sutar et al. (2013)

This is a foundational review that *specifically examines the drug regulatory approval process and the requirements for Common Technical Documents (CTD)* across Europe (EMA), the United States (FDA), and India (CDSCO). It discusses how CTD aligns with drug development stages and highlights regulatory roles in documentation and evaluation.

2.11 Chakraborty & Yadav (2018)

This review compares the regulatory requirements and approval mechanisms in the US, EU, and India. It highlights differences in procedures for marketing authorization applications (MAA) and underscores how each region's authority ensures safety, efficacy, and quality through regulatory compliance.

2.12 Shivasai et al. (2024)

This article describes and compares the procedural steps for new drug applications in the US, Europe, and India. It

covers R&D stages, regulatory submissions, and reviews how each region handles clinical trials and dossier submission leading up to MAA.

2.13 Patel et al. (2024)

While focused on generics, this review highlights how the **Abbreviated New Drug Application (ANDA)** and CTD formats are used differently across the US, EU, and India. It emphasizes regulatory challenges and harmonization issues, showing how CTD supports global dossier standardization.

2.14 Wisdomlib (2023)

This comparative review focuses on *dossier preparation requirements for generic drugs* in the US, Europe, and India, highlighting how CTD structure and content vary regionally and the rationale behind these variations.

2.15 JETIR (2025)

This recent study examines *generic drug approval procedures in compliance with CTD guidance* and discusses the regulatory implications for India, Europe, and the US, especially how standard CTD modules support evaluation

2.16 Patil & Thakre (2020)

Though broader in scope, this review includes the studied CTD requirements and their relationship with regulatory frameworks in the US, Europe, and India, offering context for its role within the full drug development lifecycle.

3. Need of the study

- Importance of Drug Regulatory Approval Processes: The drug regulatory approval process was essential to ensure that pharmaceutical products met required standards of safety, efficacy, and quality before reaching patients. Studying this process helped understand how regulatory authorities protected public health and minimized risks associated with unsafe or ineffective medicines.
- Globalization of Drug Development: Pharmaceutical companies increasingly developed and marketed drugs globally. Studying regulatory requirements in Europe, the US, and India helped address challenges related to simultaneous drug development and submissions in multiple regions.
- Differences and Similarities in Regulatory Requirements: Each regulatory authority followed distinct guidelines, timelines, and evaluation procedures. A comparative study helped identify similarities that supported harmonization and differences that required region-specific regulatory strategies.
- Structure and Requirements of the CTD: The Common Technical Document was designed to standardize regulatory submissions. Studying its structure and regional adaptations confirmed how Module requirements varied across Europe, the US, and India despite a common format.
- Challenges Due to CTD Variations: Differences in regional CTD expectations often led to duplication of documentation and increased regulatory burden. Understanding these challenges supported more efficient dossier preparation and reduced submission errors.
- Support for Regulatory Harmonization: The study contributed to ongoing harmonization efforts by identifying regulatory gaps and areas requiring alignment. This helped streamline approval processes and improve international cooperation.
- Efficient Regulatory Planning and Faster Approvals: A clear understanding of regulatory requirements supported better planning of submissions, reduced review timelines, and improved the chances of timely regulatory approval.

4. AIM AND OBJECTIVES

Aim

Study of Drug Regulatory Approval Process and Comparative Requirement of Common Technical Documents (CTD) in Europe, US and India in coordination with drug development process.

Objectives

- To study the overall drug regulatory approval process followed in Europe, the United States, and India.
- To understand the role and structure of the Common Technical Document (CTD) used for regulatory submissions.
- To compare the CTD requirements and regional regulatory variations in Europe, the US, and India.
- To analyze the coordination between drug development stages and regulatory submission requirements.
- To identify similarities and differences in regulatory expectations among the three regions.
- To assess challenges faced during regulatory submissions due to regional variations in CTD requirements.

5. PLAN OF WORK

- **Literature Review**: A comprehensive review of textbooks, research articles, regulatory guidelines, and official documents related to drug regulatory approval processes in Europe, the United States, and India was conducted. Emphasis was placed on CTD structure, regulatory pathways, and drug development stages.
- **Study of Drug Development Process**: The stages of drug development, including discovery, preclinical studies, clinical trials (Phase I–III), and post-marketing surveillance, were studied to understand their regulatory relevance.
- **Evaluation of Regulatory Authorities**: The roles and responsibilities of major regulatory authorities such as the US FDA, European Medicines Agency (EMA), and Central Drugs Standard Control Organization (CDSCO) were analyzed.
- **Study of Common Technical Document (CTD)**: The structure of CTD modules (Modules 1–5) was examined, focusing on content requirements and regional differences.
- **Comparative Analysis of CTD Requirements**: A detailed comparison of CTD requirements in Europe, the US, and India was performed to identify similarities, differences, and region-specific expectations.
- **Identification of Challenges and Gaps**: Regulatory challenges such as documentation variations, timeline differences, and harmonization gaps were identified.
- **Conclusion and Recommendations**: Conclusions were drawn based on the comparative analysis, and recommendations were provided to support effective regulatory strategy and harmonized drug development.

