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A STUDY ON IDENTIFYING GAPS IN TRADITIONAL REGULATORY DOSSIER PROCESSES AND THE ROLE OF ARTIFICIAL INTELLIGENCE IN STREAMLINING SUBMISSION WORKFLOWS

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ABSTRACT

Preparing regulatory dossiers is essential for getting pharmaceutical products approved, as it ensures their quality, safety, and effectiveness. However, current dossier processes are still largely manual, which leads to repetitive work, delays, and a higher chance of errors or compliance issues. This review identifies key gaps in conventional regulatory dossier processes and explains how Artificial Intelligence (AI) can streamline submission workflows to improve efficiency, accuracy, and global harmonization. The study explores various AI technologies such as Natural Language Processing (NLP), Machine Learning (ML), and Robotic Process Automation (RPA) that automate data collection, document authoring, and validation. Secondary data were gathered from published literature, regulatory portals, and global digital initiatives. Regulatory agencies like the FDA and EMA have already begun using AI systems, and India's CDSCO is moving toward digital transformation with SUGAM 2.0. AI-based tools including Veeva Vault, PhlexSubmission, and Genpact Cora Regulatory AI are improving accuracy, transparency, and overall workflow efficiency. The study envisions Smart Dossier Management Systems (SDMS) integrating blockchain and predictive analytics for real-time compliance and global harmonization. This shift represents a move from manual, document-heavy processes to intelligent, data-driven regulatory practices.

KEYWORDS: Artificial Intelligence (AI), Regulatory submission, Smart Dossier Management System (SDMS), Digital Transformation.

1. INTRODUCTION

The pharmaceutical industry operates under strict regulatory frameworks to ensure the safety, efficacy, and quality of medicinal products. A critical component of this regulatory landscape's the preparation and submission of dossiers for marketing authorization and clinical trials.[1] In the pharmaceutical and biotech sectors, preparing regulatory dossiers, serving as comprehensive documentation like clinical, preclinical, manufacturing (CMC), stability, safety, and efficacy modules that support the approval and commercialization of drugs and devices. Formats such as the Common Technical Document (CTD)[2] and its electronic version eCTD have become globally accepted standards, ensuring structured submission to regulatory authorities. eCTD serves as a blueprint of product lifecycle, manufacturing process, quality, safety, and efficacy data of product.[3]

In recent studies, the pharmaceutical sector is exploring advanced technologies, particularly, Artificial Intelligence (AI) and all the industries are currently transformed by AI-driven technologies.[4] This explores the growing impact of AI and Machine Learning (ML) within pharmaceutical Regulatory Affairs, particularly in dossier preparation, compilation, documentation, submission, review, and regulatory compliance. By automating time-intensive tasks, these technologies streamline workflows, accelerate result generation, and shorten the product approval timeline. AI can still present new challenges considering its vast potential. It is necessary to address issues such AI software validation, data management security and privacy, potential biases, ethical considerations, and change management requirements.[5]

The current AI-based tools actively used by regulatory professionals such as[6] DocShifter,[7] Veeva Vault,[8] RiskWatch,[9] Freyr SubmitPro,[10] Litera Microsystems,[11] cortical.io etc.,[12] examines both the benefits and obstacles of integrating these advanced systems into regulatory practices.[13] The importance of adapting regulatory frameworks and embracing new technologies. Although these developments, incorporating AI into regulatory procedures still poses difficulties, such as guaranteeing algorithm transparency, reducing bias, and preserving equity in automated decision-making.[14] Although regulatory agencies like the United Sates Food and Drug Administration (USFDA), European Medicines Agency (EMA), and Medicines and Healthcare products Regulatory Agency (MHRA) are working on guidelines for AI and ML adoption, clear, standardized protocols are still in the works.[15]

The integration of Artificial Intelligence (AI) into regulatory dossier workflows presents several potential benefits, including automation of repetitive tasks, reduction of human errors, seamless data integration, and real-time compliance monitoring. By leveraging natural language processing and machine learning, AI can assist in dossier preparation by automating content authoring, ensuring consistency across documents, extracting structured data from unstructured sources, and validating submissions against regulatory requirements.

