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AI-based Quality Control for eCTD Compilation and Completeness Checker

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Abstract: The increasing complexity and volume of electronic Common Technical Document (eCTD) submissions have amplified the demand for efficient and error-free quality control mechanisms in regulatory affairs. Traditional manual validation methods are time-consuming and prone to inconsistencies, posing risks to submission success and compliance. This paper explores the integration of artificial intelligence (AI) technologies, specifically machine learning (ML), natural language processing (NLP), and deep learning, into the quality control processes of eCTD compilation. It examines the AI methodologies applied, their implementation within real-world regulatory workflows, and the tangible benefits they offer in terms of speed, accuracy, scalability, and compliance. The discussion extends to the challenges faced in adopting AI solutions, including regulatory ambiguity, data privacy issues, and technical integration barriers. Finally, the paper highlights future directions, emphasizing innovations such as generative AI, predictive analytics, and blockchain integration that are expected to shape the next generation of AI-assisted regulatory submissions. The findings suggest that AI-based quality control has the potential to redefine the regulatory landscape by enabling smarter, faster, and more reliable eCTD submissions.

Keywords: eCTD; Artificial Intelligence; Regulatory Submissions; Quality Control; Machine Learning.

INTRODUCTION

The rapid increase in pharmaceutical innovation and regulatory control has contributed to the demand to have correct, efficient, and compliant submission processes. One of the most important aspects in this area is the electronic Common Technical Document (eCTD), an international standard in the filing of applications, amendments, and reports to regulatory authorities. Nevertheless, as the regulatory demands continue to increase in complexity, the previous approaches to developing and confirming the fullness of eCTD submissions have fallen out of favor. They tend to be labor-intensive, error-prone, and time-consuming. This provides an excellent platform upon which artificial intelligence (AI) technologies can be embraced with an aim of automating and improving quality control in eCTD compilation and completeness checking.

AI, particularly machine learning (ML) and natural language processing (NLP), is redefining the efficiency and reliability of regulatory submissions. By integrating rule-based and pattern-based analytical algorithms, quality control processes can automatically identify missing modules, formatting inconsistencies, and potential regulatory violations. Extending beyond process automation, AI-assisted technologies are also transforming the pharmaceutical, biologics, and medical-device industries by enabling more efficient handling of complex regulatory data and driving a reassessment of traditional regulatory models (Chisholm, O., & Critchley, H. 2023; Venna, S. R. 2023; Opderbeck, D. W. 2019). The current paper highlights the newly developed area of AI-assisted quality control of the eCTD submissions procedures in terms of its methods, uses, and advantages. First of all, to realize the applicability of AI to this situation, it is necessary to consider the structural and regulatory complexities of the eCTD documentation. These involve the use of multiple regional needs, maintenance of strict formatting standards, and maintenance of the integrity of data in thousands of pages of technical documentation. The necessity to use automated quality assurance to minimize human error is becoming critical, as well as to shorten the drug approval process and retain compliance with the regulations (Seymour, E. M. et al., 2013; Venna, S. R. 2020). The speed and accuracy of the AI systems are the two-fold benefit that has changed the face of quality control. The paper further examines the application of AI in improving the efficiency and accuracy of eCTD submissions, with particular emphasis on completeness checkers that confirm the inclusion of all required modules and documents within the compiled dossier. It also provides an in-depth discussion of the challenges, limitations, and future perspectives surrounding the integration of AI into regulatory documentation processes.

LEARNING ABOUT THE ECTD FRAMEWORK AND QUALITY CONTROL PROBLEMS

Advances in AI, ML, data science, and big data analytics are reshaping regulatory documentation and submission management. These technologies

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enable intelligent, self-regulating systems that emulate human reasoning to enhance efficiency and consistency in regulatory workflows. The relationship between innovation and law is crucial; while regulatory frameworks can encourage technological advancement, they may also hinder practical implementation due to compliance obligations and potential liability concerns. Within this context, AI-driven approaches are increasingly relevant to the quality control of eCTD submissions. The eCTD consists of five modules: Module 1 (administrative information), Module 2 (overviews and summaries), Module 3 (quality and manufacturing), Module 4 (nonclinical studies), and Module 5 (clinical data). Each module must conform to ICH guidelines, where AI-based analytical systems can streamline validation, detect inconsistencies, and strengthen compliance across regional submissions (Wan, W. Y. et al., 2022; Niazi, S. K. et al., 2023)

