Product Information

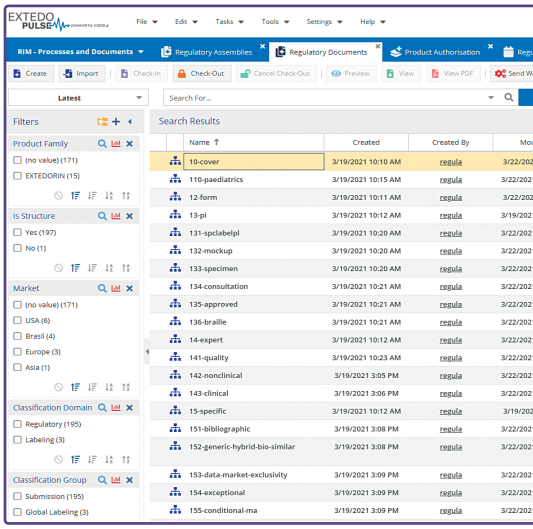
eDOCSmanager™ Powered by CARA™

A secure document management system for life sciences organizations

The development of highly complex products in life sciences can only be successful if accuracy, consistency, efficiency, and quality are guaranteed in all core business processes. These include managing clinical trials, tracking quality processes and organizing regulatory submissions.

Benefits

- **Meet corporate and regulatory standards:** gain a pre-configured solution for fast deployment matching industry requirements with eDOCSmanager for life sciences.
- **Support the full document lifecycle:** use eDOCSmanager to support your operations from creation to access, review, approval and publication.
- **Automate your work:** streamline previously manual processes using automated workflows to organize and assign work as needed down your production pipeline.
- **Easily navigate and search content:** use advanced search functions to access the information you need when you need it across your system.
- **Secure access wherever you are:** end-to-end data encryption and VPNs protect your data via PC or the mobile application.
- **Single destination management:** use a single user interface to manage content for multiple use cases such as document management, label management, structured content management or others.
- **Available in the cloud or on-premise:** eDOCSmanager is an adaptable and accessible solution.



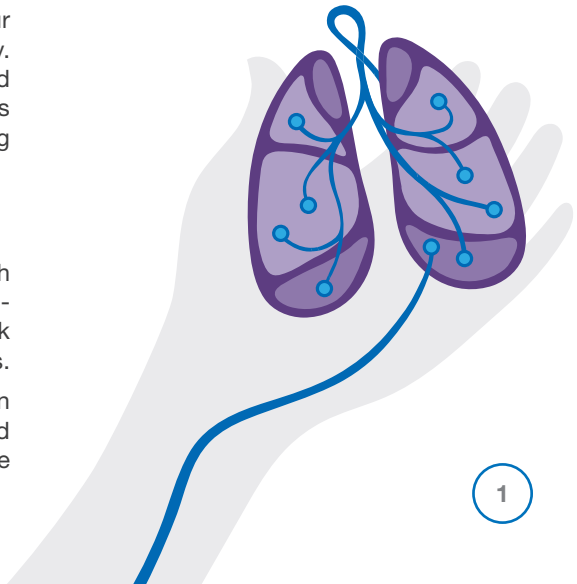
Managing regulatory data and documents with the Regulatory module

eDOCSmanager is the content management solution you need for your document management activities for clinical, quality, SOP, and regulatory. eDOCSmanager consists of different modules which work together based on your individual objectives. It is a highly configurable platform that allows easy and incremental adjustments to business processes while addressing the demanding needs of life sciences companies.

A platform created for collaboration

Managing documents is challenging and it becomes even more difficult with teams working from different office locations or with external suppliers. Duplicated content and a lack of visibility into business activities increase the risk of non-compliance and causes confusion in the workplace and your projects.

eDOCSmanager is part of EXTEDO's document management hub on the EXTEDOpulse platform. This platform is created to serve users and their specific needs and challenges within the life sciences industry. The



EXTEDOpulse platform is offered with pre-packaged applications and modules and is highly configurable to match organizational needs and regulations while enabling collaboration through a common interface shared between all business processes. Now, you can access all of your data and documents through one platform instead of having to visit separate repositories and locations to find what your team needs. The eDOCSmanager application enables data and content access between various solutions on the EXTEDOpulse platform, promoting seamless collaboration, discovery, and traceability across your organization.

