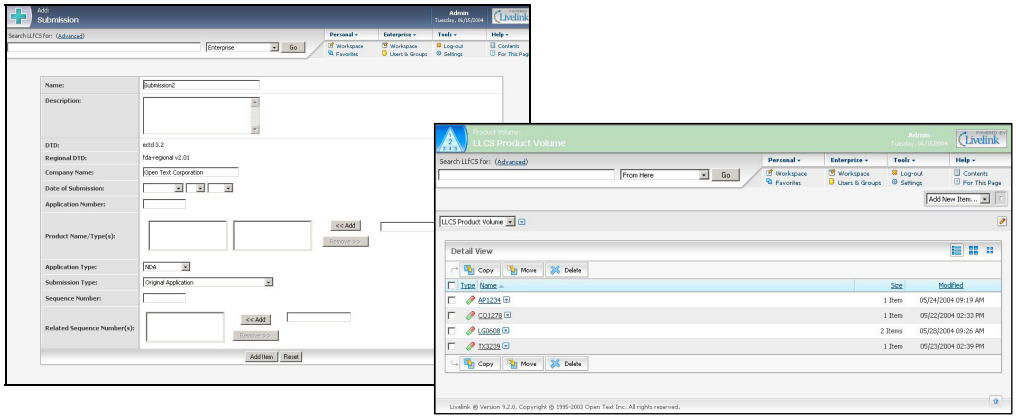
# Livelink ECM – Collaborative Submissions

Livelink ECM – Collaborative Submissions is a comprehensive, collaborative environment for the authoring, review, approval, assembly, export, and long-term management of all regulatory documents and submissions. Combining a full document management feature set, rich metadata support, huge scalability, and a wide range of secure, collaborative business-process tools, Collaborative Submissions is the premier integrated submissions environment solution.

## The need for collaborative submissions processes

As drug, biological, and medical device submissions move to electronic formats in key markets, submission management will move from batch to rolling processes. This new paradigm requires a single, unified environment that supports the lifecycle of every submission component, tracking status, and associated permissions, as well as information about each version of every resulting submission and amendment. At the same time, an increasing number of people from a wider range of departments are involved in the authoring, review, revision, and approval of multiple documents, forms, and data files that ultimately become part of submissions. Coordinating the work of individuals and teams is critical, regardless of the geographic location or time zone in which they work. Collaborative Submissions provides a comprehensive collaborative toolset that streamlines business processes and reduces delays while enabling compliance.




## A complete dossier management system

Until now, a regulatory submission management solution has required two independent systems: a document management system to manage the component documents, and a publishing system to assemble, organize, style, and distribute submissions. Coordinating these disconnected systems from different vendors has always been a challenge, and this challenge will become more severe as rolling submissions require a much more frequent exchange of information between these disparate systems. For more than 10 years, Livelink ECM has been widely deployed as a collaborative document management system by thousands of organizations, including more than 100 in the pharmaceutical and life sciences sector, who have benefited from its easily configurable compliance with FDA 21 CFR Part 11 regulations. With the addition of the new submission management features, Collaborative Submissions is the first comprehensive environment that can manage the lifecycle of all of these document components, as well as the lifecycle of all submissions and applications, in a single, consolidated solution!

With their complexity and specialized interfaces, traditional submission publishing systems are typically only used for large submissions such as late-stage Investigational New Drugs (INDs), New Drug Applications (NDAs), and Biologic License Applications (BLAs) in the United States. But now with Collaborative Submissions extending the powerful document management, electronic forms management, imaging, records management, and archiving features of Livelink ECM, you can manage every type of submission at every stage in the lifecycle of every drug, biologic, or device.

Collaborative Submissions is not limited to electronic submissions. While you can benefit from electronic processes to manage submissions, you can easily convert electronic submissions to paper equivalents, volumizing, inserting slipsheets and cover pages, converting hyperlinks to footnotes and creating the required tables of contents (ToCs).

Getting each submission 'right' is critical to getting your product to market as soon as possible. Collaborative Submissions provides role-based access controls—you can tightly control what each user can see and do at each lifecycle stage, in each module and section of every submission—even those intended for different regulatory regions. Collaborative Submissions includes powerful tools to create *Previews* of submissions as part of your Quality Assurance (QA) process, exporting content to view it in exactly the form that will be received by reviewers, and when you are ready to submit, you can freeze the completed submission. Supplemental submissions and amendments are easy to assemble in series and attach to each initial submission.