Despite its apparent uniformity, achieving standardization in developing an eCTD is a highly complex and challenging task. It entails versioning of documentation, cross-referencing, and metadata tagging. Any error in the process can lead to rejection of submissions or delays, which would significantly hinder the drug approval process. The traditional quality control techniques include manual document verification and style verification, cross-link verification, and metadata verification, all of which are time-consuming and prone to supervision (Niazi, S. K. 2023; Chen, X. et al., 2020)

The eCTD publishing process presents several technical and operational challenges that can significantly impact the quality and timeliness of regulatory submissions. One of the primary concerns is ensuring compliance with stringent formatting and validation rules set by regulatory authorities. Each submission must pass automated validation checks that scrutinize metadata accuracy, hyperlink functionality, document granularity, and XML backbone integrity. Even minor errors, such as broken links, incorrect file naming conventions, or inconsistent folder structures, can result in submission rejection or requests for resubmission, delaying the approval process. Additionally, the complexity of managing multiple sequences within a product lifecycle, such as initial submissions, amendments, and supplements, requires precise version control and document tracking. These tasks demand specialized publishing tools and trained personnel who understand both regulatory expectations and the technical nuances of eCTD structure. Beyond technical validation, the publishing phase also involves navigating regional regulatory differences, especially in Module 1, which varies by country and must be customized accordingly. This adds another layer of complexity, as publishers must ensure that region-specific requirements are met without compromising the overall submission integrity. Moreover, the reliance on third-party software tools introduces risks related to compatibility, updates, and data security. Inadequate software performance or outdated systems can lead to corrupted submissions or failed uploads. Quality control teams must also contend with the challenge of maintaining consistency across large volumes of documents, often under tight timelines. The need for robust standard operating procedures (SOPs), thorough pre-publishing reviews, and cross-functional collaboration is critical to mitigate these risks and ensure successful eCTD submissions. As regulatory expectations continue to evolve, organizations must invest in continuous training and technology upgrades to stay compliant and efficient (Sama, R. et al., 2016; Harer, S. L. et al., 2020; Ahammad, N. et al., 2019)

Furthermore, these systems are not only more efficient but also offer traceability and reproducibility, which are significant factors in pharmaceutical regulatory compliance. The following paragraph explains how AI methodologies, namely, ML and NLP, can be used to automate these tasks and enhance quality assurance through eCTD compilation processes.

AI PROCESSES IN ECTD QUALITY CONTROL

The integration of AI into the quality management of the eCTD compilation process involves the coordinated use of machine learning algorithms, NLP, and rule-based engines to review the structure and content of eCTD submissions, as illustrated in Figure 1. These technologies analyze both structured and unstructured data to detect compliance deviations, formatting errors, and information gaps, often before the final submission to regulatory authorities.

ML algorithms excel at detecting patterns and anomalies in large datasets. In eCTD quality control, supervised models trained on historical submissions can learn the attributes of compliant documents and automatically flag deviations in new filings. To ensure the reliability of such intelligent systems, their deployment must be

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supported by robust frameworks that uphold fairness, safeguard data security, and maintain transparent accountability across the AI lifecycle, thereby reinforcing the integrity of the regulatory submission process (Adeyinka, A. et al., 2023; Odetunde, A. et al., 2022). NLP is particularly valuable for analyzing unstructured data by summarizing, interpreting, and evaluating narrative content such as study protocols and reports. NLP models can detect semantic inconsistencies, mismatched cross-references, and inaccurate terminology by referencing regulatory dictionaries like MedDRA and SNOMED CT (Jadoenathmisier, K. 2022; Ross, C. 2010). This capability is especially useful in Module 2, where scientific justifications and study results are primarily presented in narrative form. Strict adherence to ICH specifications can also be verified through rule-based engines. These engines automatically assess the presence and completeness of required folders, the correctness of document naming and formatting, and the functionality of cross-references. For instance, AI-driven eCTD validation tools can simulate the review process typically conducted by regulatory authorities, effectively identifying gaps or inconsistencies that might otherwise go unnoticed (Higgins, D. C., & Johner, C. 2023; Patel, J. et al., 2021)

