



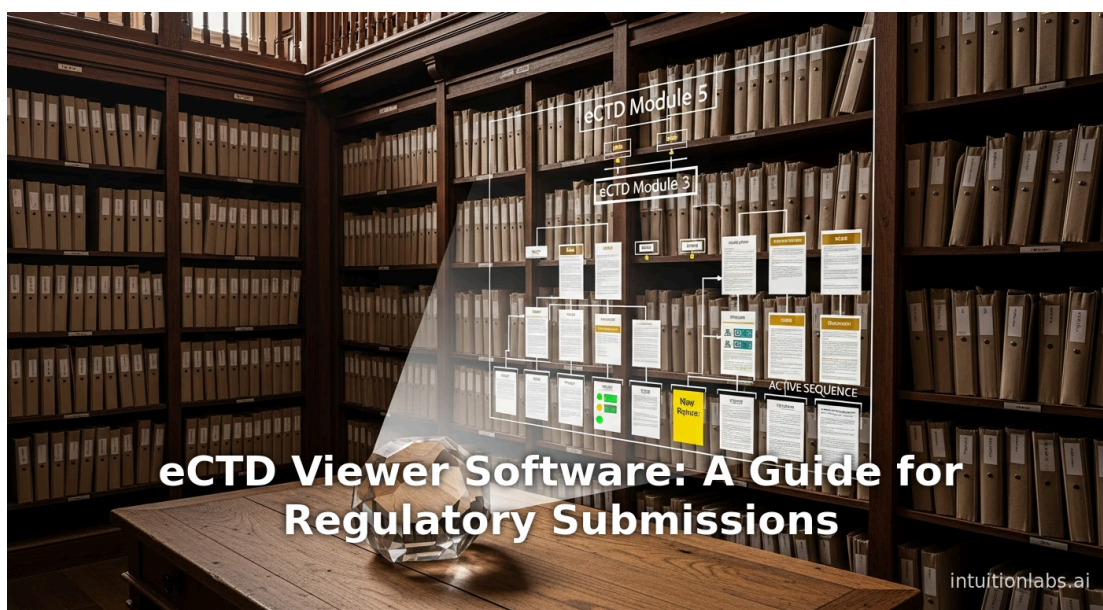
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eCTD Viewer Software: A Guide for Regulatory Submissions

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Executive Summary

Electronic Common Technical Document (eCTD) viewer software has emerged as a critical component of modern pharmaceutical regulatory operations. As health authorities worldwide adopted the harmonized eCTD format in the 2000s (globalforum.diaglobal.org) (esubmission.ema.europa.eu), regulatory submissions transitioned from paper dossiers to structured digital packages. eCTD viewers are specialized applications that allow users to navigate and review these complex electronic dossiers efficiently. They replace manual file-extraction and management workflows with centralized, user-friendly interfaces (boydconsultants.com) (boydconsultants.com). Industry sources highlight that an eCTD viewer “provides a single, centralised portal for viewing and navigating the entire submission, from individual sequences to the complete application lifecycle” (boydconsultants.com), dramatically improving the speed and accuracy of submission assembly and review. In practice, organizations report shorter review cycles and fewer errors when using viewer tools (www.sciencedirect.com) (boydconsultants.com).

This report provides an in-depth survey of eCTD viewer software: its origins, technical capabilities, market offerings, and impact on regulatory workflows. We trace the evolution of submission technology from paper Common Technical Documents (CTDs) to eCTD and beyond, discuss the driving need for viewer tools, and detail their key features. We review multiple commercial and free viewer solutions (see Table 1), drawing on product literature and expert commentary. Case studies illustrate how viewers add value (e.g. streamlining internal quality control and enabling multi-product regulatory analysis). We also examine challenges and limitations (such as fragmented data silos and learning curves) and consider future trends, including the shift to eCTD version 4.0, integration with content-management platforms, and emerging AI enhancements. Throughout, claims are supported by regulatory guidelines, published analyses, vendor documentation, and industry expert sources (esubmission.ema.europa.eu) (boydconsultants.com) (www.sciencedirect.com). The evidence suggests that as regulatory submissions continue to digitize, advanced eCTD viewer platforms will be increasingly indispensable – enabling faster reviews while highlighting the need for robust standards and training.

