eDOCS manager
powered by cara

EXTEDO
eRegulatory Affairs

Product Information

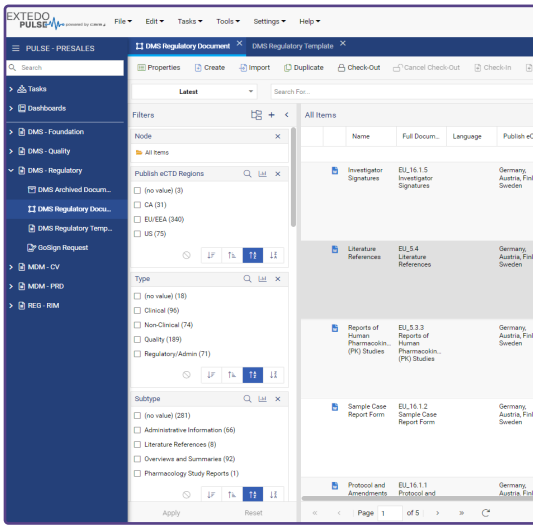
eDOCSmanager™ Powered by CARA™

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

- **Rapid deployment:** user-friendly fully validated solution that can be implemented within days and personalised to each individual's requirements.
- **Meet corporate and regulatory standards:** configure eDOCSmanager to suit your exact requirements and deploy for your organization faster.
- **Supports the full document lifecycle:** use eDOCSmanager to support your operations from creation to access, review, approval and publication.
- **Automate your work:** automated workflows organize and assign work as needed down your production pipeline to streamline previously manual processes.
- **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 from multiple systems and integrate with other EXTEDO solutions.

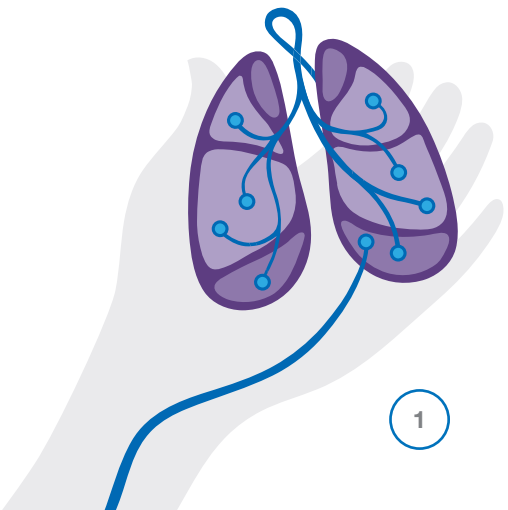


Managing regulatory data and documents with the Regulatory module

Available in the cloud or for on-premise use, eDOCSmanager Powered by CARA eliminates long project implementation planning, preparation, and validation processes, so you can be up and running within days. Parameter-based configuration allows easy and incremental adjustments to business processes to address the demanding needs of life sciences companies.

A platform created for collaboration

Managing regulatory documents is challenging and it becomes even more difficult 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 causes confusion in the workplace and your projects.



eDOCSmanager Powered by CARA is a platform that serves users and their specific needs and challenges within the life sciences industry. It 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 application instead of having to visit separate repositories and locations to find what your team needs. eDOCSmanager Powered by CARA enables data and content access between any solution on the platform, promoting seamless collaboration, discovery and traceability across your organization.

eDOCSmanager Powered by CARA can also empower easy collaboration with third parties. The dynamic per-document-per-workflow security means that access can be granted to the repository while only users within your organization can view documents. This extends to collaborative technology within your company such as SharePoint or Google Docs.

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

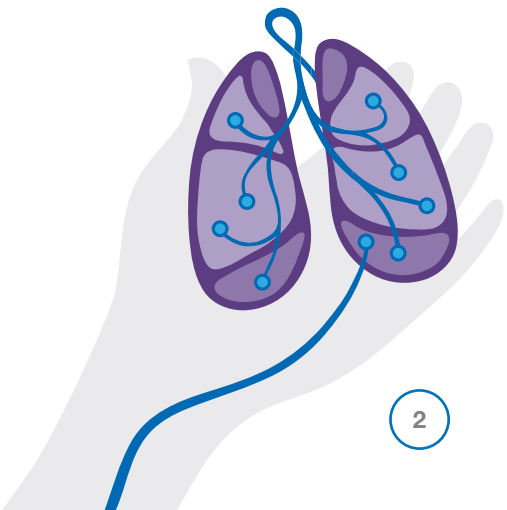
Life science project development is a demanding process requiring the manual input and output of stakeholders across your organization. With the speed of development applying pressure across your team, productivity suffers and corrective cycles are often needed. eDOCSmanager Powered by CARA provides 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 work – flows 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
- 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

