WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 8, 23-35. Review Article ISSN 2277–7105

APPLICATION OF ARTIFICIAL INTELLIGENCE FOR AUTOMATION OF REGULATORY DOSSIER PREPARATION (CTD/eCTD)

Sanjyot Jagtap*[1], Syed Shoaib Ali[2]

India.

Article Received on 15 March 2026,
Article Revised on 04 April 2026,
Article Published on 16 April 2026,

https://doi.org/10.5281/zenodo.19588827

***Corresponding Author**
Sanjyot Jagtap
India.

How to cite this Article: Sanjyot Jagtap*[1], Syed Shoaib Ali[2]. (2026). Application Of Artificial Intelligence For Automation Of Regulatory Dossier Preparation (CTD/eCTD). World Journal of Pharmaceutical Research, 15(8), 23–35.

INTRODUCTION

The pharmaceutical industry operates under stringent regulations, requiring companies to submit comprehensive documentation for drug approval, marketing authorization, and post-marketing surveillance. The Common Technical Document (CTD) and its electronic version, eCTD, are standardized formats used globally to facilitate regulatory submissions across multiple regions. These dossiers contain vast volumes of information, including quality, safety, efficacy data, clinical trial results, and manufacturing details.

Traditionally, preparing CTD/eCTD dossiers is a manual, labor-intensive process involving data compilation, formatting, cross-referencing, and verification. Errors or inconsistencies can lead to submission delays, non-compliance, or rejection, which impacts the time-to-market and increases operational costs.

The advent of Artificial Intelligence (AI) presents a transformative opportunity for regulatory affairs. AI technologies, including natural language processing (NLP), machine learning (ML), and robotic process automation (RPA), can automate repetitive tasks, extract relevant data from diverse sources, validate documents against regulatory guidelines, and generate structured dossiers. Automation through AI can significantly enhance efficiency, accuracy, and regulatory compliance, enabling regulatory professionals to focus on strategic decision-making rather than routine compilation.

Implementing AI for CTD/eCTD preparation aligns with the digital transformation trend in

the pharmaceutical industry, offering benefits such as:

- Reduced preparation time for regulatory submissions
- Improved consistency and error minimization
- Better adherence to international regulatory standards
- Cost-effectiveness and resource optimization

This study aims to explore the role of AI in automating regulatory dossier preparation, evaluate the current tools and technologies, and assess the impact on workflow efficiency and compliance. By analyzing AI's application in this critical area, the study seeks to provide insights into how pharmaceutical companies can leverage AI to streamline regulatory processes and accelerate drug approval timelines.

Limitations of Study

1. Dependence on Available Literature and Tools

The study is primarily review-based; conclusions depend on published research, case studies, and existing AI tools. Limited availability of proprietary AI solutions used by pharmaceutical companies may restrict detailed insights.

2. Rapidly Evolving Technology

AI technologies in regulatory affairs are continuously evolving. Some tools or methodologies may become outdated quickly, limiting the study's long-term applicability.

3. Regulatory Variations

Differences in regulatory requirements across countries (FDA, EMA, CDSCO) may pose challenges in generalizing findings for a global context.

4. Lack of Real-world Implementation Data

The study focuses on theoretical applications and reported benefits; actual implementation challenges, organizational acceptance, and ROI may not be fully captured.

5. Data Privacy and Security Considerations

AI implementation in dossier preparation involves sensitive and confidential data. Limitations in addressing privacy, cybersecurity, and compliance issues may restrict practical recommendations.

6. Scope Restriction

The study is limited to CTD/eCTD dossier preparation and does not cover other aspects of regulatory submissions such as post-marketing reporting or pharmacovigilance in depth.