Introduction and Background

The **Electronic Common Technical Document (eCTD)** is the internationally harmonized standard for submitting regulatory dossiers for pharmaceuticals. Established by the International Council on Harmonisation (ICH), the eCTD formalizes the modular structure of a drug submission and adds an electronic layer for transport and review (globalforum.diaglobal.org) (esubmission.ema.europa.eu). In practice, an eCTD submission consists of PDF documents organized in a predefined directory hierarchy (often called *Modules 1–5*) and indexed by XML backbone files with integrity checks (MD5 hashes) to ensure no corruption (esubmission.ema.europa.eu). The format details (e.g. ICH **eCTD Specification v3.2.2**) prescribe file naming, hyperlinks, and metadata, reflecting the content previously managed in paper dossiers (esubmission.ema.europa.eu).

The eCTD reached ICH Step 4 in 2003 ([ICH support documentation](#)), and eCTD is mandatory for submissions related to marketing authorisation in EU centralised, decentralised and mutual-recognition procedures ([EMA eSubmission](#)). Its introduction marked a “*huge impact on the speed and accuracy of regulatory submissions*” for the pharmaceutical industry (globalforum.diaglobal.org). By moving to digital submissions, sponsors could transmit large data packages electronically (often via the agencies’ electronic Submission Gateway or portals) instead of physically shipping paper. Studies note that digital tools have standardized and accelerated regulatory workflows, improving data management and reducing processing times (www.sciencedirect.com). For example, Lord (2024) observes, “technology has transformed pharmaceutical regulatory processes, improving data management and workflow efficiency” (www.sciencedirect.com). FDA describes eCTD as the standard format for applications, amendments, supplements and reports submitted to CDER and CBER ([FDA eCTD page](#)).

Despite the initial focus on digitizing submissions, the early eCTD systems often left sponsors and regulators with only the capability to compile and send the files. The submission stages before and after compilation remained poorly integrated: authors worked in disparate systems or paper, and reviewers (inside or outside regulatory agencies) had to deal with static PDF outputs. In this context, **eCTD viewer** software arose to fill the gap. The solution was to provide clients – regulatory professionals, internal reviewers, health authority staff – with software to **navigate and inspect eCTD dossiers interactively**, just as they would examine a PDF folder structure. In other words, an eCTD viewer is a specialized platform for viewing an assembled electronic dossier.

The eCTD Viewer: Definition and Role

What is an eCTD viewer? In simple terms, it is a user-friendly interface that loads the contents of an eCTD submission and lets users browse, search, and analyze it as a coherent whole (boydconsultants.com). Instead of manually unzipping eCTD sequence files and opening dozens of PDFs one by one, a viewer provides a consolidated environment. According to Boyd Consultants, “*An eCTD viewer is a user-friendly, integrated platform for viewing complex eCTD applications. It replaces the difficult, multi-step process of manually managing published outputs (such as copying and unzipping files) with a streamlined, web-based interface*” (boydconsultants.com). In practice, a viewer typically displays the eCTD document hierarchy (modules and sections) in a tree or tabbed format, and allows users to click through to view any document (e.g. a study report PDF) within the application.

The **need** for such a tool is clear given the complexity of regulatory filings. A single product dossier can consist of dozens of “Sequences” (versioned updates sent over a product’s life), each containing hundreds of documents spanning quality, nonclinical, and clinical data. For example, regulatory experts warn that without good navigation, managing large eCTD files can be slow and error-prone: *“One of the biggest challenges ... is poor document navigation. A subpar eCTD viewer can make it difficult to manage large submission files, slowing down your work and causing frustration”* ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). If a submission review team cannot quickly locate or verify key documents, it risks delays or mistakes that could impact approval timelines.

To address these challenges, modern eCTD viewers offer **centralized access and enhanced navigation**. Boyd Consultants highlights this: viewers provide a *“single-location access... for viewing and navigating the entire submission, from individual sequences to the complete application lifecycle”* ([boydconsultants.com](https://www.boydconsultants.com)). In other words, all versions and all modules are visible in one workspace. A reviewer can instantly open the current sequence or jump back to any previous one, examine older versions of documents, and see the history of each module. This contrasts with older workflows where users might have to open multiple sequence folders or rely on exported PDFs.