AI technologies are increasingly being integrated into regulatory workflows to enhance the accuracy, efficiency, and consistency of eCTD submissions. By leveraging structured content management and cloud-based platforms, AI can automate the formatting, validation, and cross-referencing of regulatory documents, significantly reducing manual errors. These systems enable real-time data exchange and support modular updates across the product lifecycle, ensuring that submissions remain compliant with evolving regulatory standards. AI-driven tools can also assist in maintaining metadata integrity, hyperlink accuracy, and document granularity, key components of eCTD quality control. The shift from document-centric to data-centric submissions allows for more dynamic and scalable publishing processes, improving traceability and reducing turnaround times (Beierle, J. et al., 2023)

In addition to automation, AI offers advanced capabilities in predictive analytics and anomaly detection, which are critical for maintaining submission quality. Machine learning models can analyze large datasets from clinical trials, manufacturing, and pharmacovigilance to identify inconsistencies or potential compliance risks before submission. These tools can simulate regulatory review scenarios, flag discrepancies, and recommend corrective actions, thereby enhancing pre-submission quality assurance. To ensure transparency and regulatory trust, explainable AI techniques such as SHapley Additive exPlanations (SHAP) and Local Interpretable Model-Agnostic Explanations (LIME) are being employed to make AI decisions interpretable and auditable. This fosters collaboration between regulatory teams and AI systems, enabling smarter, faster, and more reliable eCTD publishing while maintaining compliance with global standards (Shoenbill, K. A. et al., 2023)

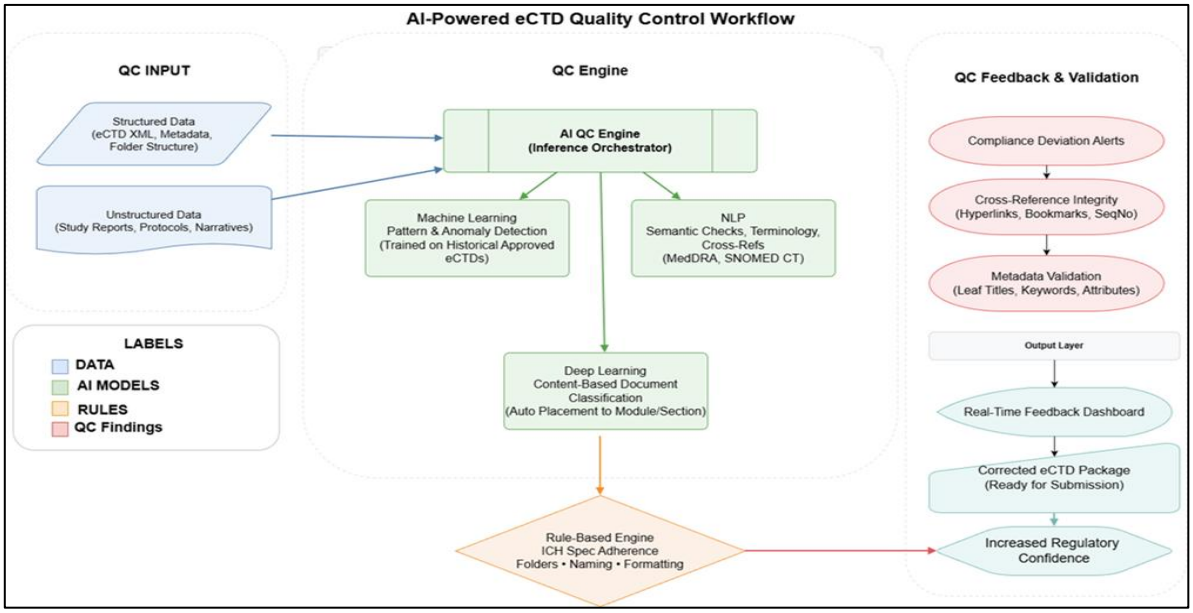

Figure 1: AI methodologies in eCTD quality control, highlighting the roles of machine learning

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IMPLEMENTATION OF AI IN REAL-WORLD ECTD WORKFLOWS

In accordance with the above-presented methodological AI approaches, the practical implementation of the AI-mediated quality control in the eCTD workflow would involve the strategic integration of a variety of steps in the preparation of documents, their validation, and submission. These implementations aim at minimizing manual interventions, eliminating human errors, and preparing high-quality submissions. In an effort to offer end-to-end quality assurance of eCTD compilation, AI systems are incorporated within the Regulatory Information Management (RIM) systems, Document Management Systems (DMS), and submission validation systems.