Table 5.1: Plan of work timeline.

Phase	Activity	Duration
Phase I	Topic selection, objective formulation, and literature review on drug regulatory approval processes and CTD	Month 1
Phase II	Study of drug development process and evaluation of regulatory authorities (FDA, EMA, CDSCO)	Month 2
Phase III	Detailed analysis of drug approval processes and CTD structure in Europe, US, and India	Month 3
Phase IV	Comparative evaluation of CTD requirements and coordination with drug development stages	Months 4–5
Phase V	Compilation of findings, report writing, conclusions, and recommendations	Month 6

6. METHODOLOGY

6.1. Collection of Literature

The study will begin with a comprehensive collection of literature from multiple sources. Textbooks on drug regulatory affairs, pharmaceutical regulatory science, and drug development will be consulted to understand foundational principles. Research articles and review papers published in indexed journals will be retrieved to analyze recent trends, comparisons, and studies related to global regulatory frameworks and CTD requirements. Online databases such as PubMed, ScienceDirect, and Google Scholar will be systematically searched using keywords like "drug regulatory approval," "CTD," "FDA," "EMA," and "CDSCO." Official regulatory guidelines and documents from FDA, EMA, CDSCO, and ICH websites will be downloaded to ensure accuracy and currency of data. The literature review will provide insight into similarities and differences in regulatory requirements, approval timelines, and documentation standards. This step will help in formulating a clear framework for the comparative analysis and ensure that the study is grounded in authentic and updated information.

6.2. Study of Drug Development Process

The next step will focus on understanding the drug development process in detail and its connection to regulatory submissions. Each stage, including drug discovery, preclinical testing, and clinical trials (Phase I, II, III), will be analyzed to determine how regulatory requirements influence the design, execution, and documentation of studies. Post-marketing surveillance will also be considered to understand ongoing compliance needs. The study will evaluate how documentation generated during each stage will later integrate into CTD submissions. By mapping regulatory requirements to the drug development timeline, the research will identify the points at which regulatory approvals and documentation must align with development milestones. This analysis will highlight potential areas where delays or discrepancies could occur and will provide guidance on planning and coordination for efficient regulatory submission. Ultimately, this step will ensure that the study links theoretical regulatory frameworks to practical drug development processes.

6.3. Evaluation of Regulatory Authorities

In this step, the study will focus on evaluating the roles, responsibilities, and procedures of major regulatory authorities: FDA (United States), EMA (Europe), and CDSCO (India). The approval pathways, submission requirements, and review timelines of these agencies will be analyzed in detail. Key aspects, such as the types of applications (IND, NDA, ANDA, Marketing Authorization Applications), criteria for evaluating safety and efficacy, and post- marketing surveillance obligations, will be reviewed. The study will also identify the similarities and differences in regulatory philosophy, documentation expectations, and review procedures among the three authorities. By understanding the regulatory framework of each region, the study will provide a basis for comparing CTD requirements and identifying areas for harmonization. This step will ensure that the research not only compares documentation but also situates it within the broader regulatory environment of each region, providing practical insight into global drug approval processes.

6.4. Analysis of the Common Technical Document (CTD)

The study will conduct an in-depth analysis of the Common Technical Document, focusing on its structure, content, and regional adaptations. All five modules of the CTD (administrative information, quality, nonclinical study reports, clinical study reports, and regional information) will be examined. Differences in requirements between Europe, the

US, and India will be identified, such as regional-specific forms, language requirements, or additional data expectations. The study will evaluate how CTD submissions reflect compliance with safety, efficacy, and quality standards at each stage of drug development. Emphasis will be placed on understanding how CTD documentation facilitates regulatory review, reduces duplication, and supports harmonization. By comparing CTD requirements regionally, the research will highlight challenges that pharmaceutical companies face when submitting the same product to multiple agencies. This step will form the foundation for a structured comparative analysis and provide actionable insights for optimizing global regulatory submissions.