Moreover, viewers include **search and review tools**. They often allow full-text search across PDFs, bookmarks, and navigation shortcuts (e.g. “Find” or “next chapter”). Boyd et al. note that viewers *“support content review”* by offering text searching and zooming for quickly checking document accuracy ([boydconsultants.com](https://www.boydconsultants.com)). Many viewers also **highlight and track changes**: they visually label documents as *New*, *Replace*, or *Delete* according to the regulatory actions in each sequence ([boydconsultants.com](https://www.boydconsultants.com)). This immediately flags any added or altered content, so reviewers do not have to manually compare sequence to sequence. Indeed, Boyd points out that with status indicators clearly identified, *“reviewers no longer need to manually search through older versions to determine what has changed”* ([boydconsultants.com](https://www.boydconsultants.com)).

Technical Features and Capabilities

eCTD viewers combine several technical capabilities to support the above functionalities. A key aspect is **XML parsing and indexing**. Each eCTD submission includes an XML backbone file (index.xml) and mapping of the folder structure. Viewers read this XML to reconstruct the module/section hierarchy on-screen. According to vendor descriptions, viewers often use “recursive XML parsing” to gather content from multiple sequences – essentially stitching together a running version of the dossier back to the first submission ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). In practice, this enables features like *“full preview of [the] current dossier (combined output of all sequences)”* so that users can see the cumulative file set or isolation of any sequence ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). In other words, the software automatically merges the sequences behind the scenes to produce an up-to-date view of the entire submission.

Once parsed, the viewer’s interface presents the dossier tree and document list. Typical UI features include:

- **Table of Contents and Hierarchical Views:** Viewers display Modules 1–5 and their subsections in a tree or tab. Users can expand and collapse sections, similar to how agencies view submissions ([boydconsultants.com](https://www.boydconsultants.com)). For example, one viewer shows sections exactly *“much like regulators see it”*, and lets users click on any study or document file directly.

- **Document Display:** When a user selects a node (e.g. *Module 3 – Quality*, or *Study Report Index*), the relevant PDF or other data file is loaded for viewing. Good viewers embed a PDF reader or invoke an appropriate viewer so that the content appears within the application window. This eliminates the need to open separate Acrobat instances.
- **Search and Favorites:** Many viewers offer text-search across all PDFs in a sequence or entire dossier, as well as bookmarking or annotation tools. This speeds finding specific data (e.g. search for a term across all clinical study reports).
- **Change Tracking Highlights:** As noted, viewers usually incorporate visual cues for each document's status (new/replaced/deleted). Some viewers can even color-code or mark changed text within documents (if text is converted or OCR'ed).
- **Hyperlink Validation:** Because eCTDs rely heavily on hyperlinks (cross-references from tables of contents or within documents), viewers often include link-checking. They can flag broken or inactive links. Boyd consultants emphasize that viewers *"facilitate easy quality control of internal and external hyperlinks"*, improving review efficiency (boydconsultants.com).
- **Multi-Sequence Comparison:** Advanced viewers may allow side-by-side comparison of two sequences or mark differences between document versions, although this is not universal. At a minimum, users can virtually load "cumulative" versus "current" views.

In sum, an eCTD viewer effectively **reconstructs the submission dossier in a user-friendly way**. Behind the scenes, it processes XML indexes, attaches metadata, and ensures that all relevant PDFs (and non-PDF content) are accessible. From the user's perspective, however, it simply appears as an integrated portal into the regulatory dossier (boydconsultants.com) (boydconsultants.com).

