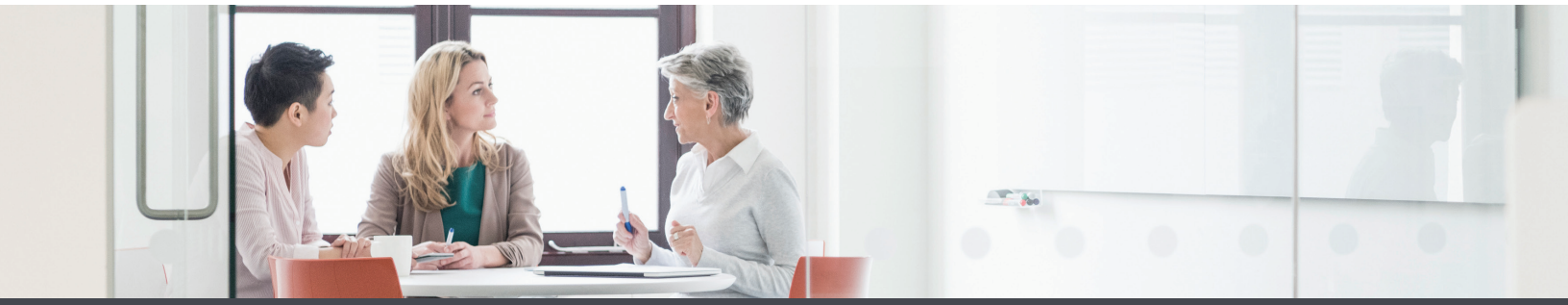

Advancing the science of compliance with Aurea Compliance Manager

Lead the way in compliance innovation

We know that your success depends on bringing life-enhancing therapies to market faster, safer, and more efficiently. We understand that every day, every document, and every dollar matters. To avoid costly delays or quality issues, you need to find every opportunity to increase speed and efficiency. Compliance is more than managing documents, it's a real science.

That's why we're changing Life Sciences with our industry leading compliance management platform, called Aurea Compliance Manager (ACM) Enterprise Edition. ACM Enterprise is designed to be open: to collaboration, to sharing data with other systems, to speeding trial start-up and regulatory filings, and to configuring workflows that drive your performance. It provides the tools you need to evaluate your practices at every level so you can identify potential gaps and redundancies, optimize your business processes, and analyze all of the metrics behind the science.

End-to-end compliance delivered, so you can focus on what's most important

At Aurea, our goal is your goal: to achieve the best results. ACM Enterprise improves performance by increasing efficiency, decreasing study start-up time, and providing real-time visibility into study milestones and events. We lower your audit risk by ensuring compliance and improving overall quality. And reduce your overall costs with a low cost of ownership and decreased regulatory filing costs due to increased productivity.

You'll have unlimited access to the entire suite of ACM Enterprise modules. Aurea Compliance Manager modules, including:

Electronic Trial Master File: Simplify, streamline, and automate clinical trial processes and clinical document management with ACM Enterprise Electronic Trial Master File (eTMF). Our collaborative platform redefines eTMF management to bring you real-time, audit-ready Electronic Trial Master Files.

Trial Exchange: Create speed, efficiency, and ease for investigators and site staff to communicate and collaborate through this simple clinical portal. With Trial Exchange, trial site staff can contribute documents to an eTMF work-stream, receive and complete tasks generated by the sponsor, easily view document status, and retrieve documents on-demand.

Regulatory Document Management: Manage regulatory and submission documents throughout their life cycle with a single, organized system. Our pre-configured solution for managing submission documentation delivers a compliant, user-friendly application that integrates seamlessly with publishing tools.

SOP & Training: Make rapid progress and ensure compliance with simple and effective SOP and employee training. The ACM Enterprise SOP & Training module provides the management and support you demand throughout the entire policy and procedure life cycle.

Quality Management: ACM Enterprise delivers a comprehensive set of quality management solutions to deliver transparency and insight across the enterprise, while minimizing demands on your already overtaxed business and IT users. Our integrated suite of Quality Management solutions include:

- **CAPA:** Manage corrective and preventative actions used for continuous improvement in quality and processes.
- **Deviations / Non-Conformance:** Automate and manage deviations and OOS from occurrence to investigation and closure.
- **Complaints:** Manage recording, routing, and resolution of all customer complaints.
- **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.

Aurea Compliance Manager

CLINICAL

Electronic Trial Master File

Trial Exchange (Portal)

DOCUMENT MANAGEMENT

SOP & Training

Quality DMS

REGULATORY

Regulatory Document Management

QUALITY MANAGEMENT

CAPA

Deviations/Non-Conformance

Complaints

Change Control

Audit Management

ENTERPRISE CONTENT AND COMPLIANCE PLATFORM

Content Transformation

- PDF Rendering
- Overlay
- Watermark
- Controlled Printing

Content Lifecycle Management

- Best-Practice Configurable Workflows
- Publishing
- Change Control
- Version Management

Intelligent Content Creation

- Smart Document Wizard
- Auto Naming
- Configurable Unique Document IDs

Content Compliance

- Electronic & Digital Signatures
- Automatic Inactivity Sign-out
- Compliant Audit Trail
- Support for 21 CFR Part II

COMPLIANCE MANAGER ENTERPRISE	STANDARD	ENTERPRISE
Regulatory Module	Available via subscription	☑
Clinical Module ▪ Clinical Documents Module (eTMF) ▪ Clinical Portal Module (TRX)	Available via subscription	☑
Quality Management Solutions ▪ SOP & Training ▪ Change Control ▪ Audit Management ▪ CAPA Module ▪ Deviations/Non-Conformance ▪ Complaints Module	Available via subscription	☑
Access to all future Enterprise releases		☑
Standard Support	☑	
Platinum Support		☑

Aurea Compliance Manager Enterprise

Aurea Compliance Manager Enterprise is built on our Enterprise content and compliance platform. The platform delivers best-in-class and fully configurable content transformation, lifecycle management, intelligent creation and compliance capabilities. Built on open standards, the platform also provides a robust API for secure collaboration and integration with third-party partners and Contract Research Organizations (CROs).

Activate your Unlimited benefits

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

Request More Information ›

Aurea