Despite these advantages, this area remains less explored compared to other pharmaceutical applications such as drug discovery, clinical trials, and pharmacovigilance.[16] The primary reasons include concerns about data integrity, lack of clear regulatory guidance, and the need for validated AI models that meet stringent compliance standards. However, the innovation potential of AI in this domain is significant, offering the ability to save time and resources, reduce manual effort, and accelerate submission timelines. At the same time, ensuring that regulatory authorities accept AI-assisted outputs is critical for successful adoption, as agencies demand transparency, traceability, and validation of automated processes. A major gap exists in the form of limited systematic studies on AI-driven regulatory documentation workflows, with most existing research focused on AI applications in research and development or safety monitoring rather than submission processes.[17] This creates an opportunity for novel contributions, as adopting AI for regulatory

documentation could fundamentally reshape submission strategies, eliminate inefficiencies, and bridge the gap between innovation and compliance, ultimately enhancing the speed and quality of global regulatory approvals.[18]

To map the gaps in conventional regulatory dossier workflows and assess which AI tools and approaches have the greatest promise for filling those gaps, a systematic evaluation is required. By doing this, policymakers and regulatory affairs specialists will be better equipped to decide how to use AI to improve submission processes, increasing productivity, ensuring compliance, and lowering risk.

2. Mapping the Gaps in Traditional Dossier Workflows

The preparation of regulatory dossiers in India and worldwide continues to rely primarily on traditional, document-centric operations that demand substantial manual effort. These workflows still have several kinds of inefficiencies that lower accuracy and cause submission deadline delays, even though they are well-structured under the Common Technical Document (CTD) or electronic CTD (eCTD) format.[19] Identifying where digital automation and artificial intelligence (AI) can provide tangible benefit requires mapping these gaps.[20]

One major gap is the lack of automation in document management, which forces teams to manually organize, update, and review large volumes of files. Along with this, regulatory submissions and variations are tracked manually, creating delays and increasing the chances of oversight. These workflows also include repetitive activities like data entry, cross-checking and reducing efficiency. Because most systems are not integrated, there is limited traceability and poor collaboration, making version control and real-time coordination difficult. Furthermore, validation and compliance checks remain time-consuming, as they rely on manual review rather than automated tools. Together, these issues form the basis of the “gap mapping” concept in regulatory documentation, where inefficiencies are identified to determine where AI and digital automation can improve accuracy, speed, and regulatory compliance.

2.1 Lack of automation in document management

Manual document production, version control, and formatting are key components of traditional dossier management. Redundancy and irregular document structures result from regulatory teams' frequent compilation of data from several departments, including production, research, and quality control.

Instead of using sophisticated Regulatory Information Management (RIM) systems, small and medium-sized pharmaceutical companies in India continue to rely on simple tools like Microsoft Word and Excel for dossier creation.[21] In addition to raising the possibility of human error, this lack of automation causes a delay in submission readiness. To combat these inefficiencies, businesses worldwide are progressively implementing AI-enabled solutions like Veeva Vault RIM and PhlexSubmission.[22]

2.2 Manual tracking of regulatory submissions and variations

The majority of submission lifecycle tracking, including post-approval modifications,[23] abbreviated new drug applications (ANDA), and[24] new drug applications (NDA), is still done manually. Spreadsheets are frequently used by regulatory teams to keep track of correspondence and deadlines, which can result in missing updates and compliance issues.[25]

CDSCO-introduced SUGAM portal in India to digitised the submission process, related to drugs, medical devices, and cosmetics. It enables companies to submit and track applications digitally, reducing paperwork and improving

transparency. The portal supports licensing, registration, permissions, and post-approval activities. It enhances regulatory efficiency by ensuring faster communication between applicants and authorities. However it is devoid of sophisticated dashboards and full AI-driven tracking.[26] On the other hand, AI-assisted tracking and validation modules have started to be added to the FDA's electronic submission gateway (ESG)[27] and the European Medicines Agency (EMA's) Integrated Regulatory Information System (IRIS) platform.[28]

2.3 Repetitive tasks like data entry and cross-checking

Repetitive data entry, or replicating the same information across CTD modules like Quality (Module 3)[29] and Nonclinical (Module 4)[30] is frequently a part of the dossier preparation process. It takes a lot of time and effort to manually cross-verify the data in these areas.[31]

Artificial intelligence (AI) tools like Natural Language Processing (NLP)[32] and Robotic Process Automation (RPA)[33] may automatically fill dossier templates with structured data that has been validated, cutting down on duplication and improving accuracy.[34]

2.4 Limited traceability and collaboration

Cross-functional teams must work together to compile regulatory filings. However, the lack of centralised digital platforms frequently leads to inadequate communication, approval, and document version traceability.