Market Landscape and Products

A variety of eCTD viewer solutions are available, ranging from free standalone tools to enterprise platforms. Some include:

- **ViewerPlus (RegApps):** A free Windows application that integrates viewing with validation. ViewerPlus is "purpose-built for regulatory professionals to efficiently view and validate electronic submissions in eCTD, NeeS, and other dossier formats" (www.regapps.net). It is optimized to open large sequences quickly and runs on all recent Windows versions (www.regapps.net). Among its features are rapid switching between the "Current View" (single sequence) and "Cumulative View" (all sequences), aiming for speed and simplicity (www.regapps.net).
- **Mono eCTD Viewer (ECTDoffice/SourceHov):** Mono offers a free Beginner edition for eCTD v3.2.2; eCTD v4.0 viewing requires a paid Expert or Master edition (www.ectdviewer.ectdoffice.com), making it forward-compatible. According to its documentation, *"Mono eCTD Viewer is a simple (powerful, customizable and feature rich) and super fast eCTD reviewing system, covering all ICH eCTD regions and submission/procedure types"* (www.ectdviewer.ectdoffice.com). It is designed to run on any Windows machine (laptop or remote desktop) and handles very large dossier sets without heavy resource use. It emphasizes "run anywhere. view it all" – including on Citrix or CloudVM environments (www.ectdviewer.ectdoffice.com).

- **ROSETTA eCTD Viewer (DoubleBridge):** This is a well-known viewer from DoubleBridge Technologies. The ROSETTA Desktop Edition supports *“the latest and all previous ICH and regional eCTD specifications since 2004,”* including a pilot-level support for eCTD v4.0 (www.ectdviewer.com). It provides multiple user interfaces (table of contents view, folder tree view, etc.) and emphasizes high-quality rendering of the full dossier. A free download/demo is available, though enterprise licensing and server versions exist. ROSETTA’s marketing highlights that it does not compromise performance or quality, implicitly warning against “cheap imitations” (www.ectdviewer.com).
- **Dossplorer (Celegence):** Celegence, a regulatory services company, offers Dossplorer as an advanced dossier viewer. Unlike basic tools, Dossplorer is geared for *enterprise-wide regulatory intelligence*. It supports normal eCTD navigation but extends beyond to analytical use cases. For example, traditional viewers focus on one product in one dossier, but Dossplorer can **aggregate across multiple submissions**. The vendor notes that this allows tasks like **Regulatory Impact Assessments** across products. Dossplorer provides *“unique viewing capabilities beyond the traditional... view”*, enabling *holistic views across multiple applications* (www.celegence.com). It also offers full-text indexing and analytics on the PDF content, recognizing that *“regulatory information is still trapped ... in the form of PDFs”* unless processed (www.celegence.com). In other words, Dossplorer blurs the line between a viewer and a broader content management/analysis platform.
- **Vault Submissions Archive (Veeva Vault RIM):** Modern regulatory content management systems (RCMS) increasingly embed eCTD viewing. For example, Veeva Vault Submissions (part of their RIM suite) includes an archive and viewer module. It dynamically orders and displays files as regulators expect (Module 1–5 structure) and lets authorized users browse the official submission history. Users can click through to any report or section directly from the Vault interface, streamlining internal quality reviews. While live documentation is proprietary, industry writers note that Vault’s viewer *“presents the hierarchy of Modules 1–5 and all the submitted files under each, much like regulators see it”*, and allows users to open specific dataverse content without manually handling files. (Other RIM systems like MasterControl RIM or Freyr’s Submit Pro similarly integrate dossier viewers connected to their overall content ecosystem.)

Table 1 summarizes select eCTD viewer offerings, their platforms, supported versions, and key features. Several other solutions exist (e.g. Informa/InnoVigil’s Dossier eScan, QbDVision’s Qdossier, ShareVault/Kivo’s viewer, etc.), but detailed, documented comparisons are limited in the public domain. Many organizations choose a viewer based on ecosystem or cost (free vs license).