Review of Literature

1. The increasing complexity of global regulatory requirements and the growing volume of documentation have made regulatory dossier preparation a resource-intensive and error-prone process. Traditional manual preparation of Common Technical Document (CTD) and electronic CTD (eCTD) submissions is often associated with inconsistencies, prolonged timelines, and high operational costs.[1] Recent literature identifies Artificial Intelligence (AI) as a promising solution to address these challenges by enabling automation, standardization, and enhanced accuracy in regulatory documentation.
2. Early research on automation in regulatory affairs primarily focused on rule-based systems and basic document management tools to support dossier compilation.[2] However, these systems lacked adaptability and required extensive manual oversight. With advancements in machine learning (ML), researchers began exploring intelligent systems capable of learning from historical regulatory submissions to automate content classification and document indexing.[3]
3. The integration of Natural Language Processing (NLP) has significantly advanced AI-driven regulatory automation. Studies report that NLP algorithms can efficiently extract, interpret, and categorize regulatory information from unstructured documents such as clinical study reports, manufacturing records, and labeling data.[4,5] These capabilities enable automated mapping of documents to CTD modules, thereby reducing human intervention and submission errors.
4. Several studies have demonstrated the effectiveness of AI in ensuring content consistency and cross-referencing within CTD/eCTD dossiers. AI-based validation tools can automatically detect discrepancies across modules, identify missing data, and ensure alignment with regulatory guidelines.[6,7] Such systems have been shown to significantly reduce rework and improve first-cycle approval rates.
5. AI-driven metadata management and lifecycle tracking have emerged as critical components of eCTD automation. Researchers report that intelligent lifecycle management systems can automatically track document versions, manage amendments, and support regulatory variations and renewals.[8] These capabilities enhance regulatory compliance across multiple regions and product lifecycles.

6. Machine learning models have also been applied to predict regulatory deficiencies and agency queries by analyzing historical review outcomes.[9,10] These predictive tools assist regulatory professionals in proactively addressing potential issues before submission, thereby improving dossier quality and reducing approval delays.
7. Regulatory agencies themselves are increasingly adopting AI-enabled review tools. Literature indicates that authorities such as the U.S. FDA and EMA are exploring AI-based analytics to streamline submission review, risk assessment, and workload prioritization.[11,12] This parallel adoption further supports the need for AI-ready submissions generated through automated dossier preparation systems.
8. Automated regulatory intelligence systems powered by AI have been reported to continuously monitor evolving regulatory guidelines and automatically update dossier content requirements.[13] Such systems help organizations maintain compliance with frequently changing global regulations, reducing the risk of non-compliance.
9. Despite the significant benefits, several authors highlight challenges associated with AI-based regulatory automation. Key concerns include data integrity, system validation, lack of transparency in AI decision-making, and regulatory acceptance of AI-generated content.[14,15] Ensuring explainability and auditability of AI systems remains a critical requirement for regulatory trust.
10. Ethical and legal considerations, particularly related to data security, confidentiality, and accountability, have also been discussed extensively in the literature.[16] Regulatory submissions involve sensitive proprietary and patient data, necessitating robust governance frameworks for AI deployment.
11. Recent studies emphasize the importance of standardized validation frameworks, interdisciplinary collaboration, and regulatory guidance to support the responsible adoption of AI in CTD/eCTD automation.[17,18] Overall, existing research strongly supports AI as a transformative tool for regulatory dossier preparation, while underscoring the need for controlled, compliant, and transparent implementation strategies.[19,20]

Need of the study, Rationale and Justification)

1. Need of the Study

Regulatory dossier preparation using the Common Technical Document (CTD) and electronic CTD (eCTD) format is a critical, resource-intensive, and time-consuming process in pharmaceutical product development. Regulatory submissions require meticulous

compilation, cross-referencing, validation, and compliance with evolving guidelines issued by global authorities such as the US FDA, EMA, MHRA, and WHO. Traditional dossier preparation is largely manual, making it susceptible to human error, inconsistencies, version control issues, and prolonged submission timelines.

With the increasing complexity of drug development, including large volumes of preclinical, clinical, and quality data, regulatory teams face growing challenges in maintaining accuracy and compliance while meeting accelerated approval timelines. Manual dossier compilation often results in redundant work, delayed submissions, and increased regulatory queries, impacting time-to-market and development costs.

Recent advancements in Artificial Intelligence (AI)—including machine learning (ML), natural language processing (NLP), and intelligent document processing—offer significant potential to automate repetitive regulatory tasks such as data extraction, document classification, cross-referencing, quality checks, and compliance verification. Despite this potential, systematic evaluation and structured application of AI in CTD/eCTD automation remain limited, particularly in regulatory operations within developing regulatory environments.