An overview of eDOCSmanager

Supporting documentation in different areas and maintaining records is a daunting challenge for the life sciences industry. With the daily use of different solutions and the regulations that go with each, the management of documentation can quickly become chaotic. eDOCSmanager facilitates the influx of documents critical to regulations so that you can manage, organize and use them effectively.

- Manage or create all your documents within one location.
- Collaborate and review documents with your team online.
- Use built-in electronic signatures to approve documents or use integrations with Adobe Sign and DocuSign.
- Automatically populate templates with placeholder documents as required.

Streamline your operations

Life science project development is a demanding process requiring the manual input and output of stakeholders across your organization. With the speed of development applying pressure across your team, productivity suffers and corrective cycles are often needed. eDOCSmanager provides structure and drives each of your projects towards completion with powerful process automation and templates optimized for productivity.

- Streamline your design and production processes with automated workflows that boost productivity across your organization.
- Harness automation to simplify your operations.
- Use customizable templates to speed up document creation and delivery.
- Automatically build structures and templates based on your needs and regulatory directives.
- Collaborate with third parties and keep your documents safe with user-permissions and access-based viewing. Use tools like SharePoint or Google Docs safely and securely.

eDOCSmanager currently offers pre-packaged modules for the following use cases:

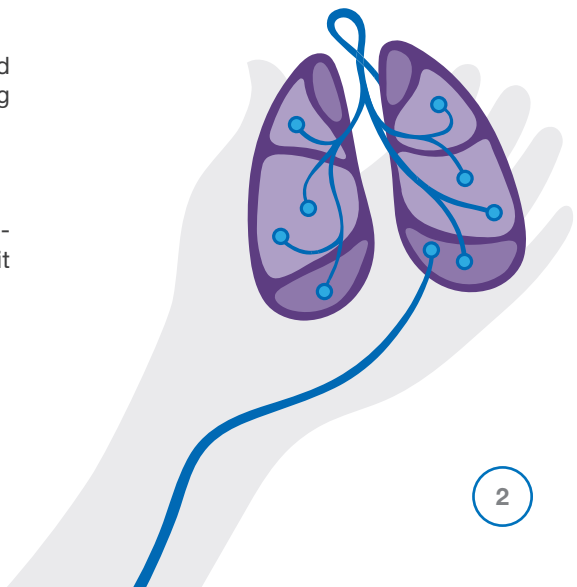
- Regulatory
- Quality
- SOP and Training Management
- Clinical (eTMF)

Further pre-packaged solutions such as options for labelling are planned but already available as custom implementations on the base of the existing EXTEDOpulse platform solution.

eDOCSmanager – The Regulatory Module

eDOCSmanager uses industry and authority best practices to achieve consistent, effective regulatory results. Considering the DIA Reference Model, it ensures that your submissions are effective, organized, and transparent.

- Document classification and metadata based on the DIA Reference Model.
- Ready-to-go submission structure templates.
- Build customized structures and assign content as needed.
- Drag & drop or add structures or individual documents to the Submission Management Hub.



- Automatically generate structures
- Store and access previous submissions in the integrated Submission Management Hub and use automatic traceability for the source components used.
- Review your past submissions across different markets and conditions.
- Planned future developments, such as the ability to publish or archive dossiers directly from the integrated Submission Management and to schedule content for automatic ingestion.

Accurate reports, more efficiency, better processes

With eDOCSmanager, you will be able to utilize yesterday's documents and use them for today's tasks. Easily find submission archive content published in Submission Management Hub thanks to the automatic traceability of the source components. Seamlessly interconnect your archives to RIM data, allowing easy reporting and viewing of related information at a later stage.

With the use of structures, re-using components or entire sections of submissions multiple times becomes easy. Use existing submission structures to assemble dossiers for different regions. Track the submission status and where individual components have been used. Use the easy update (inheritance) mechanism to multiple regions with less effort. Create Global Dossiers and assign derived regional dossiers to ensure maximum efficiency.

- Re-use existing dossiers and documents for greater productivity.
- Automatically trace and track source components of any document.
- Connect your submissions to your reports for faster, accurate reporting.
- Track the status of submission documents across your entire operation.