Software (Viewer)	Vendor/Provider	Platform	eCTD Version Support	Notable Features
Mono eCTD Viewer (www.ectdviewer.ectdoffice.com) (www.ectdviewer.ectdoffice.com)	ECTDoffice (SourceHov)	Desktop (Windows; add-in)	Free Beginner: v3.2.2; paid Expert/Master: v3.2.2 and v4.0	Free Beginner; lightweight; supports all ICH regions; cross-platform (laptop/terminal/Cloud)
ViewerPlus (www.regapps.net)	RegApps	Desktop (Windows)	v3.x (eCTD) + NeeS	Free; integrated viewing & validation; high-performance for large sequences; intuitive UI (www.regapps.net)

Software (Viewer)	Vendor/Provider	Platform	eCTD Version Support	Notable Features
ROSETTA eCTD Viewer (www.ectdviewer.com)	DoubleBridge Technologies	Desktop (Windows)	v3.x (and pilot v4.0)	Paid; supports all ICH/regional specs; multiple viewing modes; proven UI; available free trial (www.ectdviewer.com)
Dossplorer (www.celegence.com) (www.celegence.com)	Celegence (Dossolutions)	Cloud/Enterprise (Web)	v3.x (currently)	Advanced analytics; multi-application/regional viewing; full-text indexing of submissions (www.celegence.com)
Vault Submissions Archive (e.g. Vault RIM)	Veeva (Vault RIM)	Cloud (Web)	v3.x and v4.0 (with 2025 rollout)	Integrated in Veeva RIM; shows Module 1–5 hierarchy; supports concurrent review; secure, validated archive

Table 1. Selected eCTD viewer software (features and capabilities). Citations indicate source claims about features. Free tools like Mono and ViewerPlus are popular for quick viewing, while enterprise viewers (ROSETTA, Vault, Dossplorer) integrate with broader regulatory systems.

Impact on Regulatory Processes

By providing efficient dossier navigation, eCTD viewers substantially improve compliance workflows and decision-making. They help **streamline quality control (QC)**, one of the most resource-intensive steps in submissions. For example, with all documents accessible in one place, internal reviewers can systematically verify hyperlinks, check PDF bookmarks, and validate module organization without re-compiling the eCTD. Boyd Consultants reports that using a viewer in QC allowed their teams to review complex submissions more effectively from start to finish (boydconsultants.com) (boydconsultants.com). Reviewers no longer waste time extracting files or emailing PDFs; instead, the full application is on-screen under a unified interface. This cuts down the QC cycle considerably.

Quantitatively, industry sources note that digital submission tools can speed regulatory reviews dramatically. One overview asserts that adoption of e-submission software “*accelerates processes in the pharmaceutical industry*”, contributing to faster reviews (www.sciencedirect.com). While specific productivity figures are scant, anecdotal reports suggest that small percentage gains in navigation time can yield days saved per submission. More importantly, viewers reduce human error: a centralized view makes it much harder to miss an outdated reference or broken link. Regulatory consultants emphasize that clearly marking changes (e.g. green for new docs, red for deleted) “*dramatically improves the efficiency of the review process*” (boydconsultants.com). By catching errors early, companies avoid regulatory queries or rejections due to formatting mistakes.

Collaboration and knowledge sharing are other clear benefits. Where once only the author of a dossier could know exactly what was in the final eCTD, viewer platforms let multiple specialists inspect the same content in real time. Uploading a compiled submission to a review portal, or using a cloud-based viewer, means that regulatory affairs, clinical, safety, and quality teams can all see the exact content destined for the Agency. Projects become more transparent and cooperative. Boyd notes that advanced viewers even support parallel work: while one staffer assembles a new sequence, others can simultaneously review the outcomes of

earlier sequences. This breaks the bottleneck of “*one-person-at-a-time*” submission review (as was common with monolithic publishing tools). For instance, regulatory review cycles during high-pressure scenarios (e.g. expedited approvals) benefit from multiple reviewers concurrently checking submission updates.

Boyd Consultants says that document history and status indicators can improve QC review efficiency.

Challenges and Limitations

While powerful, eCTD viewer software is not without challenges. **Usability and learning curve** are common concerns. If a viewer’s interface is not intuitive, it can become an obstacle rather than a help. Even modern viewers have diverse layouts and concepts (various “views” or modes), which may confuse new users. Sponsors must invest in training their staff on the chosen viewer’s features to realize full benefit.