Most Indian companies communicate by email, which doesn't keep track of updates in real time. By Version control, secure document sharing, and live audit trails are all made possible by cloud-based AI solutions, which enhance collaboration between manufacturing, clinical, and regulatory teams.[35]

2.5 Time-consuming validation and compliance checks

Every dossier is subjected to an internal review procedure to ensure regulatory compliance. In the absence of automation, quality control teams manually verify each component for accuracy, formatting, and cross-referencing. AI-powered validation engines can promptly detect missing data, erroneous metadata, and abnormalities in format before to submission. [36] For example, international systems like PhlexEview and Genpact Cora Regulatory AI use machine learning algorithms to perform automated dossier validation, ensuring compliance with ICH and eCTD standards.[37]

2.6 Conceptual framework of “gap mapping” in regulatory documentation

In regulatory documentation, the term "gap mapping" describes a methodical process for locating inefficiencies or bottlenecks in the dossier preparation and submission lifecycle. In order to identify areas where automation can increase productivity, accuracy, and compliance, the current traditional workflow is compared to an optimised AI-driven model.[38]

Three essential steps are shown in the **Figure 1**

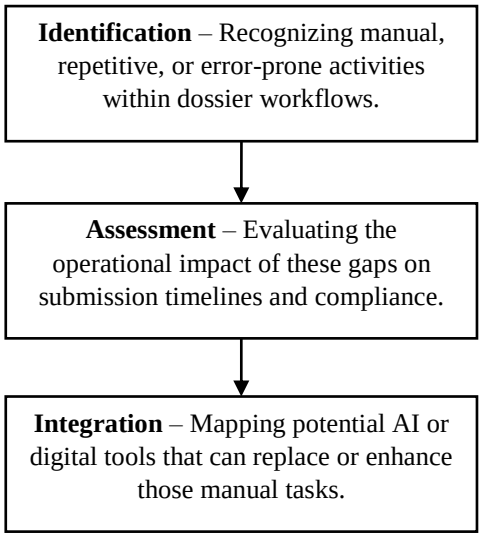

Figure 1: Framework of "gap mapping" in regulatory documentation.

3. Integration of AI Technologies and Tools in Regulatory Affairs and Dossier Preparation

Integration of AI into regulatory affairs will help with staying up-to-date on the latest industry trends and learning about the benefits of AI for regulatory approval. AI can help drug discovery professionals for new drugs to market faster and more efficiently by automating tasks, improving decision-making, and identifying new opportunities. Automation could help speed up this process by reducing the time required for collecting, segregating, and standardizing data from records, as well as by reducing the requirement for human involvement in the documentation process.[39] The role of Artificial Intelligence and automation in addressing gaps in Traditional Regulatory Dossier Workflows: Technologies, Regulatory Implementations, and Outcomes are outlined in **Table 1.**

Table 1: Gap Mapping and AI Implementation in Regulatory Dossier Workflows.

S. No.	Dossier Workflow Stage	Identified Gaps in traditional workflows	AI/Automation Solution	Technology/Tool Examples	Regulatory Implementations	Outcome
1.	Data Collection	Manual data entry from multiple departments; duplication of datasets	Natural Language Processing (NLP) and Optical Character Recognition (OCR) for automatic data extraction from structured/unstructured sources	IBM Watson Discovery, Google Cloud Document AI, Veeva Vault RIM Data Loader	Pfizer, Novartis, and Sun Pharma use NLP tools for automated extraction of CMC data	Reduces manual data entry by 60%; enhances data accuracy and consistency
2.	Document Authoring	Repetitive manual writing and formatting of CTD section	Generative AI and Natural Language Generation (NLG) for automated dossier drafting	Microsoft Copilot for Life Sciences, ChatGPT Enterprise, IQVIA Smart Authoring	Biocon, AstraZeneca, and Sanofi use AI-assisted authoring tools for clinical and regulatory documents	Reduces authoring time; improves standardization across dossier modules
3.	Document Management	Lack of centralized control; manual versioning and file tracking	AI-driven Document Management Systems (DMS) with metadata tagging and auto-classification	Veeva Vault RIM, PhlexSubmission, MasterControl	Dr. Reddy's Laboratories, Cipla, and EMA (EU) use AI-enabled RIM systems for submission management	Improves document traceability; reduces redundancy

