Agatha Quality (QMS)

Effectively managing clinical, compliance, and quality processes is a mission-critical task at life sciences companies. Quality improvements accelerate and improve processes, while quality failures can result in huge costs and disruptions. Choosing the right solution to track quality processes is a critical decision.

Agatha Quality is a complete, ready-to-use application for capturing deviations, documenting corrective and preventive actions (CAPAs), and managing change control processes. Every action is connected, from the initial issue to the new process, and every step is documented, reviewed, and approved.

More than document management, Agatha Quality is an end-to-end quality management system. Combining forms, documents, and workflows, Agatha Quality is a complete toolset for quality managers, pre-configured and validated but easy to adapt to specific process requirements

Benefits

An End-to-End Process
A complete, closed-loop process captured in an expanding form, from initial issue to preventative action.

A Complete QMS
Capture deviations, CAPAs, change controls, and audit activities to cover every part of the quality process.

Inspection-Ready
Create complete quality records with electronic signatures, recorded approvals, and audit trails, all ready for inspection.

Full Compliance
A validated system that is compliant with GxP requirements, EU Regulations, and FDA 21 CFR Part 11.
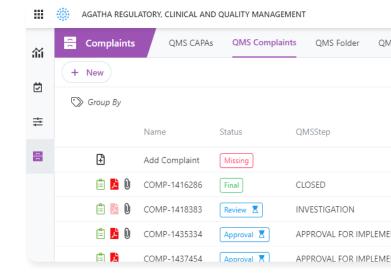

Key Capabilities

Complete Metrics and Reporting
Get all the reporting you need with built-in dashboards and reports, and export reports for external reporting requirements.

Cross Workspace Reporting
Create views and reports across workspaces and export results to Excel for dashboard reports.

Advanced Forms

Work with ready-to-use standard forms and processes, or adapt them to support your needs. Forms include rich text fields that allow the addition of images and formatted text. Use the form designer to update the look and feel of your forms.

A single multi-part form supports all steps in a process from deviation to change control. Reviews, approvals, and assignments for actions are also built-in.

Preview, Edit, and Annotate

Review and edit Word, Excel, and PowerPoint documents directly in the application (does not require an Office license). Annotate PDF, Office documents, and images with a simultaneous review of documents.

Complete Records

Get complete quality records with signatures and audit trails, ready for inspection. Agatha QMS is fully compliant with 21 CFR Part 11 and EU regulatory requirements.

Agatha's quality management application is also fully integrated with other Agatha applications making it easy to create references between them (eg. A CAPA can reference an SOP).

More Than an Online Record

QMS forms are built on a Word template. When the form is converted to PDF, it's more than a simple screenshot of the form on the page. Instead, you get a signed electronic record that is a nicely formatted PDF.

Also

Advanced Integration Toolkit

Use Agatha's Rest API to allow applications to upload or export items from Agatha (includes documentation & sample code).

Advanced Policy And Access Management

Manage policies, associated roles, and access controls easily.

Secure Cloud

Agatha Applications are cloud-based, hosted in Agatha's highly secure, highly reliant, high-performance, compliant, cloud environment.

Three Editions:

Standard, Extended, and Premium

Some features are only available in Extended or Premium editions.