PRODUCT INFORMATION

eDOCSmanager™ Powered by CARA™

Manage documents and data throughout the entire submission lifecycle in a secure document management system.

Product development in life sciences demands accuracy, consistency, and efficiency across highly regulated processes. eDOCSmanager powered by CARA provides a secure document management system (DMS) to manage, organize and re-use documents across their lifecycle – from creation and review to approval and publication.

Comprehensive Document Lifecycle Management

eDOCSmanager Regulatory manages every stage of the document lifecycle, from initial planning through to approved, compliant content ready for submission. During planning, it helps you define which documents are required for each submission by module, section, or region, assign owners and due dates, and track progress. For the document creation and review, teams work with standardized templates aligned with eCTD and company-specific structures, while configurable workflows coordinate reviews and approvals. In-place review, redlining, and comment resolution keep communication streamlined and transparent.

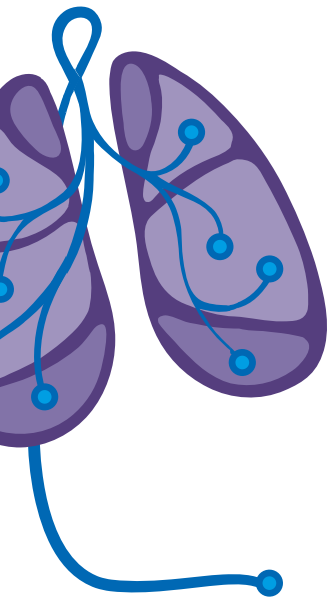
For approval and signing, users can run approvals and sign electronically via integrations with signature providers such as DocuSign and GoSign, with all compliance evidence and the full audit trail retained with the document. Once approved, documents are stored securely with complete version history, enabling traceable reuse across submissions and regions.

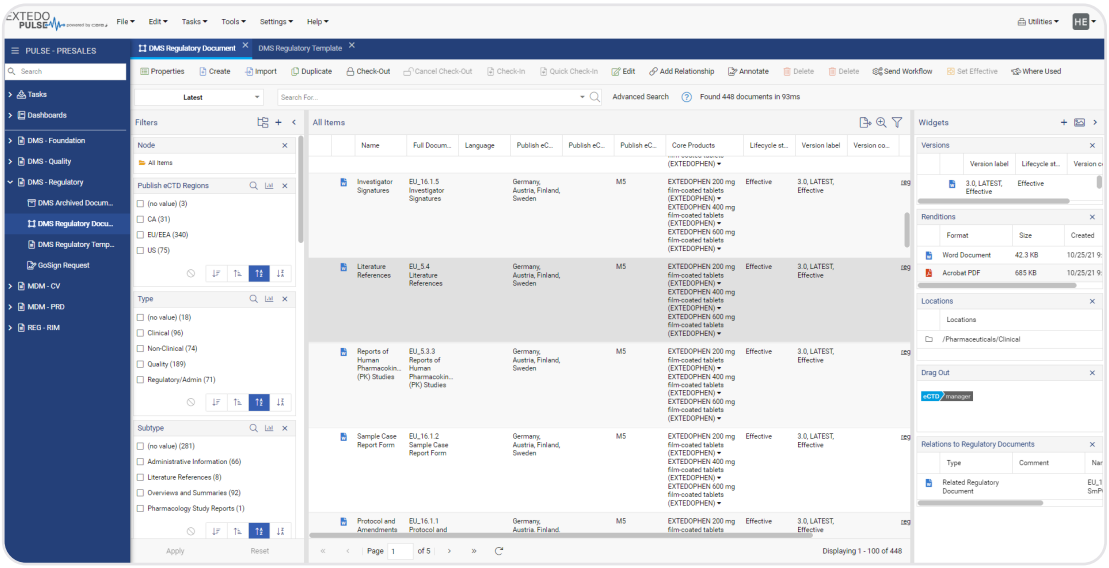
Version Control and Content Reuse

Version control in eDOCSmanager Regulatory is built for real-world regulatory complexity. Each saved version is retained with complete history. When used with the Submission Management Hub, you also see where a document version is referenced supporting informed change planning and impact analysis.