The initial implementation phase typically focuses on metadata extraction and validation. AI algorithms can identify key metadata fields such as study IDs, document names, and regulatory regions during document creation or when uploading files into a document management system (DMS). This process is enabled through named entity recognition (NER) techniques in NLP, which help ensure consistency across documents and proactively detect potential inconsistencies that might otherwise emerge during the validation stage (Smuha, N. A. 2021) The next phase involves intelligent document classification and tagging powered by supervised and deep learning models trained on historical eCTD datasets. These systems assign documents to the appropriate ICH modules, such as clinical protocols under Module 5 or manufacturing records under Module 3, while employing semantic tagging and cross-referencing for seamless navigation and compliance. At this stage, algorithmic transparency and stakeholder-centered design ensure interpretability and accountability in automated decision-making (Dobreva, J. et al., 2020)

The quality control loop represents the third and potentially most valuable phase. In this stage, AI systems iteratively verify document completeness, adherence to file-naming conventions, accuracy of cross-reference links, and compliance with the submission folder hierarchy. Unlike static validation tools, AI-enhanced systems are continuously trained with each project iteration, progressively improving their ability to detect formatting errors, missing documents, and incorrect metadata linkages (Rahman, A. et al., 2023). Moreover, AI can be able to simulate the validation standards of the different health authorities at any given time, which would ensure that the submission is under the jurisdiction of the different health authorities. Several pharmaceutical companies and regulatory consulting companies have begun integrating AI-based QC capabilities in their RIM systems. These types of integrations usually include dashboards that report on the level of readiness, and areas with high risks are also highlighted, as well as real-time suggestions on how a document could be enhanced. An example of that is an executive summary in Module 2.3, which may not have a cross-reference with critical data in Module 3, which will be automatically highlighted as a problem in the system and remediation measures recommended (Sama, R. et al., 2016; Harer, S. L. et al., 2020). Interestingly, AI can be applied not only in submissions of large size, such as New Drug Application (NDA) or Biologics License Application (BLA). It may also be used in submissions of lifecycle management (including variations, supplements, and amendments), where quick turnaround is needed, as well as version control. The AI-driven quality control system will identify and flag modified sections to ensure proper compilation, thereby reducing redundancy and minimizing submission delays. In spite of these developments, the use of AI in eCTD processes must be highly regulated to make them acceptable to regulations. In spite of the fact that agencies do not enforce the utilization of AI, they require traceability and responsibility in the quality control practice. As a result, most AI applications used in eCTD QC include an audit trail, explainability modules, and override functionality to ensure that an end-user may be able to verify or reject AI results before submitting them (Koshechkin, K. A. et al., 2022). The next section will expound on the physical benefits that AI-enhanced transformation has on the regulatory submission setting on efficiency, compliance, and scalability.

To further compare the differences between these implementations of tools, the table below will provide a selective overview of some of the AI-driven platforms that have already been implemented in regulatory settings as yet. These tools are not similar in the degree of automation, scope of integration, and the opportunities for learning and adjusting.

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Table 1: Comparative Overview of AI-based Tools Used for eCTD Quality Control in the Pharmaceutical Industry

Tool/Platform	AI Capabilities	Integration Scope	Use Case Examples	Limitations
MasterControl™	NLP-driven document parsing, rule-based validation	DMS, RIM, and submission gateway	Real-time completeness check and metadata validation	Limited adaptability to new regulatory rules without manual updates
Veeva Vault RIM™	ML-based document classification, AI-assisted QC	Full RIM lifecycle, eCTD submission	Submission readiness scoring, module mapping	Requires extensive configuration for AI features
Extedo eCTDmanager™	Pre-trained AI for eCTD structure validation	Submission compilation and validation	ICH-compliant folder validation	Minimal NLP for content-level insights
IQVIA SmartSolve™	Predictive analytics, AI-driven risk flagging	Integrated QMS and DMS	Early identification of non-compliance risks	Focused more on quality processes than eCTD specifics
ArisGlobal LifeSphere™	Deep learning for document tagging and classification	End-to-end regulatory operations	Smart tagging, cross-reference prediction	High implementation costs and longer deployment cycles