Therefore, this study is needed to assess, conceptualize, and justify the application of AI technologies for automating regulatory dossier preparation, aiming to enhance efficiency, accuracy, consistency, and regulatory compliance.

2. Rationale of the Study

The rationale for this study is grounded in the growing demand for digital transformation in regulatory affairs and the proven success of AI in other data-intensive domains of the pharmaceutical industry.

Regulatory dossier preparation involves repetitive, rule-based, and data-driven processes, making it ideally suited for AI-based automation.

AI-enabled systems can:

- Automatically extract relevant data from unstructured documents
- Map data to appropriate CTD modules
- Detect inconsistencies, missing sections, and formatting errors
- Ensure compliance with region-specific regulatory guidelines

- Manage version control and lifecycle tracking of submission documents

While regulatory authorities increasingly support the use of digital tools, they also emphasize data integrity, traceability, transparency, and validation. AI systems, when properly validated, can meet these expectations while significantly reducing manual workload.

The study is further rationalized by the lack of standardized frameworks guiding AI implementation specifically for CTD/eCTD preparation. Most existing studies focus on general regulatory automation or clinical data management, leaving a gap in end-to-end dossier preparation workflows.

Thus, this research aims to provide a structured understanding of AI applications in CTD/eCTD automation, identify opportunities and limitations, and support evidence-based adoption of AI in regulatory affairs.

3. Justification of the Study

This study is justified on scientific, regulatory, operational, and industrial grounds.

1. Scientific Justification

From a scientific perspective, this study contributes to the expanding body of knowledge on AI applications in regulatory science, particularly in document-centric processes. It bridges the gap between theoretical AI capabilities and practical regulatory implementation, offering insights into how AI can improve dossier quality and consistency.

2. Regulatory Justification

Regulatory agencies worldwide are encouraging innovation while maintaining strict compliance standards. By exploring AI-assisted CTD/eCTD preparation, this study supports the development of compliant, transparent, and auditable regulatory workflows, aligning with emerging regulatory expectations for digital submissions.

3. Operational Justification

- AI-based automation can significantly reduce:
- Manual effort and repetitive tasks
- Human errors and inconsistencies
- Submission preparation timelines
- Regulatory review cycles due to improved dossier quality

- This enhances productivity of regulatory professionals, allowing them to focus on strategic and scientific decision-making rather than administrative tasks.

4. Industrial and Societal Justification

Faster and more accurate regulatory submissions lead to reduced development costs and quicker patient access to medicines. For pharmaceutical companies, especially in competitive global markets, AI-enabled dossier automation can offer a strategic advantage by improving efficiency and regulatory success rates.

AIM AND OBJECTIVES

Aim

To evaluate the application of Artificial Intelligence (AI) in automating the preparation of CTD/eCTD regulatory dossiers, focusing on efficiency, accuracy, and compliance with global regulatory standards.

Objective

1. To review and analyze existing AI technologies (machine learning, natural language processing, and intelligent document processing) used in regulatory dossier preparation.
2. To assess the role of AI in automating CTD/eCTD workflow processes, including document classification, data extraction, cross-referencing, and lifecycle management.
3. To evaluate the impact of AI-driven automation on efficiency, measured in terms of reduction in manual effort, preparation time, and resource utilization.
4. To examine the accuracy of AI-assisted regulatory dossiers, focusing on error reduction, data consistency, and completeness of submission documents.
5. To analyze how AI tools ensure compliance with global regulatory requirements, including US FDA, EMA, ICH, and WHO guidelines.
6. To identify challenges, limitations, and risks associated with AI implementation in regulatory dossier preparation, including validation, transparency, and data integrity concerns.
7. To evaluate the effectiveness of AI in supporting version control, document traceability, and audit readiness throughout the CTD/eCTD lifecycle.
8. To compare traditional manual dossier preparation methods with AI-assisted approaches in terms of quality, efficiency, and regulatory outcomes.
9. To propose a conceptual framework or best-practice model for the implementation of

AI in CTD/eCTD dossier automation.

