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Enhancing Regulatory Compliance in Global Pharmaceutical Submissions Using Veeva Vault and Digital Workflow Automation

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Abstract

Global pharma submissions encountered growth in complexity as QA, non-clinical, and clinical dossiers grew in size and scope to satisfy differing standards of agency submission filings (e.g., FDA, EMA, PMDA, NMPA), unequally established regulatory documentation requirements, eCTD filing formats, categorization of post-approval change types, and data expectations, heavily taxing legacy systems relying on isolated document repositories, spreadsheets, mailing lists, and manual hand-offs, causing frequent version-control errors, time-consuming impact analysis, and compromised data integrity, attributable to ALCOA+ principles. This paper reviews how Veeva Vault RIM (Registrations, Submissions, Submissions Publishing, and Submissions Archive), partnered with digital workflow automation, closes these gaps. Using a literature review, published case-study discussion, and an affinity diagram, the work finds that the platform establishes a single source of truth, streamlines content planning, and enables continuous publishing with system-level, 21 CFR Part 11 and EU Annex 11-compliant audit trails and electronic signature boxes, and results in reduced cycle times, consistent first-pass readiness, streamlined global registration monitoring, and higher state of inspection-readiness. The conclusion advocates adopting a regime-specific, purpose-built RIM platform and suggests exploring AI-assisted planning along with agentic workflows, without losing human judgment or validated system requirements.

Keywords

Veeva Vault RIM; regulatory compliance; pharmaceutical submissions; eCTD; digital workflow automation; 21 CFR Part 11; global regulatory affairs; IDMP.

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1. INTRODUCTION

Regulatory submissions have been identified as a key control point for the lifecycle of a pharmaceutical product. They draw on years of data from quality, nonclinical, and clinical areas to produce a series of structured dossiers that set the agenda for market access and product availability. The introduction of the Common Technical Document (CTD) (formally introduced through ICH M4) provided a harmonized structure, reducing the need for extensive region-specific reformatting and enabling the required multi-agency review process (U.S. Food and Drug Administration [FDA], 2017). The electronic CTD (eCTD) set out requirements for lifecycle management, hyperlinking, and technical validation, which are now adopted by major authorities. The content, accuracy, and delivery timelines of submissions throughout the lifecycle are important parameters of first-cycle approval rates, the rate of implementation of post-approval variations, and supply security.

Global submissions continue to suffer from entrenched fragmentation. Divergent national regulators' requirements for post-approval changes (PACs), such as under differing classification schemes, stability data requirements and

administrative documentation, routinely prolong approval timescales and risk supply disruption. A 2023 industry survey of select ICH members and observers documented minimal application of ICH Q12 tools and reaffirmed that long, unpredictable timescales remain the biggest hurdle (Deavin et al., 2024). An analysis of 145,919 total PACs across 156 countries demonstrated that only a small number of regulators consistently clear submissions within six months, many far beyond (Vinther et al., 2024). Complexities are further compounded by labeling differences and region-specific Module 1 content, while time-saving assessment speed squeezes preparation timeframes and amplifies demand to prepare at the earliest possible point. Meanwhile, ALCOA+ data-integrity expectations demand attributable, contemporaneous, original, accurate, complete, consistent, enduring, and available records at every step of the submission lifecycle (McDowall, 2022; U.S. Food and Drug Administration, 2024).

Existing processes intensify these issues. Paper-based workflows, disparate electronic document repository and archiving systems, shared network drives, spreadsheets, and standalone eCTD publishing tools create version mismatches, incomplete audit trails, and repeated manual content assembly. Data is most often trapped in static PDFs, unused, unable to be shared, and prepared for multiple markets simultaneously. Each functional group has its own repository and tracking tools, meaning information about the same product exists in multiple places, with various degrees of update and consistency. Cross-referencing clinical, quality, and regulatory information is time-consuming and error-prone. These systems were not built to facilitate global coordination, 21 CFR Part 11 and EU Annex 11-compliant e-signatures, or an audit trail. All of these factors lead to a more administratively heavy CMC department, longer variations & renewal preparation cycles, and missed opportunities to improve product quality and supply resilience. Practically, administration spends too much time on document-to-document and metadata reconciliation, instead of strategy & science.