Source: Compiled by the author through synthesis of data and concepts from the literature (Sama, R. et al., 2016; Harer, S. L. et al., 2020; Ahammad, N. et al., 2019; Adeyinka, A. et al., 2023; Odetunde, A. et al., 2022; Jadoenathmisier, K. 2022, Koshechkin, K. A. et al., 2022; Mayer, M. et al., 2019; Richmond, K. M. et al., 2024)

BENEFITS OF AI-BASED QUALITY CONTROL IN ECTD COMPILATION

There are several significant benefits of AI applications to the eCTD quality control that directly address the drawbacks of the system of manual reviewing, as represented in Figure 2. The first and most evident one is efficiency. The AI systems are very quick in comparison to those of human reviewers, where thousands of checks of validation can be done within a few seconds. This is a time-saving in discussing, approving, and submitting regulatory documents, and increases the rate of drug development and speeds up market readiness (Harer, S. L. et al., 2020). The other aspect that is relevant is improvement in compliance accuracy. Given the scope of the regulatory changes and the frequency at which the changes happen on the regional level, the human QC teams might find it very difficult to stay on top of the entire situation. However, the central update of new validation rules and guidelines is possible in AI systems. All these are automatically updated in any project in progress, and maintenance of a consistent level of compliance is attained with minimal or no disruption (Shoenbill, K. A. et al., 2023). AI also provides consistency, which may be particularly useful in terms of international submissions, where the local regulatory authorities may ask to resubmit or have information requests for such submissions because of even minor variations in the formatting or the use of a term.

Another important attribute is scalability. As the number of eCTD submissions continues to grow with expanding product portfolios and entry into new markets, manual quality control processes struggle to keep pace with this increasing complexity. In contrast, AI systems can effortlessly scale, enabling the processing of large volumes of submission data without compromising accuracy or speed. This enables organizations to receive huge volumes of submissions without a proportional increase in the regulatory affairs staffing. The quality control decisions, such as traceability and auditability, are also promoted by the AIs. The document classification for error detection and all the activities of the system are documented and can be verified in case of audit or inspection. The transparency not just establishes trust between the regulatory bodies but also assists the internal teams in identifying the areas where the process is not efficient, and also in the areas that can be improved. Moreover, AI systems commonly contain graphical visualization software systems, which display submission readiness dashboards, such as completeness scores and

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compliance indicators, that supply strategic data on the well-being of projects.

On top of that, the use of personal knowledge is minimized with the adoption of AI. QC processes in the traditional setups are a prerequisite for the experience of regulatory professionals. It leads to quality and risk inconsistency where the key employees are not accessible. AI formalizes the procedures in QC, and thus, whatever results are attained, it is the same regardless of the members in the team. It also frees regulatory experts to engage in strategic decision-making and content development, rather than reviewing trivial mistakes.