6.5. Comparative Study of CTD Requirements and Coordination with Drug Development

In the final methodology step, the study will perform a systematic comparative analysis of CTD requirements across Europe, the US, and India. Similarities, differences, and region-specific expectations will be identified and tabulated for clarity. Coordination between drug development stages and CTD documentation will be evaluated to determine how preclinical, clinical, and quality data feed into regulatory submissions. Challenges such as varying documentation formats, regional compliance requirements, and approval timelines will be analyzed to provide recommendations for efficient regulatory planning. The study will also explore the potential for harmonization and reliance strategies to streamline submissions across multiple regions. By integrating findings from literature, regulatory guidelines, and drug development processes, this step will allow the research to generate practical conclusions and recommendations for pharmaceutical companies, regulatory professionals, and researchers seeking efficient global drug approvals.

7. EXPECTED OUTCOME

- **Comprehensive Understanding of Regulatory Processes**: The study is expected to provide a clear and detailed understanding of the drug regulatory approval processes in Europe, the United States, and India. It will outline the roles and responsibilities of major regulatory authorities such as the FDA, EMA, and CDSCO, including their submission pathways, review timelines, and approval criteria.
- **Detailed Comparative Analysis of CTD Requirements**: The research will identify the similarities and differences in the Common Technical Document (CTD) requirements across the three regions. Differences in content, format, module requirements, and regional adaptations will be highlighted, providing a structured reference for pharmaceutical professionals and researchers.
- **Integration with Drug Development Process**: The study will demonstrate how the regulatory requirements, especially CTD documentation, coordinate with various stages of drug development. This will help in planning and generating documentation efficiently during preclinical, clinical, and post-marketing phases.
- **Identification of Challenges and Gaps**: Potential regulatory challenges, discrepancies in CTD requirements, and regional gaps will be identified. The study will point out areas where harmonization could improve efficiency and reduce duplication in submissions.
- **Guidance for Regulatory Planning**: The research is expected to provide actionable insights for pharmaceutical companies, regulatory professionals, and researchers, helping them streamline global submissions, optimize timelines, and ensure compliance.
- **Contribution to Harmonization Efforts**: The study will contribute to understanding and supporting global regulatory harmonization initiatives, promoting faster approval of safe, effective, and high-quality medicines for patients worldwide.

ACKNOWLEDGEMENT

I would like to express my sincere gratitude to several individuals for supporting me throughout my graduate study. First, I wish to express my sincere gratitude to my supervisor and Professor for their enthusiasm, patience, insightful comments, helpful information, practical advice that have helped me tremendously at all times in my review article. Without their support and guidance, this review article would not have been possible.

My profound gratitude goes to my wonderful supervisor, **Prof. SYED SHOAIB ALI** for their valuable support, patience, time and guidance in seeing me to the completion of this review work.

I express my sincere thanks to **Shri Dhaneshwari Manav Vikas Mandal's, Dr. Vedprakash Patil Pharmacy College, Chhatrapati Sambhajinagar** for providing facilities. It is my privilege to express thanks to my respected Principal of Dr. Vedprakash Patil Pharmacy College, Chhatrapati Sambhajinagar.

I am thankful to teaching and non-teaching staff for their help and cooperation.

8. REFERENCES

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *The Common Technical Document for the Registration of Pharmaceuticals for Human Use: M4 Guideline*, ICH; 2003.
2. European Medicines Agency (EMA). *Procedural advice for marketing authorisation applications*. EMA, London; 2024.
3. United States Food and Drug Administration (USFDA). *Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications*. FDA, Silver Spring; 2023.
4. Central Drugs Standard Control Organization (CDSCO). *Guidance for Industry on Preparation of Common Technical Document (CTD) for Drug Registration in India*. CDSCO, New Delhi; 2022.
5. Gupta PK. *Drug Regulatory Affairs*. 2nd ed. New Delhi: CBS Publishers and Distributors; 2018.
6. Berry IR, Martin RP. *The Pharmaceutical Regulatory Process*. 2nd ed. New York: Informa Healthcare; 2008.
7. ICH. *ICH Harmonised Tripartite Guideline: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use (M4)*. ICH; 2003.
8. European Commission. *Notice to Applicants: Volume 2A – Procedures for Marketing Authorisation*. Brussels; 2023.
9. US Food and Drug Administration. *New Drug Application (NDA) Review Process*. FDA, Center for Drug Evaluation and Research; 2022.
10. Ministry of Health and Family Welfare, Government of India. *Drugs and Cosmetics Act, 1940 and Rules, 1945 (as amended)*. New Delhi; 2023.
11. ICH. *Guideline for Good Clinical Practice E6 (R2)*. ICH; 2016.
12. Central Drugs Standard Control Organization (CDSCO). *New Drugs and Clinical Trials Rules, 2019*. Government of India; 2019.
13. Wasiullah, M., Yadav, P., Yadav, S., & Nishad, R. "The Drug Approval Process: A Comparative Analysis between Global Regulatory Agencies." *International Journal of Pharmaceutical Research and Applications*, 2025; *10*(2): 2717–2721.
14. Madagoni, K., Saidireddy, U., & Himaja. A review on drug approval process in US, Europe and India-dossier,