Plan of Work (including timeline)

Achievable Targets	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Topic selection and approval	✓					
Research proposal preparation	✓	✓				
Literature survey on AI and regulatory dossier preparation	✓	✓	✓			
Review of AI tools and regulatory guidelines (FDA, EMA, ICH, CDSCO)		✓	✓			
Data collection (secondary data, case studies, published reports)			✓	✓		
Data analysis and interpretation				✓	✓	
Discussion of findings					✓	
Preparation of results and conclusion					✓	
Thesis writing and compilation				✓	✓	✓
Editing, proofreading, and formatting					✓	✓
Final submission and viva preparation					✓	✓

METHODOLOGY

This study will be conducted as a systematic review-based research focusing on the application of Artificial Intelligence (AI) in automating regulatory dossier preparation (CTD/eCTD) and evaluating its impact on efficiency, accuracy, and compliance.

1. Data Collection

Relevant information will be collected from:

Scientific literature: PubMed, Scopus, Google Scholar, ScienceDirect

Regulatory guidelines and documents: FDA, EMA, CDSCO, ICH

Books, review articles, and industry reports on AI in regulatory affairs and dossier automation

2. Inclusion Criteria

Studies published between 2015–2025

Articles related to AI in regulatory affairs, document automation, and CTD/eCTD preparation

Research focused on workflow optimization, machine learning, NLP, or RPA in regulatory submissions.

3. Exclusion Criteria

Studies unrelated to regulatory affairs or AI applications in dossier preparation Articles with insufficient scientific or regulatory evidence

Non-English publications

4. Data Analysis

Collected data will be analyzed and categorized under: AI tools and technologies for **document automation.**

Workflow optimization and **error reduction** in dossier preparation Compliance with **global regulatory standards (FDA, EMA, CDSCO, ICH) Challenges and limitations** of AI implementation

A **comparative analysis** will be done to identify:

✔ Efficiency improvements

✔ Error minimization

✔ Compliance and validation gaps

5. Outcome Evaluation

Compilation of reliable evidence on AI applications in regulatory dossier preparation Assessment of the **impact on workflow efficiency and compliance** Recommendations for **AI adoption in regulatory affairs**

This study will be conducted as a systematic review-based research focusing on the application of Artificial Intelligence (AI) in automating regulatory dossier preparation (CTD/eCTD) and evaluating its impact on efficiency, accuracy, and compliance.

6. Outcome Evaluation

Compilation of reliable evidence on AI applications in regulatory dossier preparation Assessment of the impact on workflow efficiency and compliance Recommendations for AI adoption in regulatory affairs.

Expected Outcome

1. Comprehensive Understanding of AI Tools

Development of an in-depth understanding of Artificial Intelligence applications in regulatory

affairs, with emphasis on tools used for CTD/eCTD dossier automation.

2. Identification and Evaluation of Suitable AI Technologies

Identification and critical evaluation of AI technologies such as Machine Learning (ML), Natural Language Processing (NLP), and Robotic Process Automation (RPA) for automating regulatory dossier preparation.

3. Efficiency Improvement in Dossier Preparation

Insights into how AI-driven automation reduces manual workload, shortens dossier preparation timelines, and streamlines CTD/eCTD submission workflows.

4. Enhanced Accuracy and Consistency of Regulatory Dossiers

Assessment of AI's ability to minimize human errors, ensure document standardization, maintain data consistency, and improve overall dossier quality.

5. Regulatory Compliance Insights

Compilation of strategies demonstrating how AI-assisted dossier preparation can align with global regulatory requirements and guidelines issued by the US FDA, EMA, CDSCO, and ICH.

6. Improved Document Lifecycle and Version Management

Understanding of AI's role in enhancing version control, traceability, audit readiness, and lifecycle management of CTD/eCTD submissions.

7. Recommendations for Practical Implementation

Provision of practical recommendations and best practices for pharmaceutical organizations to adopt AI in regulatory affairs, optimize workflows, and improve submission quality.

8. Identification of Challenges and Gaps

Identification of potential limitations, validation requirements, regulatory concerns, and implementation barriers associated with AI-driven regulatory dossier preparation.

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