

Product Information

# The Quality Module

From EXTEDO eDOCSmanager™ powered by CARA™

## A complete Quality DMS with extended functionality

The maintenance of Quality Management Systems is complex yet essential to compliance. Life science organizations have an obligation to provide quality assurance at every stage of development, ensuring that they stay compliant. However, effective quality control relies upon the reliability and access to essential data, usually located in various silos within an organization. eDOCmanager's Quality Module helps life science companies identify and fulfil their quality tasks and obligations faster and more consistently.

### Benefits

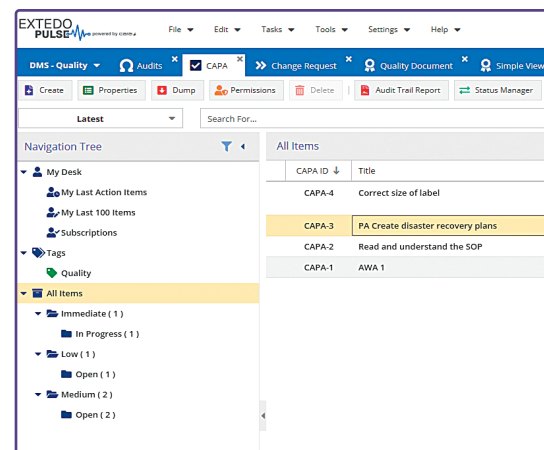
- **Empower quality with automation** – use automatic workflows for review, approval, periodic review, and redundancy activities.
- **Gain quality insights and direction** – provide your team with detailed Effectiveness Evaluations to consistently improve quality throughout your organization.
- **Send and utilize automated change requests** – incorporate effective quality preventative action as an automatic part of your control measures.
- **Go beyond QMS Management** – by creating and managing quality events, CAPA, and reference models.

The Quality Module has everything you expect from a Quality DMS as well as supporting your quality processes. 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 fast, efficient and reliable.

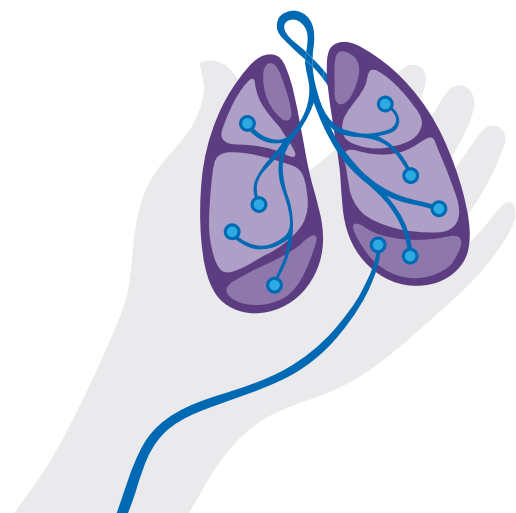
### Advanced Quality Automation

- Create automated Quality Events for your workflows
- Generate reports, suggestions, and directives
- Link each Quality Event to associated content
- Share Quality Events with third parties for efficient auditing

The Quality Module within eDOCSmanager enables you to incorporate quality into your natural workflow. Easily create internal or external Quality Events for regular quality assurance checks, audits, complaint resolution, and more. You can even create and manage CAPA items for Quality Events, including sharing with external auditors to allow them to update CAPA info directly.



Overview of CAPAs in the Quality module of the DMS



With the advanced quality automation provided by the Quality Module, you'll be able to generate events within a single document automatically. You can also create quality reports, suggestions, directives, and more based on the data. From there, you can link each event to associated content to ensure wider traceability and integrity.

## Quality tools for QA excellence

- › Take Risk-Based Assessments for proactive quality assurance
- › Conduct Root Cause Analysis reviews to accelerate investigations
- › Create and manage interactive Change Requests
- › Use Quality Event Effectiveness evaluations to constantly improve

The Quality Module from eDOCSmanager provides the tools and processes you need to make your QA outstanding on every front. Undertake and capture Risk-Based Assessments to identify potential threats to quality before they happen, or conduct a Root Cause Analysis to streamline investigations.

You can also create and manage Change Requests while linking them to documentation in order to ensure traceability and consistency. When you want to improve your quality assurance processes, you can take a Quality Event Effectiveness test to evaluate how effective your past quality solutions were to improve future QA activities.

## SOP and Training Management

- › Empower your training and SOP activities with automatic workflows.
- › Capture training efforts and mark completion with certificate attachments.
- › Track and report on training efforts across your organization.
- › Use customizable templates for documents like SOPs, work instructions, and more.

Creating SOPs has never been so easy. The quality module enables you to quickly create and manage controlled documents such as SOPs and Policies with pre-made or customized templates. Build entire training matrices and manage training on SOPs by logging training from external systems.

The quality module's SOP and Training Management tools facilitate the management of your SOP documentation, including training records. It offers standard document creation, review, approval, sign-off, and publishing features to ensure that your SOP creation and training activities are efficient and easy.



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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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