Accurate reports, more efficiency, better processes

With eDOCSmanager Powered by CARA, you will be able to utilise yesterday's documents and use them for today's tasks. Easily archive submissions from eCTDmanager with automatic traceability to the source components used for later reference. The submission archive can even be seamlessly interconnected to the source submission documents and 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 archived components to assemble dossiers for different regions more quickly, while also allowing tracking of the submission status and where individual components have been used. This means easier updates to multiple regions with less effort. Now, you can create a Global Dossier and assign regional derived dossiers with archived content 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.
- Use the submission content planning functionality to transparently prepare and concept your regulatory documents.

Master administration

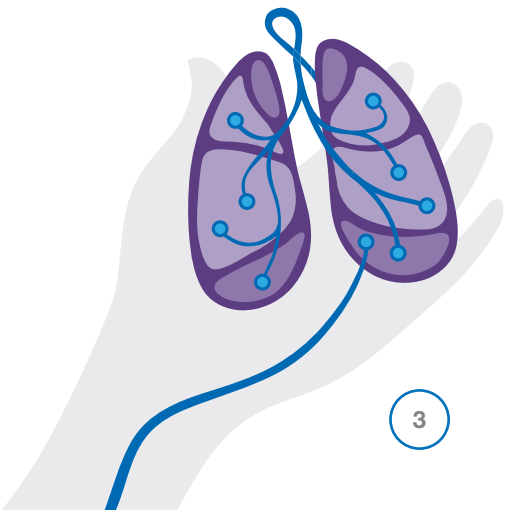
Manage administrative tasks more efficiently, simplifying your business processes while saving time and resources. eDOCSmanager Powered by CARA fully integrates with eCTDmanager allowing documents to be added to a submission directly using drag-and-drop. With version control and permissions management, 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. It gives you the power to manage your quality control documents effortlessly with unprecedented convenience and supports SOP documentation activities 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 quality control and SOP processes efficient.

- Assign automatic workflows for review, approval, periodic review, and redundancy activities or SOP and other documents.
- Capture training documents and activities within a simple, easy-to-use interface.
- Track and report on training across your organization.
- Use templates to quickly design training, SOP and quality control documents.
- Automate your quality control and training efforts with automated workflows.
- 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.
- Create (un)-controlled prints and view print dashboards.

eDOCSmanager – The Clinical Module

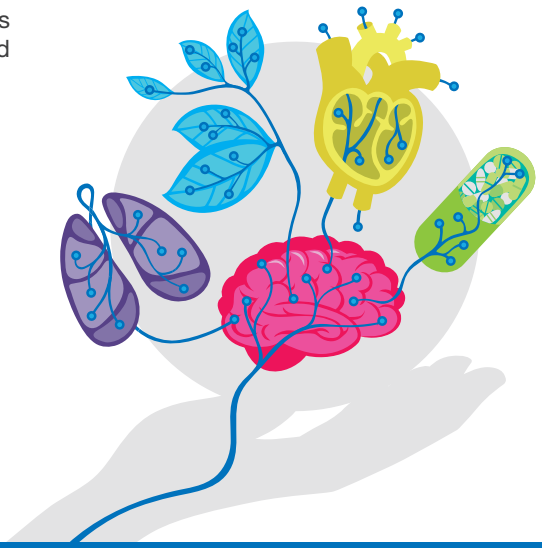
Clinical regulations and management for Electronic Trial Master File (eTMF) documents is a daily, time-consuming activity for life science companies. Now, with eDOCSmanager, you can create inspection-ready electronic TMF documents and records on the fly.

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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For further information contact your local EXTEDO representative:

EXTEDO Germany
+49 89 189454-0
info@extedo.com
www.extedo.com

EXTEDO US
+1 (855) 328 3500
info@extedo.com
www.extedo.com

EXTEDO China
request@china.extedo.cn
www.extedo.cn

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 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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