The collective weight of these trends is particularly heavy on organizations that have global portfolios of scale or a significant output of post-approval-change submissions, as resources alone, combined with increasing complexity across systems and a need to operate in parallel while remaining compliant for all countries in scope, are impossible to reconcile via legacy solutions patching (Deavin et al., 2024; Vinther et al., 2024). Teams are frequently diverted and have to rush filings, respond to agency questions at record speed, and maintain current registration data under pressure of increasing data-integrity requirements. Manual workarounds take hold and introduce new risks of missed commitments and failing to flag duplicate updates sent across agencies. In this time, point investments in document storage or publishing applications only mitigate certain pain points and tend to contribute interfaces that require new validation and support overhead. The role of regulatory operations evolves toward integrated end-to-end platforms that go beyond structured product data collection and managed document workflows to deliver transparency across all markets, embed controls into normal operations, and prevent processes from diverging into separate downstream activities (Khalil et al., 2023; DIA RIM Working Group, 2022).

Cloud-focused Regulatory Information Management (RIM) systems and digital workflows automation are organized solutions to these “limitations”. Integrated RIM structures gather all information related to product registration, submission content planning, ongoing publication, and archiving on proven, audit-ready, single-source platforms, allowing for process-level automation. Embracing the digital revolution has always been a focus of digital transformation research, which advocates moving away from elements and documents toward data and interoperability to ensure regulatory compliance and operational agility (Khalil et al., 2023; DIA RIM Working Group, 2022).

This paper considers the contributions of two initiatives to increasing inspection readiness, operational effectiveness, and regulatory compliance within a global pharmaceutical regulatory submission setting. Drawing on peer-reviewed literature and published case results, and building on a conceptual model, the discussion covers the proven benefits and impediments of both initiatives.

2. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Regulatory submission formats have evolved to the point that current practices are moving away from a series of paper or PDF common technical documents (CTD) to machine-readable, lifecycle-aware submissions that use a robust framework for the interchange of regulated product data. The original CTD has successfully standardized submission formatting and information across ICH regions; later, eCTD introduced XML structure, sequence number management, and technology-based data validation. The recent specifications for eCTD 4.0, along with ongoing migration efforts toward ISO Identification

of Medicinal Products (IDMP), mandate submissions based on structured product information regarding drug, package, and dose-form substances, to enable parallel submissions to multiple regulatory authorities using connected and interoperable data sets (Algorri et al., 2022).

Two central compliance frameworks serve as minimum acceptable levels of confidence in electronic records and processes. 21 CFR Part 11 in the US and Annex 11 in the EU identify audit trail requirements, electronic signatures, security access procedures, and system validation, etc. Other regulatory and guidance documents that also complement these compliance requirements include ICH guidelines such as M4 for the format of the common technical document (CTD) and Q8-Q12 for product design, pharmaceutical quality risk management (QRM), and product lifecycle management (PLM). In this space of interest, the 'ALCOA+' guidelines establish a framework around data integrity by identifying a requirement for records to remain Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available over a record's entire history (McDowall, 2022; European Commission, 2011).

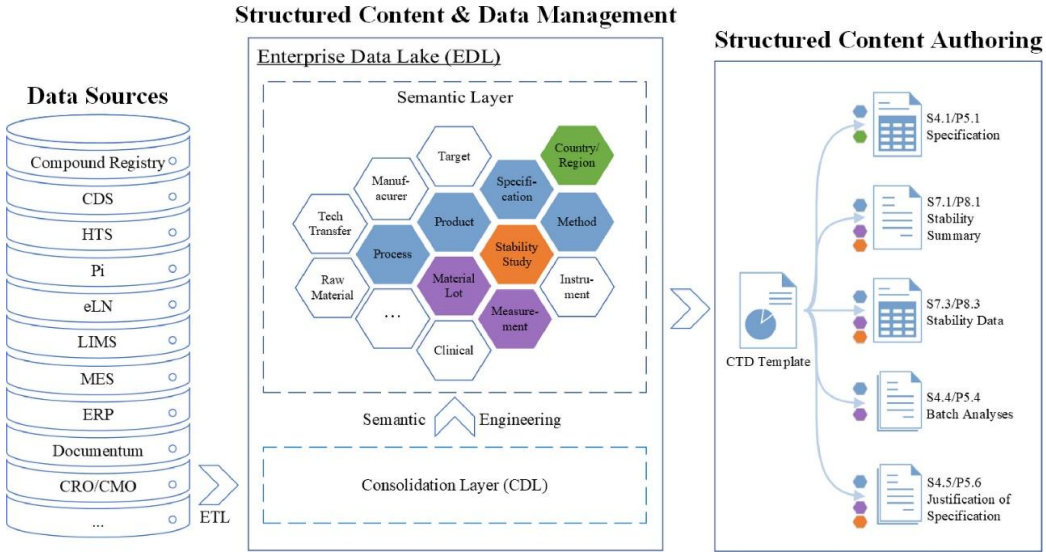

Figure 1; The Structured Content Authoring of Module 3 via a CMC-Unified Data Model (CMC-UDM) enabled by Structured Content and Data Management (SCDM); adapted from Algorri et al. (2022)