4.	Quality Review & Validation	Manual QC of formatting, data consistency, and metadata	Machine Learning (ML) models for predictive validation and error detection	PhlexEview, Genpact Cora Regulatory AI, IQVIA Quality Check Engine	Genpact with global pharma clients; EMA IRIS platform integrates automated validation	Cuts validation time by >50%; reduces submission rejections
5.	Submission Tracking	Spreadsheet-based monitoring; delays in updates or lifecycle management	Robotic Process Automation (RPA) for automated submission tracking and notifications	UiPath Regulatory Suite, Automation Anywhere, ArisGlobal LifeSphere Regulatory	GSK, Roche, and CDSCO SUGAM 2.0 (under development) applying AI/RPA for tracking	Ensures real-time submission tracking and deadline alerts
6.	Collaboration and Workflow Management	Fragmented communication and lack of version traceability	Cloud-based AI Collaboration Platforms integrating workflows across teams	OpenText Life Sciences Solution, Veeva Vault QMS, Ascent Regulatory Cloud	EMA's IRIS Portal, Sun Pharma's internal RIM system, Health Canada e-Review pilot	Improves transparency and cross-functional teamwork
7.	Post-Approval Updates & Variations	Manual tracking of variations, renewals, and labeling updates	Predictive Analytics and RPA bots for regulatory intelligence and change management	ArisGlobal RIM, SAP Intelligent Regulatory Management, Indegene AI RegIntel	Cipla, Pfizer, Aurobindo Pharma leveraging predictive AI for variation tracking	Enhances compliance; reduces renewal delays
8.	Compliance & Regulatory Intelligence	Difficulty in monitoring global regulatory updates	AI-driven Regulatory Intelligence Engines for automatic policy scanningand summarization	IQVIA Regulatory Intelligence AI, Indegene Cognitive Platform, Elsevier PharmaPendium AI	EMA, FDA, and Indian Pharma Alliance members implementing AI dashboards for regulatory intelligence	Increases awareness of real-time global updates; ensures faster compliance

The analysis of global and Indian initiatives reveals that AI implementation is strategically addressing key gaps in traditional regulatory dossier workflows such as manual data handling, document validation, and submission tracking. Regulators like the FDA and EMA have successfully transitioned to AI-assisted systems that enhance review speed, accuracy, and transparency. Meanwhile, India's CDSCO is in a developing stage, with SUGAM 2.0 laying the groundwork for digital dossier automation. Overall, the findings highlight a global trend toward AI-enabled regulatory ecosystems, with India progressing toward partial adoption and significant potential for scalability and harmonization.

4. Global Scenario of AI submission workflow

The integration of Artificial Intelligence (AI) in regulatory affairs is progressively transforming how pharmaceutical organizations and regulatory agencies manage, review, and submit dossiers. While global adoption has reached advanced stages, India is at a promising early phase, showing strong potential for rapid digital evolution.[40]

4.1 Industry-Led Adoption

Leading pharmaceutical companies throughout the world, including Pfizer, AstraZeneca, Novartis, and Roche, have adopted AI-driven solutions to improve lifecycle management, automate dossier generation, and streamline regulatory documentation. These businesses use technology including machine learning (ML) to forecast compliance, natural language processing (NLP) to extract data, and regulatory information management (RIM) systems.[41]

To ensure uniformity and data integrity across Common Technical Document (CTD) modules, Pfizer, for example, has implemented AI-assisted submission authoring capabilities integrated inside Veeva Vault RIM. AstraZeneca automates

the creation of narratives and version control for regulatory reports using IQVIA Smart Authoring. Large pharmaceutical firms in India, including Sun Pharma, Cipla, and Dr. Reddy's Laboratories, have started experimenting with AI for post-approval variation tracking, quality review automation, and internal document management.[42]

4.2 Regulatory Body Initiatives

AI integration is being advanced by regulatory bodies in key nations as part of their frameworks for digital transformation.

