

Product Information

The Regulatory Module

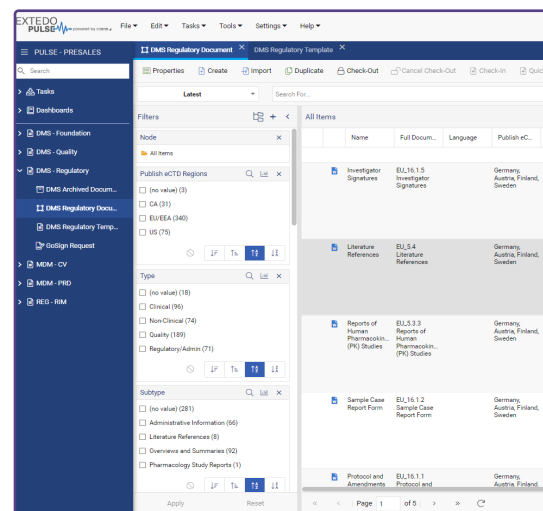
From EXTEDO eDOCSmanager™ powered by CARA™

Ensure consistent, effective regulatory results

Every product, region, and authority has various regulations that must be adhered to if a life sciences organization wants to sell a product to a particular market. Keeping track of changing conditions, product specifications, and regional requirements is a significant drain on resources in even the largest pharmaceutical companies. However, the Regulatory Module from eDOCSmanager resolves this challenge. By offering a turnkey solution that considers the DIA Reference Model, eDOCSmanager ensures your submissions are practical, organized, and transparent.

Benefits

- › **Ready-to-go submission templates** – the Regulatory Module offers submission structure templates for easy and fast submissions.
- › **Automatic source component traceability** – store and access previous submission documents when needed for swift submission applications.
- › **Create rapid submissions** – use drag and drop functionality and automated workflows to create applications quickly.
- › **Document classification and metadata based on the DIA Reference Model** – for ensured compliance, efficiency, and approval.
- › **Build customized structures and assign content as needed** – take complete control over your submission process and adjust past applications as required.
- › **Prepare and concept your documents transparently and detailed** – use the submission content plan to efficiently generate your regulatory documents.
- › **Extensive dashboard functionalities** – use the dashboard to filter your regulatory documents by status, country, module or registered product.

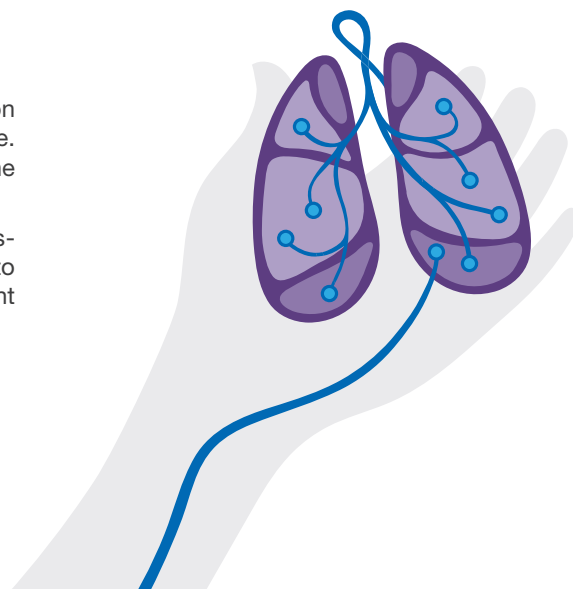


Structure of regulatory documents and filter options

Keep track of your documents effortlessly

Create an intuitive and reliable dashboard that unveils relevant information about your regulatory documents throughout the entire document lifecycle. Based on metadata, you can filter all your regulatory documents within the DMS e.g. by country, status, registered product or even module.

The dashboard helps you to obtain relevant performance indicators in a user-friendly surface and graphical visualization. From colourful pie charts to informative columns and lines, the dashboard provides you with convenient access to all the information you need.



More efficiency for administrative and archiving tasks

The Regulatory module reduces the time and complexity involved before submission, providing a consolidated and authoritative source for regulatory submission content. With the Regulatory module, you can manage administrative and archiving tasks more efficiently, streamlining your business processes while saving time and resources.

Furthermore, it fully integrates with the rest of the EXTEDOpulse platform, allowing documents to be added to a submission directly using drag-and-drop functionality. Easily find submission archive content published in the 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.

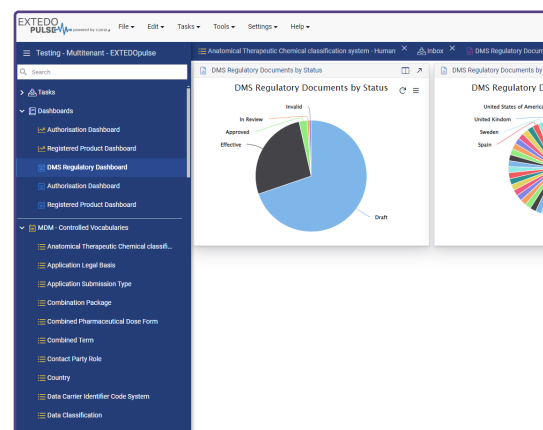
Get flexible with publishing and attachments

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 and authorities for faster review and submission. Track submission approval status and where individual components have been used throughout the entire process. Use the easy update mechanism to submit to multiple regions with less time and effort, and create global or derived regional dossiers to ensure maximum efficiency.

- Easily convert forms and attachments to PDF
- View, edit, and work on attachments directly from the repository
- Import or attach documents directly onto forms
- Clone metadata from forms to attachments

With the Regulatory Module from eDOCSmanager, you can take full control of the documents and attachments for your submissions or registration publications. Import or attach documents directly onto your forms, clone metadata from them to your attachments and create automatic relationships between them upon saving. You can also view, edit and work on attachments from the form directly in the repository for convenience or extract attachments and metadata directly from documents and emails.

The Regulatory Module enables you to render your forms and attachments to a standard PDF format for publication or archival. From there, you can push data to submission or registration tracking systems and notify subscribed or defined users of the action automatically.



Example of eDOCSmanager Regulatory Dashboard



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

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