There is a well-documented trail of operational challenges resulting from varied regulatory approaches in the industry. Chemistry, manufacturing, and controls issues, problems with manufacturing sites, and labeling matters are commonly cited as reasons for delays in complete response letters (Sears, 2025; analysis of FDA CRLs 2020-2024). Problems with version-control discipline, late PAC impact assessment, and challenges finding adequate resources to address multiple markets often persist, particularly with disengaged systems being the only means of operating across markets.

Digital transformation of regulatory affairs focuses on shifting regulatory operations from archive and repository systems toward a platform with a data-centric and process-centric approach that delivers a single source of truth. Advanced platforms of this kind should eliminate redundancies across manual and automated systems, support online and real-time work, and provide continuous publication. From a socio-technical systems approach, combined with 'compliance-by-design' and 'business-process improvement' frameworks, these platforms can be assessed and reflected through a theoretical lens. Cross-application platforms must align technology, processes, and practices to balance compliance and operational effectiveness. While there is increased use of automation and commercial RIM platforms, synthesis of outcomes achieved by these systems in peer-reviewed literature, especially for commercial systems such as Veeva Vault, is not as advanced as for digital tools in general (Rees, 2025; Algorri et al., 2022).

Recent industry studies point out that structured data within chemistry, manufacturing, and controls is the key enabler before automation can deliver harmonized submissions instantly across cells and the globe. Unstructured proprietary documentation collected manually still generates errors, but more importantly, it cannot scale. Structured computable data enables faster, richer authoring and better integrity, and enables efficient health-agency review (BioPhorum, 2025).

3. OVERVIEW OF VEEVA VAULT RIM ARCHITECTURE AND CAPABILITIES

Veeva Vault RIM is a multi-tenant, cloud-native platform built for regulated life-sciences companies. The Vault architecture includes a system-level audit trail, electronic signature, role-based access controls, and configurable document lifecycle controls built in to meet 21 CFR Part 11 and EU Annex 11 requirements (Veeva Systems, 2024). These capabilities, included by design rather than added on later, allow companies to preserve validated status on upgrades and roll-outs while still tailoring workflows, access rules, and metadata to local regulatory requirements. As all RIM applications are built on top of the same fundamental data model, there is no duplication of data or multiple synchronizations involved. In addition, having one source of the data at the platform level reduces GxP elements, such as data integrity risk, associated with handling additional data sets (Veeva Systems, 2024).

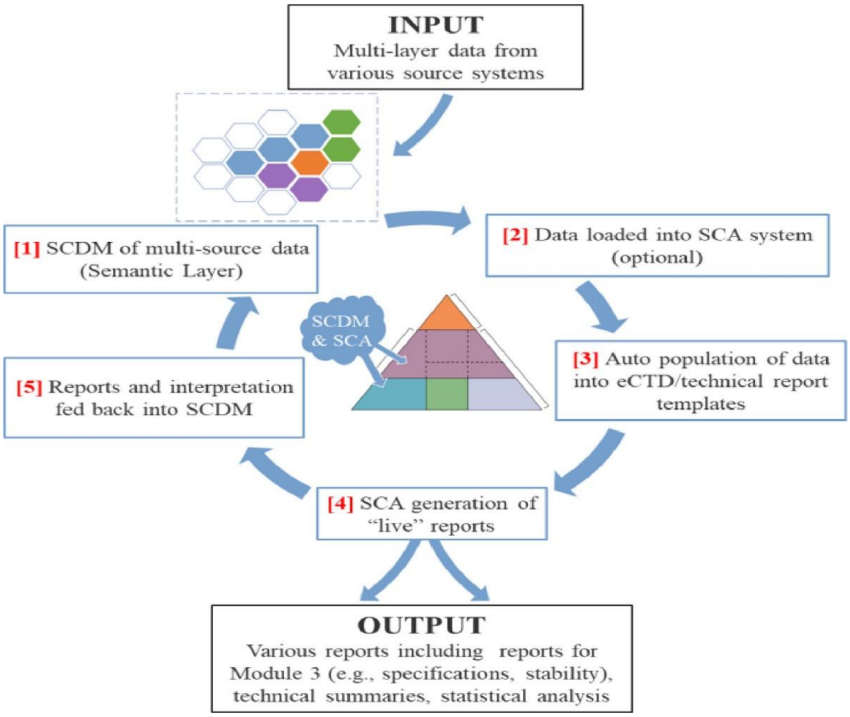

Figure 2: The end-to-end Structured Content and Data Management (SCDM) and Structured Content Authoring (SCA) lifecycle from multi-source data aggregation through semantic transformation, template population, review/approval, and feedback into the data layer; adapted from Algorri et al. (2022)

