



# Quality Management Solutions for collaboration and transparency

Quality Management Solutions (QMS) – part of the Aurea Compliance Manager (ACM) integrated suite of document management solutions for Life Sciences – is designed to remove non-compliance at every step. With pre-configured, cloudbased solutions for managing deviations, complaints, audit findings, change control, and CAPA, ACM QMS can save your organization valuable time and money.

Aurea QMS enables real-time tracking of any process or activity, as well as comprehensive search and reporting tools to maximize process transparency. With system intelligence to flag incomplete or overdue processes, as well as surface overall quality trends to appropriate personnel, QMS provides the visibility required to elevate quality management to a new level.

## Quality management without complexity

Aurea Compliance Manager Quality Management Solutions (QMS) provide a collaborative, cloud-based platform to ensure quality standards, and effectively connect people, processes, and tasks across global Life Sciences organizations.

Built on the Aurea Compliance Manager platform, QMS fully leverages our end-to-end enterprise content management capabilities. ACM delivers best-in-class and fully configurable content transformation, lifecycle management, intelligent creation, and compliance capabilities tailored to meet the unique needs of the Life Sciences industry.

The ACM Quality Management Solutions deliver capabilities to enable transparency and insight.

### QMS INCLUDES:

**CAPA:** Manage Corrective and Preventative Actions (CAPA) to drive continuous improvement in quality and processes.

**Deviations / Non-Conformance:** A fully configurable and automated solution to manage Deviations and out-of-specification (OOS) issues from occurrence to investigation and closure.

**Complaints:** Manage recording, routing, and resolution of all customer complaints faster and more easily.

**Change Control:** Control changes or modifications to products and processes together with the management of associated tasks.

**Audit Management:** Provide complete tracking of observations, findings, and recommendations.

### QMS BENEFITS:

- End-to-end solutions to manage deviations, complaints, audit findings, change control, and CAPA
- Generates a complete audit trail to track observations, findings, and
- Available in the Cloud for speed and flexibility

# Aurea Compliance Manager across the Life Sciences lifecycle

Quality Management Solutions are part of the comprehensive Aurea Compliance Manager (ACM) suite. Aurea Compliance Manager delivers integrated solutions designed to address the specific workflow, compliance, and regulatory needs in the Life Sciences.

**Electronic Trial Master File:** Simplify, streamline, and automate clinical trial processes and clinical document management with ACM Electronic Trial Master File (eTMF).

**Trial Exchange:** Create speed, efficiency, and ease for investigators and site staff to communicate, collaborate, and submit/review documents through this simple clinical portal for trial site staff.

**Regulatory Document Management:** Ensure compliance and manage regulatory and submission documents throughout their lifecycle.

**SOP & Training:** Deploy effective and compliant SOP & Training processes throughout the entire policy and procedure lifecycle.

The screenshot displays the 'Audit' form in the Aurea Compliance Manager. The form is divided into several sections: 'Audit Details' with fields for Audit Number, Site, Audit Title, Schedule Owner, Audit Owner, Audit Team, Main Auditee, and Additional Auditees; 'Audit Plan' with a checkbox for 'Use attachments'; 'Procedure Reference' with a table for 'Requirement (Checkpoint)', 'Findings', and 'Outcome'; 'Schedule Owner Review' with a 'Review Comments' field; and 'Final Approval' with a table for 'Username', 'Timestamp', and 'Approval Role'. At the bottom, there is an 'Attachments' section with a red error message: 'Error: The file you are attempting to upload already exists in the Attachments library.' and an 'Upload Attachment' button.

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Your subscription includes every Aurea product, plus onboarding to get started.

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