Collaborative Submissions supports the latest electronic Common Technical Document (eCTD) format by directly interpreting the current eCTD Document Type Definition (DTD) from the International Conference on

**Livelink ECM – Collaborative Submissions lets you manage all submissions by product, with dynamic creation of the submission hierarchy according to overall submission specifications (such as the eCTD DTD) and regional regulatory agency requirements.**

Harmonization of Technical Requirement for Registration of Pharmaceuticals for Human Use (ICH), as well as the individual regional and study-tagging DTDs. Intelligent controls determine which additional submission components can be added to the base “tree and leaf” structure, according to the appropriate DTDs for submissions intended for specific regulatory regions. Customized DTDs can be used to enable Collaborative Submissions to create submissions of any type.

Collaborative Submissions includes full hyperlink management capabilities, enabling you to effectively manage even the most complex relationships between document content. You can create links between specific versions of a source and a target document, and all of the link information is managed in a designated database. Each new version added (or deleted) to a document is tracked, and you can quickly view comprehensive reports to determine the status of links. When you need to export a submission from Collaborative Submissions, either to preview or to submit, all of the links are created in the PDF rendition of the document.

## Features

- **Combines Document Management and Submission Publishing:** Collaborative Submissions is a unified solution that brings together document, forms, and records management with submission publishing capabilities in a single, environment. Collaborative Submissions supports a wide range of business processes from *ad hoc* to tightly sequenced workflows, enabling full support for the lifecycle of completed submissions as well as all of their constituent documents and components.
- **Manages All Submissions Types:** All regulatory submissions, of all sizes, formats, and types can be managed in a unified environment at every stage in the development and approval process for each drug or device.
- **Applies Unified Taxonomy:** You can organize supporting documents according to predefined taxonomies, such as the eCTD DTD, but extend these to match your internal needs and processes.
- **Manages Hyperlinks:** All links between submission components are managed dynamically in Collaborative Submissions. Reports track the status of links, including version changes to the source and target documents.
- **Creates Previews:** At anytime during the assembly process, you can create a Preview of a work-in-progress, to see what a completed submission will look like. You can even export this Preview snapshot to a file system.
- **Freezes Submissions:** When the assembly and approval phases are finished, you can *freeze* the entire submission, locking it against further changes, then export the complete submission to the document repository, generating all of the required XML.
- **Automates Business Processes:** Automate business processes using workflow, electronic forms, and electronic signature capabilities—improving productivity and ensuring accuracy and auditability. Design electronic forms and workflows with easy-to-use, graphical design tools. Convert paper-based forms to electronic format and use them to initiate business processes.
- **Complies with the FDA’s 21 CFR Part 11:** Collaborative Submissions supports both electronic and digital signatures as required under the FDA’s 21 CFR Part 11 regulations and guidelines for electronic submissions.
- **Provides Role-Based Access Controls:** Tightly regulate access rights and permissions at any level in a submission according to creation, assembly, approval, and publishing roles.
- **Manages Submission Components:** Manage the full lifecycle of component documents with services such as check-in/check-out, version history, event auditing, signing, and access control using permissions, alternate renditions, and compound documents.
- **Integrates with the Desktop:** Work with items in the document repository via menus and drag-and-drop directly from the Windows desktop in online or offline mode, using Microsoft Office, Adobe Acrobat, Windows Explorer, and WebDAV-compliant applications.

## Minimize risk and enhance corporate accountability

Whether configured as your corporate submission dossier system, or your submission management system, you can be confident that you are managing your submissions with a proven platform from Open Text, the leading global Enterprise Content Management (ECM) vendor. Collaborative Submissions minimizes exposure to the risks associated with audit, regulatory, and litigation issues by carefully managing all access controls, role rights, and system events in an auditable manner. Collaborative Submissions meets government regulatory and corporate requirements for records retention, electronic signatures, paper elimination, and more.

With its rapid deployment capabilities, support for validation, consolidated framework, and reduced integration costs, you can be sure that an investment in Collaborative Submissions is an ongoing investment in a competitive advantage that will deliver lasting business benefits.

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