Software limitations can also arise. Some viewers handle only pure eCTD content; they may not easily incorporate non-eCTD documents (legacy files, internal lab reports) without reformatting. Integration with other systems is not always seamless. For example, clinical trial teams might store protocols in a separate database, requiring extra steps to link them into the eCTD viewer. Similarly, regulatory metadata (e.g. product numbers, regulatory action dates) may live in a tracking system, not automatically reflected in the viewer. Some users note that regulatory outputs still feel like “*digitalised paper*” – PDFs that are only marginally more searchable than physical scans (www.celegence.com). In fact, Celegence emphasizes that much critical information remains locked in static PDFs unless advanced indexing is applied (www.celegence.com). As a result, companies are still seeking features like machine-readable data extraction and semantic search to break these silos.

Another practical issue is **multiple concurrent formats**. Global companies often have submissions in both eCTD and legacy NeeS (electronic Non-eCTD) formats, or even maintain old paper records. A viewer that only handles eCTD sequences leaves gaps. Some advanced platforms now offer unified archive views (importing various formats), but many organizations still need separate viewers or conversion steps for non-ICH regions.

Using third-party viewer tools may entail **validation and compliance work**. FDA Part 11 applicability depends on the electronic records or signatures and applicable predicate rules, so validation and controls should be assessed for each viewer’s intended use and record-integrity risk ([FDA guidance](#)). This overhead can deter smaller companies from adopting out-of-the-box tools and lead them to rely on home-grown solutions (although that carries its own compliance burdens).

Finally, **cost and vendor lock-in** are concerns. Commercial viewers and RIM systems can be expensive, especially enterprise editions with collaboration modules. Companies must weigh the license and implementation costs against productivity gains. Some firms address this by using free viewers (ViewerPlus or Mono) for everyday checks, reserving heavy-duty viewers for final QC. However, free tools may lack enterprise features (like user management or audit trails). The decision of which viewer to use can also depend on publishers’ tools; some publishing vendors bundle their own viewer, subtly encouraging clients to stay within the same ecosystem.

Case Studies and Perspectives

Quality Control (QC) Empowerment: In a recent blog, Boyd Consultants – a regulatory strategist – described the benefits of incorporating an eCTD viewer into its QC process after a major filing: *“such investment delivers value from the initial to the final review”* ([boydconsultants.com](https://www.boydconsultants.com)) ([boydconsultants.com](https://www.boydconsultants.com)).

Regulatory Impact Assessment (RIA) across Products: Celegence illustrates a different use case beyond mere QC. Typically, eCTDs are per-product. However, companies often need to analyze regulatory filings across multiple products at once – for example, when assessing the impact of a change in one product on others. In a published webinar outline, Celegence showed using Dossplorer to support a global RIA. Traditional viewers only handle one product/country at a time; by contrast, Dossplorer can present *“holistic views across multiple applications”* (www.celegence.com). For instance, if a sponsor wants to propagate a CMC update to several drug registrations, Dossplorer can load all relevant dossiers and highlight which already contain the update versus which do not. Celegence notes that without such a viewer, companies had to manually open each product’s dossier or cross-check spreadsheets, a highly error-prone practice. This case demonstrates how an advanced viewing tool can break down functional silos and enable strategic regulatory planning.

User Experience Lessons: Not all feedback is positive. As one industry article cautions, users must evaluate whether their current viewer truly “gives [them] the full picture” ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). For example, one Sarjen (KnowledgeNet) blog post asked customers to consider if their viewing tool was merely displaying one sequence at a time, or if it parsed **every** XML sequence to show the complete dossier history ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). In their words, a sophisticated viewer should ensure *“you always have a complete overview”* of the submission ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). This reflects real experiences: some earlier software only let users see one sequence in isolation, meaning reviewers often had to guess whether older documents were still present. In contrast, newer viewers highlight cumulative content, making omission or duplication errors immediately apparent.

Another reported issue is fragmented submission data. Buyer beware: Sarjen warns that an inferior viewer with weak navigation can itself become a bottleneck. If the tool does not quickly load large files or does not allow easy navigation to older sequences, then *“the software doesn’t allow easy access to different sequences or individual documents”*, which can *“lead to delays and mistakes”* ([knowledgenet.sarjen.com](https://www.knowledgenet.sarjen.com)). Thus, in practice, organizations must verify that the viewer they adopt truly supports their content sizes and workflow.