Master administration

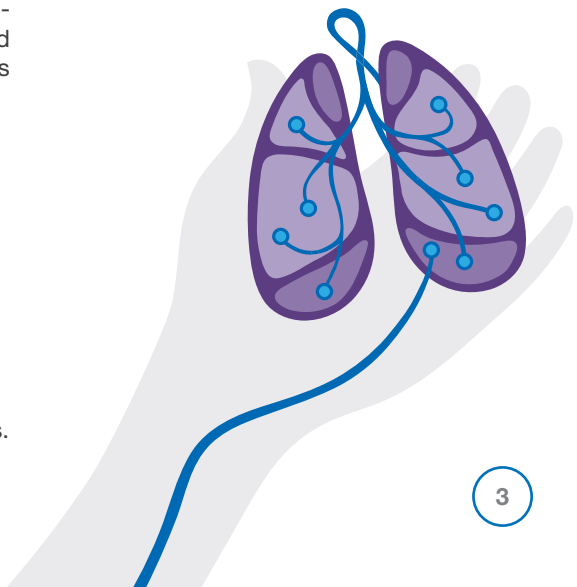
Manage administrative tasks more efficiently, simplifying your business processes while saving time and resources. eDOCSmanager allows documents to be added to a submission directly using drag-and-drop. With version control and permissions management, you can rest assured your organization's documents are securely accessed, updated and managed in a controlled manner.

- Create or import files, records and other information directly within eDOCSmanager.
- Transfer your documents into a variety of formats including ZIP Files or convert them to Word or PDF.
- Co-author and review documents with your team in real-time.
- Use drag-and-drop functionality to add documents to your submissions.

eDOCSmanager – The Quality Module

Gain access to a complete Quality DMS with extended functionality. eDOCSmanager has everything you expect from a Quality Management System (QMS) and more. It gives you the power to manage your quality control documents effortlessly with unprecedented convenience. The solution includes all standard document creation, review, approval, sign-off, and publishing features for your team to make your quality control processes efficient.

- Assign automatic workflows for review, approval, periodic review, and redundancy activities.
- Review quality event definitions for your entire organization.
- Use Risk Assessment tools to identify and counter threats before they happen.
- Streamline your quality reports with Root Cause Analysis tools.
- Take effective steps for quality Corrective Action and Preventative Action (CAPA) items.
- Send and utilize change requests as part of your quality control measures.
- Gain insights and direction with detailed Effectiveness Evaluations.



eDOCSmanager – The SOP and Training Management Module

eDOCSmanager supports you with your SOP documentation including the management of training records. The solution includes all standard document creation, review, approval, sign-off, and publishing features for your team to make your SOP creation efficient and easy. eDOCSmanager also offers Training Management for documentation as well as external training tracking and the ability to attach certificates.

- Assign automatic workflows for Review, Approval, Periodic Review for your SOP documents.
- Capture document training (e.g. SOP) within a simple, easy-to-use interface.
- Capture external training efforts and mark completion with certificate attachments.
- Track and report on training processes across your organization to gain control over the development of your team.

eDOCSmanager – The Clinical Module

Clinical regulations and management for Electronic Trial Master File (eTMF) documents is a daily, time-consuming activity for life science companies. Now, with eDOCSmanager, you can create inspection-ready electronic TMF documents and records on the fly.

eDOCSmanager uses the DIA Reference Model for eTMF documents to provide a structure for all metadata configurations. The solution utilizes a template-based approach for fully configurable document creation, eTMF structures and additional sites on demand. It streamlines the clinical regulation and management activities for life science organizations to boost productivity and eliminate human error.

- Reduce data duplication and errors.
- Use dashboards and reporting based on metadata to manage eTMF information.
- Create rapid TMF files with drag and drop functionality.
- Manage the entire eTMF lifecycle from start to finish from one location.
- Gain access to easy-to-use eTMF template structures.
- Collaborate with your team with simultaneous authoring with your team or third parties.

eDOCSmanager for Corporate – Designed for any department

eDOCSmanager can be used for any purpose – from life science projects to human resources, legal, marketing or digital asset management activities. Its capabilities for sign-off and approval, fast document review and automated functionalities make it well suited to serve your organization.

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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 850 maintained customers across 60 countries to deliver Effortless Compliance™.

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