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Review Article

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The Regulatory Affairs Automation tools used in the Pharmaceutical Industry: An overview

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Abstract

Automation is becoming increasingly prevalent in various industries, including healthcare and pharmaceuticals. The pharmaceutical business is influenced by a variety of worldwide trends, with one of the most significant being the use of automation technologies, which will have a transformative effect on the research and development of new pharmaceutical products as well as the speed and efficiency with which products reach patients in need. Regulatory automation is enabled by a variety of technology tools, such as Electronic Document Management Systems, Regulatory Information Management (RIM) Systems, Artificial Intelligence (AI) Analytics Tools, Natural Language Processing (NLP) Tools, and Submission Publishing Tools. Automation tools can be used to automate regulatory activities such as administrative work, dossier completion, data extraction, auditing, regulatory implementation as well as quality management. Automation tools establish process links and minimize complexity, resulting in a more efficient management system. Human-AI interaction creates new prospects in regulatory concerns. This article investigates the potential use of automation techniques in pharmaceutical regulatory concerns.

Keywords: Automation tools, Electronic Document Management Systems, Regulatory Information Management (RIM) Systems, Artificial Intelligence (AI) Analytics Tools, Natural Language Processing (NLP) Tools, and Submission Publishing Tools, eCTD submissions

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1. Introduction

For years, regulatory publishing was done manually. Publishers used to spend hours formatting documents, creating Agency-compliant PDFs, running quality checks, gathering documents for submissions, and troubleshooting submission-related issues. Furthermore, pharmaceutical businesses face enormous pressure to provide error-free paperwork within strict deadlines. The inability to meet the timelines delays the product introduction. (1)

Regulatory affairs refers to the teams or functions within pharmaceutical businesses that serve as a link to regulatory authorities in the host nation or overseas, working to get product approval in accordance with current legislation. In turn, regulatory agencies authorize medicines based on data and papers submitted at every stage of the process, from drug research to product development. Automation could help speed up this process by shortening the time required to collect, separate, and standardize data from records, as well as eliminating the need for human intervention in the documentation process.

Automation provides an opportunity to improve processes and workflow when preparing eCTD submissions in existing markets while expanding into fresh areas. As businesses investigate automation for eCTD requests, it is critical to assess the features that will benefit and increase efficiency. Some firms are currently building automation solutions employing databases, which is a time-consuming and laborious operation.(2)

2. Current Challenges for Manual Publishing and Submissions

Time-consuming: tasks include manual bookmarking, hyperlinking, validating PDF attributes, and page-by-page document quality checks. In such cases, rework is a major cause of submission delays.

Training: To ensure consistency throughout the submission process, firms must train their teams on the SOPs.

Multiple Tools: Each resource working on the document will need a separate license for each tool and technology.

Large submissions require a significant amount of effort, including manually uploading hundreds of documents to the eCTD publishing software.

Correct Version: Several versions of the same document can be displayed on the publisher's desktop. Before uploading the document, the publisher must ensure it is the correct version.

eCTD Structure: Each submission request must have the correct sequence and eCTD structure.

Manual Errors: There is a considerable probability of errors while giving metadata or file naming during document submission. (3)

3. Discussion

3.1 Electronic Document Management Systems (EDMS)

Example: Veeva Vault

Description: Veeva Vault is a cloud-based platform specifically designed for life sciences organizations to manage regulated content, including documents, submissions, and quality records. It offers features such as document versioning, controlled access, automated workflows, and electronic signatures, enabling efficient document management and compliance with regulatory requirements.

Veeva Vault stands as a leading Electronic Document Management System (EDMS) tailored to meet the intricate needs of the life sciences industry. It serves as a pivotal platform for managing regulated content, providing a seamless solution for document storage, collaboration, and compliance. Unlike generic document management systems, Veeva Vault is meticulously designed to cater to the stringent regulatory requirements governing pharmaceutical, biotechnology, and medical device companies. (4)

At its core, Veeva Vault offers a suite of robust features aimed at simplifying the complexities inherent in regulatory document management. One of its key functionalities is version control, ensuring that users have access to the latest approved versions of documents while maintaining a comprehensive audit trail for compliance purposes. Moreover, the system incorporates sophisticated access controls and permissions, enabling organizations to restrict document access based on roles, responsibilities, and regulatory requirements.

Veeva Vault's automated workflows streamline document review and approval processes, accelerating time-to-market for new products and minimizing compliance risks. Through configurable workflows, stakeholders can collaborate seamlessly, facilitating efficient cross-functional collaboration and ensuring adherence to regulatory timelines. Additionally, Veeva Vault integrates seamlessly with other enterprise systems, enabling data exchange and synchronization to further enhance operational efficiency and data integrity.

One of the hallmark features of Veeva Vault is its cloud-based architecture, which offers scalability, reliability, and security in managing regulated content. The platform adheres to stringent regulatory standards, including FDA 21 CFR Part 11, EU Annex 11, and GxP guidelines, providing organizations with confidence in data integrity and compliance. Furthermore, Veeva Vault's intuitive user interface and mobile accessibility empower users to access critical documents and collaborate effectively from anywhere, at any time.