The Mono vendor says browser navigation of eCTD XML backbones could be cumbersome and recommends a dedicated viewer ([Mono eCTD Viewer](#)).

Regulatory and Industry Trends

Regulatory authorities themselves are driving the evolution of submission formats. The latest development is **eCTD v4.0**, which transitions from a “document-centric” XML to a more flexible HL7 RPS (Regulated Product Submission) model. This is expected to allow more structured data submission (component-level links, multi-language support, etc.). Adoption timelines vary by region: FDA supports v4.0 for new NDA, BLA, ANDA, IND and master-file submissions from September 16, 2024, and says it will give advance notice before accepting only v4.0 ([FDA eCTD page](#)). From 22 December 2025, EMA has allowed applicants to optionally submit new

Marketing Authorisation Applications (MAAs) for Centrally Authorised Products (CAPs) in eCTD v4.0 (esubmission.ema.europa.eu). Applicants must contact the EMA eCTD v4.0 team before any eCTD v4.0 submission. PMDA began accepting eCTD v4.0 in April 2022 ([PMDA implementation schedule](#)); it accepted v3 submissions only for approval applications made through March 31, 2026 ([PMDA](#)).

These transitions have implications for viewer software. Version 4.0's RPS backbone will alter the file structure (for example, multiple linked "documents-of-common-interest" across sequences). Viewers must adapt to render this new structure properly. Several vendor roadmaps now include eCTD 4.0 support (e.g. ROSETTA's pilot, Vault's early releases) (www.ectdviewer.com) (www.fda.gov). Users should consider future-proofing: a viewer that handles only v3.2.2 will become obsolete as jurisdictions shift.

The broader **digital transformation** of regulatory affairs is also shaping viewer needs. One major trend is integration with regulatory information management (RIM) and content management systems. As noted above, platforms like Veeva Vault now embed viewers into a larger ecosystem that includes registration tracking and submission record-keeping. In this model, the viewer is not a stand-alone utility but part of a "single source of truth" architecture. Viewers in such systems may eventually interface with data from other functions (e.g. linking clinical study data back to an eCTD module).

Another major trend is **automation and artificial intelligence**. Regulatory authorities and industry are experimenting with AI-driven tools for submission preparation (often called "pre-flight" checks). While AI is still maturing in this space, some software can now automatically validate certain regulatory rules or flag inconsistencies. As regulators note, the potential is large but demands careful controls: *"Artificial Intelligence enhances pharmaceutical processes but requires precise regulations to ensure rigorous evaluation"* (www.sciencedirect.com). In the context of eCTD viewers, AI could one day enable semantic search across all submissions, automated anomaly detection in dossiers, or predictive analytics on submission status. For example, a future viewer might highlight unusual document patterns or compare a new submission's structure to historical archives to catch omissions. Journals emphasize that as data standards improve, such AI functions will become a cornerstone of digital regulatory strategy (www.sciencedirect.com) (www.sciencedirect.com).

Global harmonization efforts also continue. The underlying message is that eCTD format itself may eventually evolve into an even more modular standard (RPS/Regulated Product Submission). Viewers will then need to display not just PDFs but potentially XML data fields (e.g. structured product labeling, serialized quality data). Vendors are already envisioning viewer extensions (like annotation of structured content or integration with eCTD 4.0 vocabularies) (esubmission.ema.europa.eu). One example: the EMA's recent updates include new M1 validation criteria and codified vocabularies for eCTD 3.2.2 (esubmission.ema.europa.eu). As such, advanced viewers may start embedding these validation rules into their displays, highlighting missing or non-conformant information in real time.

Conclusions

Electronic Common Technical Document viewer software has become an indispensable part of modern regulatory submissions infrastructure. By providing a central, interactive view of complex eCTD dossiers, these tools transform what was once a manual, error-prone process into an efficient, auditable workflow

(boydconsultants.com) (boydconsultants.com). Industry experts unanimously agree that the gains in review speed and accuracy are substantial; Boyd Consultants even characterizes viewer integration as delivering “value from the initial to the final review” (boydconsultants.com).