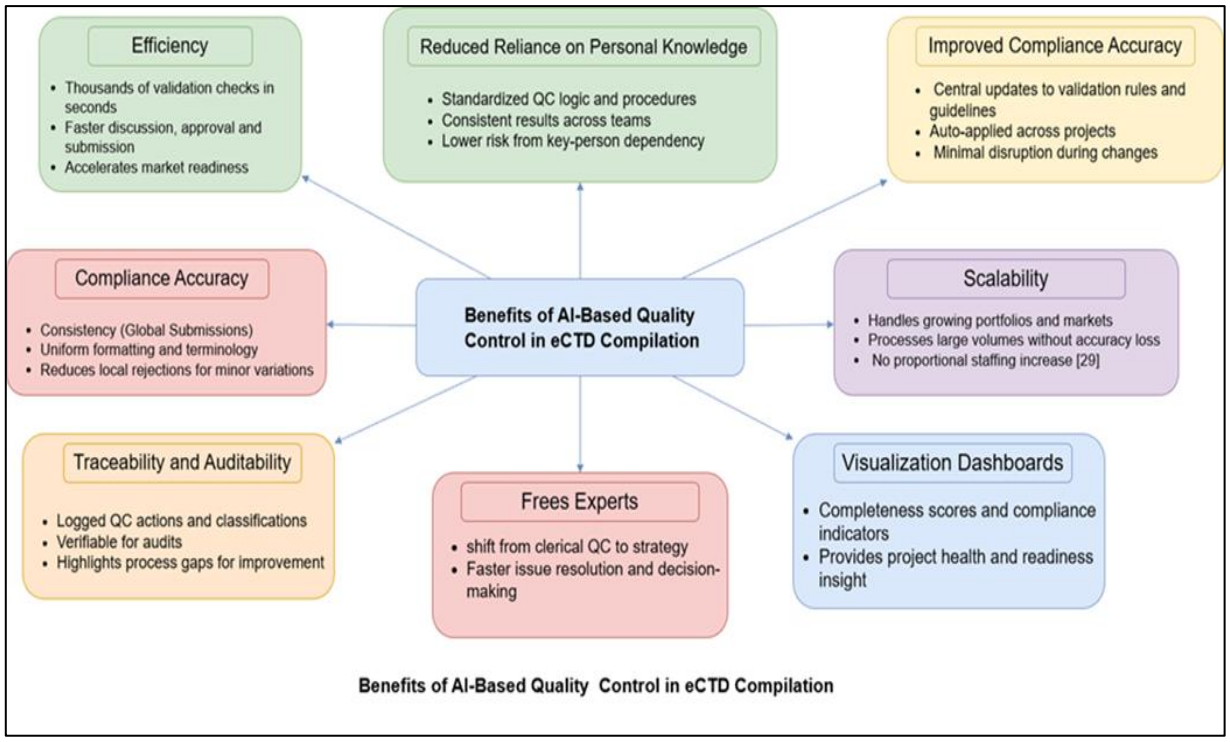

Figure 2: Key benefits of AI in eCTD quality control

CHALLENGES AND LIMITATIONS OF AI IN ECTD QUALITY CONTROL

Despite the evident advantages of AI in the quality control of eCTD, the route to its widespread application is hampered by a set of technical, regulatory, and organizational challenges. One of the most crucial issues is the quality of the data. Big and high-quality datasets should be trained to make AI models. However, the past regulatory submission data may be incomplete or inconsistent, or not structured in a way that is susceptible to machine learning. This limits the functionality and reliability of AI systems, particularly in the early system deployment phases (Smuha, N. A. 2021; Dobreva, J. et al., 2020)

Another major concern is the absence of clear regulatory guidance on the use of AI in eCTD submission processes. Regulatory authorities have not yet formally validated or certified AI-based quality control tools, raising questions about their regulatory acceptability. While such systems can be utilized as part of internal quality assurance workflows, companies remain ultimately responsible for ensuring compliance with all outputs. This continued need for human parallel validation partially offsets the efficiency gains promised by AI and introduces additional operational challenges (Higgins, D. C., & Johner, C. 2023; Patel, J. et al., 2021; Beierle, J. et al., 2023; Shoenbill, K. A. et al., 2023; Smuha, N. A. 2021; Dobreva, J. et al., 2020; Rahman, A. et al., 2023; Koshechkin, K. A. et al., 2022; Mayer, M. et al., 2019). The issue of model interpretability also exists. The majority of AI models, and deep learning systems, in particular, are black-box systems, and it is difficult to understand how specific decisions are made. Such a lack of transparency may be a problem in a regulatory environment where traceability and justification are accorded a first priority status. Although there are still attempts at developing explainable AI (XAI) frameworks, which are poorly developed, they are still in early stages of development and have not yet established themselves in the

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regulatory technology market on a large scale (Mayer, M. et al., 2019).

Many pharmaceutical organizations still rely on legacy infrastructures for document management, metadata processing, and regulatory submissions. Integrating AI into these systems often requires extensive modernization and re-engineering, making implementation both costly and complex. Moreover, regulatory and quality assurance teams may lack the structural readiness to manage such transitions, necessitating close collaboration between IT, QA, and regulatory affairs to maintain consistent data governance and compliance. Successful AI deployment across the pharmaceutical lifecycle demands a holistic, interoperable approach. Yet most implementations remain fragmented and domain-specific, limiting scalability and end-to-end automation. Meanwhile, concerns about data privacy persist, as regulatory submissions include highly sensitive intellectual property and patient data. Privacy-preserving AI models that incorporate differential-privacy safeguards help ensure compliance with global standards such as GDPR and HIPAA, particularly for cloud-based systems spanning multiple jurisdictions (Richmond, K. M. et al., 2024; Singh, A. K., & Gupta, R. 2022; Singh, K. 2023). Governance and audit mechanisms further strengthen transparency, accountability, and trust in automated regulatory systems. AI-driven compliance frameworks continuously monitor documentation accuracy, traceability, and deviations across business units, enhancing regulatory adherence. Nevertheless, organizational resistance remains a key barrier often rooted in skepticism about automation reliability or concerns over job displacement. Overcoming this requires well-structured change management, pilot initiatives, and targeted training to demonstrate tangible efficiency gains and foster trust. With mature governance, privacy alignment, and sustained collaboration, seamless AI adoption in eCTD quality control becomes an achievable reality.