bioavailability and bioequivalence studies. *International Journal of Applied Pharmaceutical Sciences and Research*, 2017; *1*(04): 133–146. https://doi.org/10.21477/ijapsr.v1i4.6892

15. Matin s. lipsky, lisa k. sharp, The drug approval process, Jabfp, sep-oct 2001; 14(5): 12. Jaime R hornecker, Generic drugs: history, approval process and current challenges, US pharm2009; 34(6): 26-30.
16. Jaime R hornecker, Generic drugs: history, approval process and current challenges, US pharm2009; 34(6): 26-30.
17. Gupta PK. *Drug Regulatory Affairs*. 2nd ed. New Delhi: CBS Publishers and Distributors; 2018.
18. Berry IR, Martin RP. *The Pharmaceutical Regulatory Process*. 2nd ed. New York: Informa Healthcare; 2008.
19. Shah S, Patel J. Comparative study of drug approval process in US, Europe and India. *Journal of Pharmaceutical Sciences and Research*, 2017; 9(6): 1021–1027.
20. Bhatt A. Evolution of clinical research: a history before and beyond James Lind. *Perspectives in Clinical Research*, 2010; 1(1): 6–10.
21. Pisano DJ, Mantus DS. *Textbook of Pharmaceutical Regulatory Science*. New York: Springer; 2015.
22. Shivasai, B., Zareena Begum, S., & Sunayana, S. Comparative Study of New Drug Application Procedure in US, EU and India**.** *International Journal of Allied Medical Sciences and Clinical Research*, 2024.
23. Chakraborty, K. & Yadav, K. Drug Approval Process In Us, Europe And India And Its Regulatory Requirements: A Review. *International Journal Of Drug Regulatory Affairs.* 2018.
24. Patel, Bhoomi D., Suthar, Shailesh P., Mansuri, Arman M. & Joshi, Vishvash D. A Comparative Analysis Of Generic Drug Assessment And Regulatory Approval In The Usa, Europe And India. *Chinese Journal Of Applied Physiology*, 2024.
25. Patil, A. & Thakre, A**.** Overview Of Drug Regulatory Affairs And Drug Approval Process In Us, Europe, India And Canada: A Review. *International Journal Of Drug Regulatory Affairs*, 2020.
26. Mahapatra, A. K., Sameeraja, N. H. & Murthy, P. N**.** Drug Approval Process In United States Of America, European Union And India: A Review**.** *Applied Clinical Research, Clinical Trials And Regulatory Affairs*, 2014.
27. Regulatory Requirements And Drug Approval Process In India, Europe And Us – Sawant, A. M., Mali, D. P. & Bhagwat, D. A. *Pharmaceutical Regulatory Affairs*, 2018.
28. A Comprehensive Review On Registration Requirements For Drug Approval In India, South Africa And Us – Veer J. Patel & Dasharath M. Patel. *International Journal Of Drug Regulatory Affairs*, 2021.
29. Regulatory Requirements For The New Drug Approval Process In Different Countries – Sangavi C. *International Journal Of Drug Regulatory Affairs* (202x).
30. Rakesh, P., Adilakshmi, C., Nagabhushanam, M. V. Et Al. Comparative Study Of The Generic Drug Approval Procedure And Registration In Europe, The United States, And India In Compliance With Ctd**.** *Jetir*, 2025.
31. Neetu, Setia, A. & Thakur, M. Critical and Comparative Analysis of Anda Filling of Tablets In India, Europe And Us. *Pharmatutor*, 2017.
32. Rick, N. G. Drugs From Discovery To Approval. *John Wiley & Sons*, 2015.
33. Berry, I. R. & Martin, R. P. (Eds.) The Pharmaceutical Regulatory Process**.** *Informa Healthcare*, 2008.