- The U.S. Food and Drug Administration (FDA) has implemented ELSA (Enhanced Learning and Submission Analysis) and the Knowledge-aided Assessment and Structured Application (KASA) system to support reviewers through data-driven dossier analysis and automated quality evaluation.[43] [44]
- The European Medicines Agency (EMA) operates its IRIS digital platform, which incorporates automation and data validation features for regulatory submissions and scientific advice management.[45] [46]
- In India, the Central Drugs Standard Control Organization (CDSCO) has launched the SUGAM 2.0[47] initiative, a major digital transformation project intended to incorporate AI modules for submission tracking, dossier validation, and predictive review analytics.

4.3 India’s Position and Opportunities

India's adoption of AI in regulatory affairs is still in its infancy. Infrastructure and standardisation issues continue to impede large-scale deployment, despite growing industry awareness and interest. An important first step towards automation is the CDSCO's SUGAM 2.0 digital platform, which offers chances to use AI for regulatory intelligence, document classification, and dossier validation.[26]

Additionally, collaboration among AI startups, IT companies, and regulatory bodies can accelerate the incorporation of technologies such as RPA-driven submission tracking and NLP-based dossier screening into national workflows. India might move towards a "Digital Regulatory Ecosystem" by implementing international best practices from the FDA and EMA, which would guarantee quicker approvals, improved compliance, and standardised regulatory standards.[48]

Table 2 illustrates how AI-driven platforms ranging from dossier review and automated authoring to document validation are enhancing efficiency, accuracy, and transparency in regulatory operations. While agencies like the FDA and EMA have fully operational systems, India’s CDSCO and domestic firms are in pilot stages, marking an evolving but promising shift toward automation in regulatory affairs.

Table 2: Global and Indian Adoption Landscape.

S. No	Entity	AI platform	Purpose	Stages of implementation	Outcome
1.	FDA (U.S.)	ELSA & KASA	AI-assisted dossier review and structured application assessment	Fully operational	Improved review timelines and data integrity
2.	EMA (Europe)	IRIS Platform	Automated document routing,	Operational	Enhanced efficiency and

			validation, and communication		transparency
3.	CDSCO (India)	SUGAM 2.0	Digital dossier submission and planned AI modules	Pilot / Developing	Foundational step toward automation
4.	Pfizer	Veeva Vault RIM + AI authoring	Automated dossier compilation	Actively use	Consistent CTD document generation
5.	Sun Pharma (India)	Internal AI RIM system	Document management and validation	Pilot	Improved internal efficiency
6.	Dr. Reddy's Labs (India)	AI-based document QC	Validation and metadata correction	Pilot	Reduced manual verification time

5. Future Prospective of Artificial Intelligence in Regulatory Affairs

AI-driven Smart Dossier Management Systems (SDMS)[49] have the potential to revolutionise regulatory affairs by converting the conventional, document-heavy regulatory procedure into a framework that is data-centric, intelligent, and predictive. Global regulatory operations and decision-making will be redefined by the incorporation of cutting-edge technologies like blockchain, predictive analytics, and collaborative data ecosystems in **Figure 1**.[50]

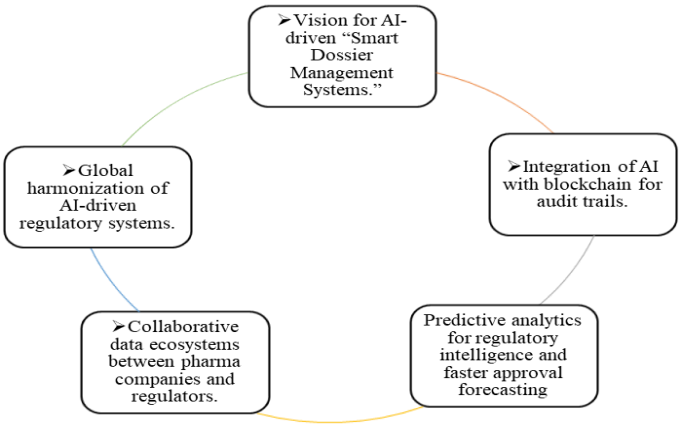

Figure 2: Future Prospective of Artificial Intelligence.