The four application suites collectively support the entire regulatory lifecycle. Vault Registrations facilitates planning, tracking, and reporting of global product registrations, regulatory events and commitments, health-authority communication, and the creation of regulatory documents, with its data model structured to ISO IDMP principles to support the information-requirement relationships between medicinal products (Veeva Systems, 2024). Vault Submissions supports collaborative content planning, real-time co-authoring, structured review and approval workflow, and the creation of content plans whose tables of contents match eCTD hierarchy. Vault Submissions Publishing facilitates continuous publishing; as source documents are published for final approval, HTML-hyperlinked, technically validated eCTD and regional package content is dynamically generated according to the latest agency requirements. Vault Submissions Archive securely stores and conveniently makes searchable final versions of published dossiers, Active Dossier views reflecting current valid product-market content, and manages health-authority correspondence (Veeva Systems, 2026b; IntuitionLabs, 2025).

Cross-functional connectivity and workflow automation continue the platform through the rest of the product lifecycle, not just key regulatory activities. Out-of-the-box Quality - RIM integrations enable potential quality events, such as manufacturing batch and labeling updates, to automatically trigger human review for regulatory impact assessment. Integration with clinical and commercial Vault applications enables control of any downstream use of data (such as safety reports, submission packages, and labeling translations) throughout the lifecycle. Gateway interfaces enable direct submission to the USFDA Electronic

Submissions Gateway or the EMA submission portal, as well as acceptance of submission acknowledgments. Systemized, role-based, configurable workflows with notifications, document assembly from metadata, real-time dashboards of efficiency and compliance, and bulk operations reduce manual effort. Together with a system-enforced audit trail, controlled labels and glossaries, compliance-by-design features such as rigorous version control, and self-auditing submission reports, the platform provides a compliance-by-design backbone that supports compliant and efficient workflows throughout the lifecycle (Veeva Systems, 2024).

4. MECHANISMS OF ENHANCED REGULATORY COMPLIANCE THROUGH AUTOMATION

VEEVA Vault RIM enhances regulatory compliance by creating a single source of truth, replacing duplicate files and version conflicts with a single set of consistent metadata throughout planning, authoring, and publishing. The simplified submission lifecycle from structured content plan to collaborative authoring, continuous publishing, gateway delivery, and archiving reduces manual hand-offs and rework. Global registration and post-approval change (PAC) management functionality allow rapid impact analysis for manufacturing or labeling changes, tracking across multiple markets, and automated follow-up of commitments. System-level audit trails produce a comprehensive, attributable, and searchable history of all actions, decisions, and health-authority correspondence, providing inspection readiness. Reduced risk associated with continuous publishing and automated validation thwarts technical errors, hyperlinks, and regional requirement mismatches at the earliest possible opportunity rather than at the final assembly stage.

The positive business outcomes of these capabilities are represented in published case experience. Organizations report up to 50% or greater cycle time improvements for change management impact analysis, significant increases in monthly submission volume using the same FTEs, and the merger of disparate legacy systems into a consolidated solution (Veeva Systems, 2024). With ongoing publishing, initial review cycles are delivered earlier, and technical content issues are identified sooner. These trends also support an organization's compliance strategy regarding eCTD 4.0 technical requirements, a shift to a more structured content strategy, and future adherence to the ISO IDMP models (Algorri et al., 2022).