FUTURE DIRECTIONS AND INNOVATION IN AI-BASED ECTD QUALITY CONTROL

The next generation of AI-based eCTD QC systems will evolve from static automation toward intelligent, adaptive, and predictive frameworks that can proactively manage compliance across the entire regulatory lifecycle. Emerging developments in ML, NLP, and generative AI are enabling context-aware document understanding, which allows systems to interpret regulatory intent rather than relying solely on predefined templates or rule sets. Such advancements can transform QC workflows from post-submission validation to real-time compliance monitoring, identifying potential deviations even before dossier compilation begins. Integrating federated learning and privacy-preserving AI models will be essential to maintain data security while allowing collaborative learning across multiple regulatory jurisdictions and sponsors. These approaches enable decentralized model training without sharing sensitive data, supporting global harmonization under frameworks such as ICH and regional data-protection laws. Additionally, cloud-native AI ecosystems combined with blockchain-based audit trails can ensure version control, traceability, and immutable documentation records, thus enhancing regulatory confidence and transparency (Richmond, K. M. et al., 2024; Singh, A. K., & Gupta, R. 2022; Singh, K. 2023).

Future eCTD systems will also benefit from AI-driven regulatory intelligence platforms that continuously scan and analyze changes in guidance documents, regional submission standards, and authority feedback to automatically update validation criteria. This continuous-learning capability will reduce manual oversight, shorten approval timelines, and ensure alignment with evolving agency expectations. Finally, the sustainable implementation of AI in regulatory quality control will depend on cross-functional governance models. Collaboration among regulatory affairs, IT, quality, and data-science teams will be critical for ethical AI governance, interpretability, and long-term trust. Investments in XAI and human-in-the-loop systems will ensure that automation complements rather than replaces expert judgment, setting the foundation for resilient, transparent, and globally interoperable eCTD ecosystems (Richmond, K. M. et al., 2024).

CONCLUSION

The use of AI in the quality control of the eCTD compilation process is a groundbreaking change to the sphere of control regulation in the pharmaceutical world. As the level of complexity, strict deadlines, and changing regulatory conditions continues to increase, the use of a manual quality control system is not enough to ensure accuracy, efficiency, and compliance. The use of AI technologies, especially ML, NLP, and deep learning, provides a strong alternative since it

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can be used to validate documents automatically, identify structural and content-related inconsistencies, and provide submission completeness in real-time. In this paper, we have highlighted the structural issues of eCTD submission, the array of AI methodologies used to solve these issues, how they have been implemented in real life, and the actual advantages that they present. The analysis also highlights the existing constraints that hinder wider adoption of AI and explores emerging directions expected to transform the regulatory submission landscape in the coming years. Ranging from improving speed and precision of submissions to allowing predictive compliance and smart content creation, AI is at the center of the second generation of regulatory operations. For pharmaceutical companies, the question of adopting AI in eCTD quality control is no longer about *if* but rather *when* and *how effectively* it can be implemented. Organizations will not only be able to make better submission results by investing in AI technologies, developing cross-functional partnerships, and ensuring readiness for the regulatory environment of the future, but also achieve a competitive edge in providing their therapies to the market sooner and more consistently. With regulatory agencies starting to draw closer to technological developments, the future will be highly automated, standardized, and collaborative, all supported by the potential of AI.

Table of Abbreviations

Abbreviation	Full Form
AI	Artificial Intelligence
BLA	Biologics License Application
DMS	Document Management System
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
FDA	Food and Drug Administration
GDPR	General Data Protection Regulation
ICH	International Council for Harmonisation
LIME	Local Interpretable Model-Agnostic Explanations
MedDRA	Medical Dictionary for Regulatory Activities
ML	Machine Learning
NDA	New Drug Application
NER	Named Entity Recognition
NLP	Natural Language Processing
QC	Quality Control
QMS	Quality Management System
RIM	Regulatory Information Management
SHAP	SHapley Additive exPlanations
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SOP	Standard Operating Procedures
XAI	Explainable Artificial Intelligence
xml	Extensible Markup Language

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