5.1 Vision for AI-driven Smart Dossier Management Systems

These Smart Dossier Management Systems (SDMS) will leverage Natural Language Processing (NLP) to extract structured data from unformatted documents, Machine Learning (ML) to predict data inconsistencies, and Robotic Process Automation (RPA) to handle repetitive submission tasks. Such systems could drastically reduce submission timelines and improve compliance by ensuring real-time alignment with dynamic regulatory updates.[51] As the system processes more documents, it refines its algorithms through supervised or unsupervised learning, adapting to industry-specific jargon or evolving document formats. This self-improvement loop ensures that even niche documents, such as medical records in healthcare or blueprints in engineering, are handled with precision.[52]

5.2 Integration of AI with blockchain for audit trails

The emergence of artificial intelligence (AI) and blockchain technology has introduced new possibilities for enhancing auditing practices. AI offers capabilities such as automated data analysis, anomaly detection, and predictive analytics, which can streamline routine tasks and improve accuracy.[53] The integration of these technologies promises to revolutionize traditional auditing methodologies, making them more efficient, reliable, and resilient to fraud. Despite

the promising benefits of AI and blockchain in auditing, their integration into traditional auditing practices poses several challenges. These challenges include technical difficulties related to system integration, regulatory and compliance uncertainties, data privacy concerns, and resistance from staff. Additionally, the effectiveness of these technologies in addressing traditional auditing issues, such as accuracy and fraud detection, remains a topic of investigation.[53] Understanding how AI and blockchain can be effectively integrated into auditing processes, and the challenges that organizations face in doing so, is crucial for leveraging their full potential and ensuring a smooth transition.[54]

5.3 Predictive analytics for regulatory intelligence and faster approval forecasting

AI-based predictive analytics will play a vital role in regulatory intelligence by forecasting approval timelines, identifying potential deficiencies in dossiers, and predicting regulatory outcomes based on historical patterns.[55] Machine learning algorithms trained on global regulatory databases can assist both regulators and industry in anticipating review bottlenecks, planning submissions strategically, and improving overall submission success rates. Such systems could also support regulatory decision-making through continuous learning from previous evaluations.[56]

5.4 Collaborative data ecosystems between pharma companies and regulators

Collaborative data ecosystems in pharma securely connect life sciences and healthcare data to drive AI-powered insights or advanced analytics on these distributed datasets. They enable shared use of real-world data without exposing sensitive information, overcoming data silos while ensuring privacy and compliance. The future regulatory landscape will be characterized by data-sharing ecosystems that enable real-time collaboration between pharmaceutical companies, contract research organizations (CROs), and regulatory agencies. Cloud-based AI systems will allow simultaneous dossier co-authoring, automated feedback loops, and harmonized document updates across multiple stakeholders.[57] This will not only improve transparency and efficiency but also help build a regulatory intelligence network, accelerating approval processes and ensuring consistent data integrity.[58]

5.5 Global harmonization of AI-driven regulatory systems

To fully realize the benefits of AI in regulatory affairs, global harmonization will be essential. Initiatives led by organizations such as the International Council for Harmonisation (ICH)[59] and World Health Organization (WHO)[60] aim to establish unified frameworks for AI governance, ethical use, and interoperability in regulatory workflows. Collaborative efforts between regions such as the FDA’s AI pilot programs, EMA’s automation roadmap, and CDSCO’s digital transformation indicate a shift toward a globally interconnected regulatory ecosystem driven by AI and digital standards.

Such harmonization will facilitate mutual recognition of dossiers, reduce duplication of review efforts, and support the faster global availability of life-saving medicines.

CONCLUSION

The integration of Artificial Intelligence into regulatory dossier workflows represents a transformative step toward modernizing global and Indian pharmaceutical regulatory systems. Traditional dossier preparation processes characterized by manual documentation, redundancy, and limited traceability are increasingly being optimized through AI-driven automation, natural language processing, and robotic process automation. While India's CDSCO is progressively moving towards digital adoption through programs like SUGAM 2.0, international regulators like the

FDA and EMA have already shown how AI can improve review accuracy and operational efficiency. AI tools are being used by industry heavyweights such as Pfizer, AstraZeneca, Sun Pharma, and Dr. Reddy's Labs for the collection, validation, and submission management of dossiers. The study envisions Smart Dossier Management Systems (SDMS) integrating blockchain and predictive analytics for real-time compliance and global harmonization. This shift represents a move from manual, document-heavy processes to intelligent, data-driven regulatory practices.

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