The platform's harmonized data model ensures not only the above operational efficiencies but also reinforces traceability between quality events and regulatory action. With a "single version of the truth" for both product and process information, each deviation from standard quality practices, change control, or labeling revision automatically becomes connected to associated regulatory commitments and submission data. When new production or labeling changes occur in an associated quality system, and the impact statement is generated, the related sections of extant dossiers are immediately found, corresponding markets identified, and the impacts described and drafted with available, approved data; thus, ensuring quality events are not forgotten, and different authorities do not receive disparate communications (Veeva Systems, 2024). This automated alignment is critical to more effective lifecycle management; instead of teams wrestling with complex, decentralized, "tribal" knowledge and painstakingly linking cross-referential information, the software presents immediate linkages of dependencies for speedy decisions and for delineating ownership for action items. Moreover, during inspections, you have all regulatory data showing exactly how the quality event was reviewed, how the assessment was finalized and authorized, and how subsequent variations/notifications were filed, leading to fewer inspectional observations related to unmanaged or non-compliant change control, regulatory communications, or submissions. Continuous Publishing and early tech review also move quality to the earliest possible points. When rules for a product dossier or content have historically been reviewed after the entire dossier has been written, continuous publishing brings this validation activity directly to the document and data objects in which that content is written. A missing specification, an obsolete standard, or an incorrectly filled-out field is not discovered only when the whole dossier has come together, but as those specific pieces of documentation or data objects are created (Veeva Systems, 2024). This reduces late-stage corrections, improves quality, and leads to far more predictable timelines with less rework. When these activities of bringing forward both of these different processes have occurred, compliance that used to be, in essence, a "last mile check" has now "gone home and become something, not so late on the time curve but a quality and content, day-of-the-week activity (Algorri et al., 2022). That is certainly, as stated, a powerful transformation of not just efficiency but of confident operations in terms of regulatory concerns.

5. IMPLEMENTATION CONSIDERATIONS, BENEFITS, CHALLENGES, AND BEST PRACTICES

Implementation for Veeva Vault RIM is a gated process which requires a detailed discovery and gap analysis; designing the application: lifecycle configuration, designing the taxonomy (Controlled vocabulary), the user and their roles, Computer Systems Validation (IQ/OQ/PQ), Controlled data migration, Training the users, Post-go live hypercare, the scoping of interfaces (e.g. ERP) in the early phases and putting in place a data governance plan on metadata values prevent any rework. Because cloud-based GXP platforms operate differently, common validation methods established for legacy on-premises platforms (fixed at a particular point in time, Ullagaddi, 2026) no longer apply. Benefits previously observed included shorter submission cycles, minimized version control errors in documents, improved regulatory compliance, lowered administrative costs, improved cross-functional collaboration, greater ability to scale to new geographies and modalities, and ultimately a robust compliance position.

Common problems included managing Organizational Change and User Adoption, Inconsistent or missing Legacy data, integration with other enterprise systems (SAP), required validation resources, and process alignment across global affiliations. Even if organizations can migrate away from document-focused processes and toward data-centric authoring and common content, without continuous training and leadership support, users will go back to their old ways. Legacy data commonly contains missing fields, duplicates, or conflicting information, and can be very messy and require a lot of data cleansing before it can be populated in a unified model. Integrations with enterprise systems require mapping and ongoing synchronization, and validation (within regulated areas) is a resource-intensive activity that requires significant documentation effort. Finally, aligning variations in terminology, approvals, and local procedures across regions slows things down even further. Solving this involves a unified program of people, process, and technology that ideally incorporates a road map for change, work to improve data quality, staged integration of solutions, and a governing structure across global functions. The implementation must generate an ROI through these capabilities (Johanning, 2025).

Best-practice recommendations suggest line-of-sight for automation, treating compliance configuration as a first-phase design decision, maintaining strong metadata and taxonomy governance, capitalizing on prescriptive Quality–RIM connections, enacting phased rollouts with well-defined KPI targets, balancing intensity of training investment with process refresh investment, minimizing solution validation efforts in the first phase, and developing cost-sharing strategies for break/fix iterations to correction validation efforts. Risk mitigation strategies for validation and ongoing maintenance include risk-based validation approaches consistent with the current CSA requirements, reuse of vendor qualification packages where feasible, and monitoring of system performance and regulatory updates (Ullagaddi, 2026; Veeva Systems, 2025).

Data Quality Needs to Be a Front-End Foundation, Not a Back-End Migration Task. High-performing companies assign formal data ownership and governance and master-data standards (e.g., IDMP-ready substance-, dosage-, pack-form, and product-level identifiers, with product registration and global site-master identifiers). Prior to migration, they also define scope, systematically evaluate whether source data are consistent and complete, clean the records of those that are obsolete or duplicate, and enrich absent descriptive details before migrating data to the target Vault environment. After go-live, such organizations deploy post-implementation features - the mandate for validation and mandatory fields during data entry, carefully controlled vocabularies, ongoing quality audits, dashboards for business users to display metrics, - to protect and defend data integrity, thereby avoiding repetition of the old inconsistencies (Product Life Group, 2024; Gens & Associates, 2024).