In essence, Veeva Vault plays a pivotal role in transforming regulatory document management for the life sciences industry. By providing a centralized platform for document storage, collaboration, and compliance, Veeva Vault empowers organizations to streamline their regulatory operations, accelerate product development, and ultimately bring innovative therapies to market faster while ensuring compliance with regulatory requirements. (5)

3.2 Regulatory Information Management (RIM) Systems

Pharmaceutical and medical device businesses can use regulatory information management (RIM) systems to keep track of regulatory documents and actions throughout the product development lifecycle. Regulatory affairs (RA) personnel rely on these systems to keep each product's information up to date and verify that it meets all regional regulatory standards for market approval and post-market surveillance. RIM systems allow collaborative production of supporting documentation for regulatory submissions, product registration, unique device identification (UDI) labels, key principles, and standards management. They also provide high-level visibility into every stage of the pre-to-post-market lifecycle, which simplifies the audit process. Once a product reaches the post-market stage, RA teams employ RIM systems to collect vital product data about safety and performance and take any necessary actions. (6)

Example: ArisGlobal's Regulatory One

Description: Regulatory One is a comprehensive RIM solution that provides end-to-end capabilities for regulatory submissions, registrations, commitments tracking, and regulatory intelligence management. It integrates with other systems within the organization to streamline regulatory processes and ensure consistency and compliance across regulatory operations.

The solution provides ISO identification of medicinal products (IDMP)-compliant SPOR (substance, product, organization, and referential) data for regulatory activities throughout the product life cycle, enabling for better informed, proactive regulatory choices that promote public health and safety. The SPOR data harmonization technology solution, which is employed by five of the world's top 20 pharmaceutical firms as well as many European authorities, will be integrated into ArisGlobal's branded end-to-end (E2E) technology platform, LifeSphere. (7)

3.3 Artificial Intelligence (AI) Analytics Tools

In recent years, the application of artificial intelligence (AI) in the pharmaceutical and biomedical industries has progressed from science fiction to science fact. Pharma and biotech organizations are increasingly using more efficient, automated procedures that include data-driven decisions and predictive analytics technologies. The next

iteration of this approach to sophisticated data analytics will include artificial intelligence and machine learning. (8)

Example: Informatica Axon Data Governance

Description: Informatica Axon Data Governance utilizes AI and machine learning algorithms to analyze and govern data assets, including regulatory data, across the enterprise. It enables organizations to identify data quality issues, ensure compliance with regulations such as GDPR and HIPAA, and improve data governance practices through automated data profiling, lineage tracking, and anomaly detection.

Informatica Axon Data Governance (Axon) provides valuable context for your organization's use of data. Axon promotes collaboration among diverse populations that may not recognize their interdependence or shared resources. (9)

3.4 Natural Language Processing (NLP) Tools

Natural language processing (NLP) integrates linguistics and computer science to help machines understand genuine human discourse. In the pharmaceutical sector, NLP can be used to assess the market potential of a newly created medicine or to better target patients for current medications.(10)

Example: Linguamatics I2E

Description: Linguamatics I2E is an NLP-based text mining platform that allows organizations to extract valuable insights and knowledge from unstructured text data, including regulatory documents, scientific literature, and clinical trial reports. It enables users to perform sophisticated searches, entity recognition, and relationship extraction, facilitating regulatory intelligence analysis, adverse event detection, and literature review automation. (11)

3.5 Submission Publishing Tools

Every regulatory organization strives to produce compliant regulatory filings as efficiently as possible. Having a single publishing solution that can efficiently generate a range of submission output formats gives you a significant advantage in terms of flexibility, training, and total cost of ownership.

- Common Technical Document (CTD) for paper publications
- eCTD and NeeS (non-eCTD electronic submission) for electronic publications
- vNeeS for veterinary sector
- eCopy for medical devices (12)

Example: Lorenz docuBridge

Description: Lorenz docuBridge is a submission publishing software designed to streamline the compilation, validation, and publishing of electronic regulatory submissions in various formats, such as eCTD, NeeS, and VNeeS. It offers features such as document formatting templates, regulatory agency validation rules, electronic signature support, and submission tracking capabilities, ensuring compliance with global regulatory standards and requirements. (13)

4. Conclusion

The pharmaceutical regulatory procedure is time-consuming due to its complexity and need for regular updates. Traditional regulatory processes are slow, and automation techniques have previously been used in areas other than regulatory issues within the pharmaceutical sector. Combining AI and human intelligence has enormous potential and increases the amount of time available for strategic preparation of regulatory clearances. Automation tools can be used to automate regulatory activities such as administrative tasks, dossier completion, data extraction, auditing, regulation implementation, and quality monitoring. Automation tools establish process links and minimize complexity, resulting in a more efficient management system. Human-AI interaction creates new prospects in regulatory concerns.

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