Benefits

- Plan, organize, and refine documents in a detailed submission content plan for efficient document generation.
- Extend functionality with eCTDtemplates as an add-on to accelerate and reuse document assembly with ready-made submission templates.
- User-friendly fully validated solution that can be implemented within days and personalized to each individual's requirements
- Configure eDOCSmanager to suit your exact requirements and deploy faster for your organization
- Document classification based on the DIA Reference model.
- Easily navigate and search content using advanced search functions whenever needed.
- Extensive dashboard functionalities to filter regulatory documents by status, country, module or registered product.
- AI-powered assistance for data and document interaction.
- Flexible reminder notifications keep upcoming deadlines in sight, while update notifications alert you to changes in data items.





Managing regulatory data and documents with the Regulatory module

Submission Planning, Publishing and Archiving

eDOCSmanager Regulatory enables you to plan, track, and structure submission content with complete visibility, from the first draft through to the approved dossier. You can define submission structures by module, section, and region, assign timelines and owners, and monitor readiness in real time. Teams can also start assembling submissions earlier by moving draft documents or placeholders from content plans into the submission structure. This parallel workflow accelerates compilation while maintaining automatic metadata and relationship updates.

Submissions are then securely archived for long-term, compliant retention, and archived dossiers maintain full traceability to their source components, creating a single source of truth for audits and future reuse. Comprehensive operational and compliance reporting provides transparency into status, timelines, reuse, and activity, ensuring end-to-end traceability from document creation to submission output.

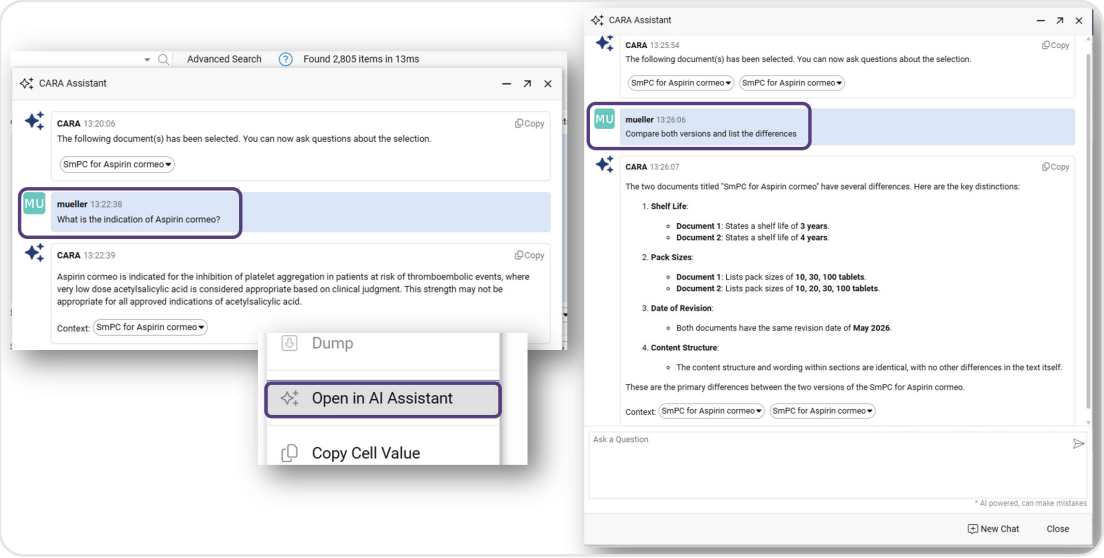
Document Publishing with Confidence

Reusing established structures makes it easy to assemble dossiers for new regions and authorities. Teams can reuse components or entire sections, track approval status, see where components are referenced throughout the process, and update once to roll out changes efficiently across regions – supporting both global and derived regional dossiers. Features include

- the ability to view, edit, and work on regulatory documents directly from the repository
- duplicate documents with metadata cloning to create compliant variants quickly
- notify defined users on key actions; push documents and associated data seamlessly to your submission or registration tracking solution
- and render documents to PDF for publication or archival.

Document Tracking and Reporting

Stay in control of your regulatory operations with real-time dashboards and metadata-driven tracking. Filter documents by country, status, product, or CTD module to quickly find what you need. Visual dashboards provide readiness indicators and cycle-time analytics, overdue task tracking, and clear graphical visualizations such as pie charts, columns and trend lines. These insights help regulatory specialists act early and maintain compliance timelines.