This report surveyed the historical context and current state of eCTD viewers, citing regulatory documentation, technical analyses, and vendor insights. We detailed core features – such as multi-sequence navigation, full-text search, status labeling, and hyperlink QC – that address the intrinsic challenges of electronic submissions (esubmission.ema.europa.eu) (boydconsultants.com). Multiple products, both free and commercial, now implement these features at scale (see Table 1). Case examples show that viewers not only streamline internal QC but also enable advanced regulatory strategies like cross-dossier analytics (www.celegence.com) (www.celegence.com).

Looking ahead, several trends will shape eCTD viewers. Adoption of **eCTD v4.0/RPS** by regulators will require viewer platforms to handle new data models (www.fda.gov) (globalforum.diaglobal.org). Cloud-based, cross-functional document archives will make viewers part of a broader enterprise content infrastructure. Meanwhile, emerging tools like AI and semantic search offer the promise of “mindful” viewing – automatically flagging risks and connecting submission content to wider organizational knowledge.

Overall, properly deployed eCTD viewers are central to regulatory efficiency. As one review notes, digital solutions have “transformed pharmaceutical regulatory processes” – and eCTD viewers are a prime example of that transformation in action (www.sciencedirect.com). They embody a move from isolated submission assembly toward integrated, transparent regulatory intelligence. To fully capture their benefits, companies must pair the right software with validated workflows and skilled users. With agencies pointing toward more data-rich formats and global harmonization, the role of viewing tools will only grow. Future work should continue to evaluate outcomes (approval timelines, error rates) and refine best practices for viewer adoption in the pharmaceutical and biotech industries.

Table 2. eCTD and Related Regulatory Milestones. *Key events in the evolution of electronic regulatory submissions, including adoption of eCTD standards by ICH and regulatory agencies (sources).*

Date	Event	Source
2003	eCTD reached ICH Step 4 (ICH)	ICH M2/ELECTRONIC CTD Guideline
December 2015	ICH Step 4 endorsement of eCTD v4.0 (RPS-based)	ICH eCTD 4.0 Guidelines
May 5, 2017	FDA eCTD requirement begins for NDA, ANDA, and BLA submissions (FDA)	FDA eCTD submission standards
May 5, 2018	FDA eCTD requirement begins for commercial IND and master-file submissions (FDA)	FDA eCTD submission standards
Sep 16, 2024	FDA (CDER/CBER) supports eCTD v4.0 for new NDA, BLA, ANDA, IND and master-file applications (www.fda.gov)	FDA Announcement (2024)
Dec 1, 2025	EMA mandates updated EU Module 1 spec v3.1.1 for eCTD submissions (esubmission.ema.europa.eu)	EMA eSubmission Notice (2025)

Date	Event	Source
Dec 22, 2025	EMA allows optional eCTD v4.0 submissions (new CAP MAAs) (esubmission.ema.europa.eu)	EMA eSubmission Notice (2025)
April 2026	PMDA accepts eCTD v3 submissions only for approval applications made through March 31, 2026 (PMDA)	PMDA
Date not announced	FDA says it will provide advance notice before accepting only eCTD v4.0 (FDA)	FDA

Sources: ICH and agency guidances, press releases, and expert analyses (globalforum.diaglobal.org) (www.fda.gov) (esubmission.ema.europa.eu) (globalforum.diaglobal.org).

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://globalforum.diaglobal.org/issue/july-2024/how-did-we-get-here-a-history-of-ectd-and-prospects-for-ectd-4-0/>
2. <https://esubmission.ema.europa.eu/ectd/>
3. <https://boydconsultants.com/how-to-accelerate-regulatory-reviews-with-an-ectd-viewer/>
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5. https://admin.ich.org/sites/default/files/inline-files/eCTDv4_0_SupportDocumentation_v1_3.pdf
6. <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>
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16. <https://www.pmda.go.jp/files/000278140.pdf>
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18. <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/ectd-submission-standards-ectd-v40-and-regional-m1>
19. <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/ectd-submission-standards-ectd-v322-and-regional-m1>

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