

Agatha Quality

A complete, closed-loop system for managing CAPAs, Deviations, Audits, and Change Control activities.



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 solution 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.

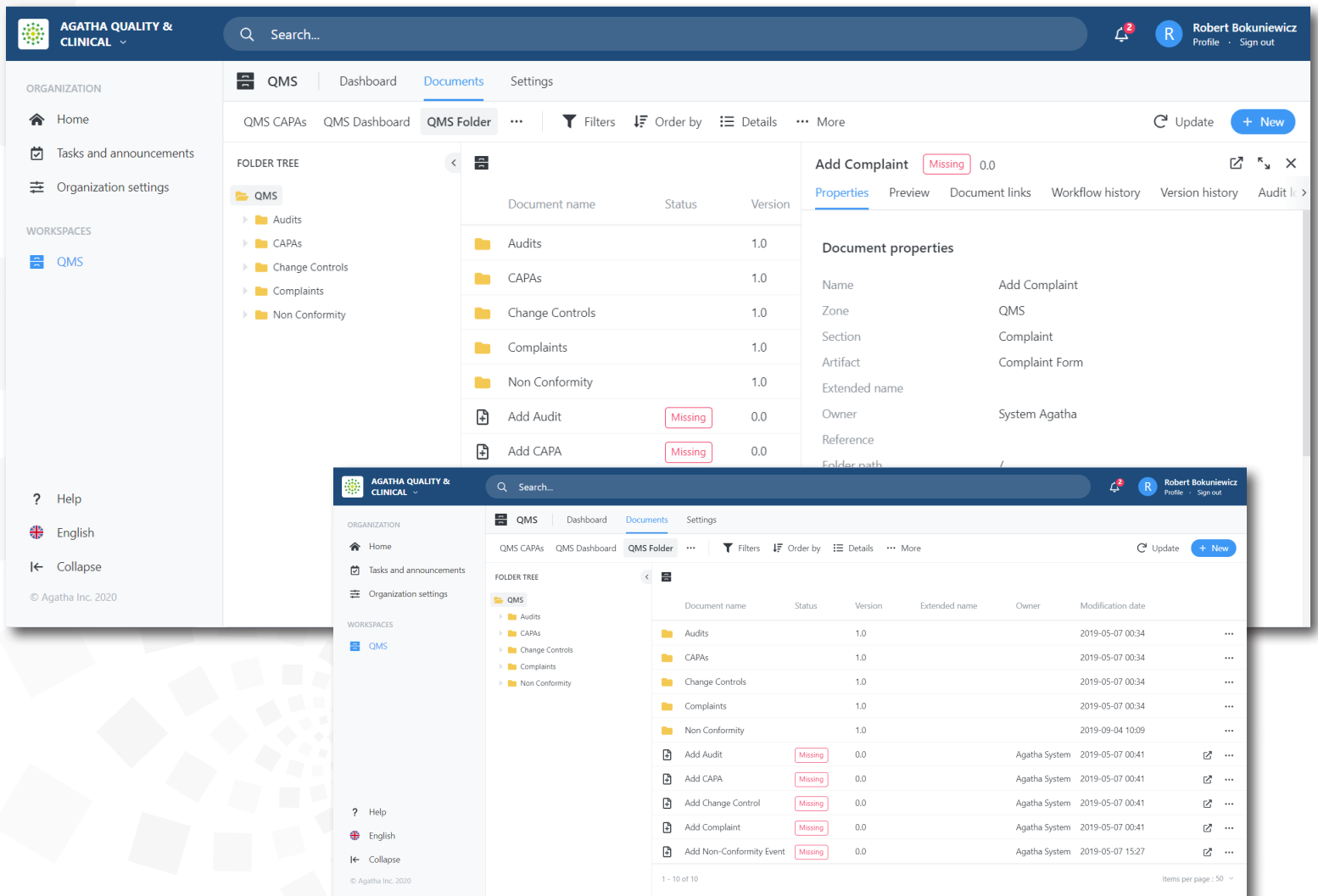
More than document management, Agatha Quality is an end-to-end quality management system. Combining forms, documents, and workflows, Agatha Quality is a complete toolset for quality managers, pre-configured and validated but easy to adapt to specific process requirements.

Key Capabilities

- Documents every step in the quality process, from the initial issue to the change process
- Creates complete quality records with signatures and audit trails, ready for inspection
- Provides ready-to-use standard forms and processes, but easy to adapt and tailor to specific procedures
- Includes metrics and dashboards to track progress and open issues
- Allows easy export of metadata, files and audit logs for external reporting

Benefits

- Ready-to-Use: A complete system, in the cloud, ready for you to start using within days
- Closed-Loop: Ensures a complete, connected process because every step in the quality process is captured in a single, dynamically expanding form
- Compliant: Pre-validated and compliant with GxP regulations and FDA 21 CFR Part 11
- Consistent: Enforces and documents review and approval steps with complete, configurable workflows
- Inspection-ready: Auditor and inspector views, exports, and metrics are always available



The screenshot displays the 'AGATHA QUALITY & CLINICAL' interface. The main view is the 'Documents' section, showing a 'QMS Folder' with a table of documents. The table has columns for Document name, Status, and Version. Documents include Audits, CAPAs, Change Controls, Complaints, Non Conformity, Add Audit, and Add CAPA. Some documents have a 'Missing' status.

| Document name | Status | Version |
|-----------------|---------|---------|
| Audits | | 1.0 |
| CAPAs | | 1.0 |
| Change Controls | | 1.0 |
| Complaints | | 1.0 |
| Non Conformity | | 1.0 |
| Add Audit | Missing | 0.0 |
| Add CAPA | Missing | 0.0 |

A secondary screenshot shows a detailed view of the 'Documents' section with a table including columns for Document name, Status, Version, Extended name, Owner, and Modification date. The table lists various documents, including 'Add Audit', 'Add CAPA', 'Add Change Control', 'Add Complaint', and 'Add Non-Conformity Event', all with a 'Missing' status.

| Document name | Status | Version | Extended name | Owner | Modification date |
|--------------------------|---------|---------|---------------|---------------|-------------------|
| Audits | | 1.0 | | | 2019-05-07 00:34 |
| CAPAs | | 1.0 | | | 2019-05-07 00:34 |
| Change Controls | | 1.0 | | | 2019-05-07 00:34 |
| Complaints | | 1.0 | | | 2019-05-07 00:34 |
| Non Conformity | | 1.0 | | | 2019-09-04 10:09 |
| Add Audit | Missing | 0.0 | | Agatha System | 2019-05-07 00:41 |
| Add CAPA | Missing | 0.0 | | Agatha System | 2019-05-07 00:41 |
| Add Change Control | Missing | 0.0 | | Agatha System | 2019-05-07 00:41 |
| Add Complaint | Missing | 0.0 | | Agatha System | 2019-05-07 00:41 |
| Add Non-Conformity Event | Missing | 0.0 | | Agatha System | 2019-05-07 15:27 |