AI-powered Analysis of Data and Documents

A Solution created for Collaboration

Managing regulatory documents is challenging, especially with teams working from different offices or with external suppliers. Duplicate content and a lack of visibility into regulatory activities increase the risk of non-compliance and cause confusion. eDOCSmanager powered by CARA centralizes work in one application with configurable workflows and single-document security, enabling safe collaboration with third parties and platforms like SharePoint.

AI-Powered Assistance for Data and Document Interaction

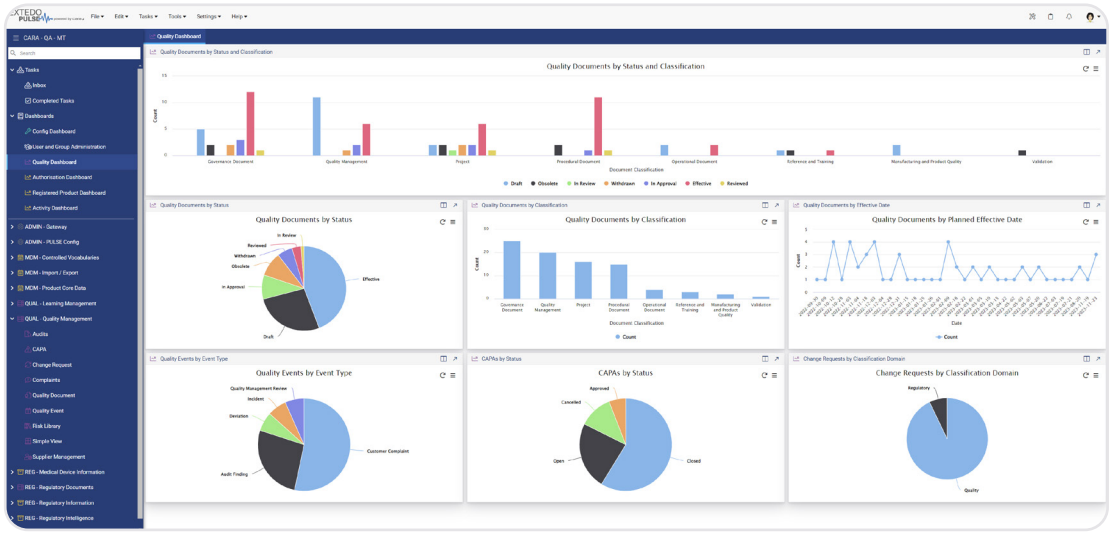
The AI feature in the EXTEDOpulse Document Management Hub supports your regulatory teams in leveraging their data to facilitate searches, collaboration and the creation of new information. The EXTEDOpulse AIxpt offers fully auditable methods to maximize the use of information in your repositories.

Leverage AI-powered assistance to interact seamlessly with your regulatory data and documents. Users can ask targeted questions, generate concise summaries, or compare multiple document versions to quickly identify key differences and insights. This intelligent support reduces manual effort, accelerates decision-making, and enhances the accuracy of regulatory workflows—turning complex document landscapes into accessible, actionable knowledge.

Automated translations into different languages as well as intelligent comparison tables, make data verification easier and more efficient than ever.

Unified Master Data Management

Built specifically for life sciences, eDOCSmanager Regulatory combines an intuitive user experience with governance, compliance, and auditability at its core. Using a DMS that is an integral part of the EXTEDOpulse solution suite, you benefit from the inbuilt Master Data Management (MDM) and controlled vocabularies without extra licensing cost to ensure accuracy and consistency across your organization. This improves metadata quality and document tagging, enhances automation and reporting capabilities, and increases consistency across teams, systems and business hubs. By applying consistent, governed terminology across teams, eDOCSmanager Regulatory ensures your regulatory documents have a single source of truth.



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Unified Access & Integration

UseDOCSmanager to manage all regulatory content and connect seamlessly with other EXTEDOpulse and third-party system solutions such as Adobe Sign, DocuSign, Sharepoint or Google Docs. Available in the cloud or on-premises, eDOCSmanager Regulatory fits seamlessly into your existing IT infrastructure and strategy. Its parameter-based configuration allows incremental adjustments to business processes, reducing implementation and validation effort while meeting the demanding needs of regulatory operations.

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