Ongoing value is also a function of planned, ongoing post-go-live optimization. Once hypercare ends, companies benefit from an established process for monitoring continuous performance metrics such as data completeness, process cycle times, first-time-right rates, and user adoption levels by function and region. Performance metrics should be reviewed frequently and used to refine configuration, adjust workflows, and retrain individuals or teams exhibiting poor adoption or high error rates. Continuous measurement will also help organizations proactively respond to new regulatory mandates such as changes to eCTD formats or extended IDMP requirements. Without this layer of continuous improvement, even a technically successful implementation will fall into disuse over time, processes will shift, and the single source of truth the system was intended to achieve will be undermined.

6. FUTURE DIRECTIONS: AI, AGENTIC AUTOMATION, AND EMERGING CAPABILITIES

Combining large language models, generative AI, and intelligent user engineering on decentralized systems like Veeva Vault will likely accelerate submission planning, generate first drafts of health-authority correspondence, conduct content reviews against approved labels and local requirements, and predictively estimate review times. In turn, these features can prevent redundant work while reducing global dossier prep timelines. Agentic workflows can take this a step further by dispatching software agents to do operational efficiency tasks like populating metadata, detecting inconsistencies, and conducting initial validations. Human-complementary and fully auditable process oversight will remain essential to maintain accountability and data fidelity. Along these lines, simultaneous advances in structured data submissions, ongoing access to a robust feed of regulatory intelligence, and increased integration across quality, regulatory, and supply-chain functions will further minimize the lag between operational changes and regulatory readiness.

Other research and industry needs include standard outcome metrics to compare the savings from efficiency and compliance improvements between platforms, long-term return-on-investment studies, and practical advice on validating AI tools in GxP environments. Risk-based mitigation frameworks that adapt Computer Software Assurance concepts to the ongoing verification/validation of AI models are especially critical as these tools transition from pilot to production (Kalidoss, 2026; FDA, 2025).

7. DISCUSSION AND IMPLICATIONS

Veeva Vault RIM with digital workflow automation aligns technology directly to global submission pain points: siloed information, conflicting versions, lag in post-approval change evaluation, and incomplete audit trails. It establishes a single source of truth, supports evergreen publishing, and embeds system layers of controls in conformance with 21 CFR Part 11 and Annex 11, strengthening the compliance paradigm while reducing cycle times and overhead. This case illuminates regulatory science and digital transformation literature by applying socio-technical systems theory and compliance-by-design to a behavior-changing, high-volume, operationally accepted platform, demonstrating the importance of going hand in hand with technology, process redesign, and organizational change to achieve the desired value proposition.

Implications are sector-specific. Large pharma entities can leverage scale to extend their global footprint and rationalize legacy systems; medium-sized firms and cutting-edge biotech's have a new product/market platform that is enterprise class not just enterprise scale, but without equivalent arithmetical increase in staffing levels; contract research and manufacturing organizations (CRO/CMOs) can present their clients or franchise partners with enhanced transparency and short turnarounds; health authorities will be The benefit here is indirect, as the impact on health authorities is only indirect, since the end products of strategic Data Management projects will be higher quality and more consistent dossiers, with fewer technical validation failures and clarification inquiries. This synthesis has limitations: some of the evidence base is drawn from vendor case studies, or from secondary industry reports, but without independent, peer-reviewed empirical studies; few comparative long-term studies have been put in place, based on common outcome indicators; finally, admittedly obvious, technology as such does not guarantee success; sending American Express to the doing room does not guarantee an efficient executive.

8. CONCLUSION

Specifically, Reg IM platforms such as Veeva Vault, used together with digital workflow automation, provide a high-ROI way to enhance global regulatory submission compliance. By providing a 'single source of truth', eliminating version duplication, shortening submission cycle times, maintaining data integrity in compliance with ALCOA+ rules, and system-level audit trails and controlled procedures, continuous inspection readiness is enabled; case evidence shows improvement in efficiency, scalability across multiple markets and product modalities, and maintenance of a post-approval change workload with current staff levels. Adoption of systems built for compliance (compliance-by-design) is likely to continue, supported by independent research that empirically proves long-term gains. Also, organizations need to be prepared for next-generation requirements such as structured data, eCTD 4.0, IDMP, and appropriate use of AI agents and agents of agents within validated GxP environments.

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