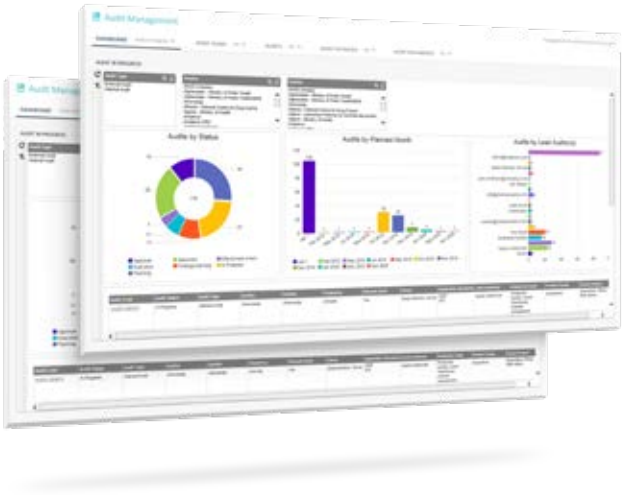
AMPLEXOR
AN ACOLAD COMPANY

LIFE SCIENCES SUITE

Improving Quality Management



End-to-end support for quality management

Efficiently addressing the quality management needs of life sciences companies dealing with industry-specific quality and compliance challenges in R&D, Clinical, Regulatory, Pharmacovigilance and, Manufacturing can be a challenge itself. Creating powerful business insights and transparency, as well as increasing workforce collaboration and efficiency is key to ongoing success and ensuring harmonized global compliance.

That's why Amplexor has developed **QualityExpert™**, a preconfigured quality management solution which provides a set of process-driven and user-friendly workspaces for Quality Event Management, Audit Management and CAPA Management, Change Management, Supplier Qualification, Quality Document Management and others.

QualityExpert™ is powered by the Compliance Foundation platform, which enables unified management of data, content and processes in a familiar user interface, combined with powerful automation engine that drives complex process automations, migrations and integrations. This scalable and flexible platform is suitable for both cloud and on-premises deployment models.

QualityExpert™ solution brings out-of-the box coverage of industry quality management and compliance requirements and common practices, easily adjustable to be tailored to customer specific requirements. Amplexor also offers best-in-class after sales service, as well as strong domain expertise, to guarantee successful deployments and operations.

QualityExpert™ helps users to manage quality and compliance processes and related documents and records through a single user-friendly interface and in a single environment, reducing complexity, lowering costs and promoting standardization, all while improving operational efficiency. From the overall perspective, it offers:

- Quality Process Management: a preconfigured set of business processes designed for the quality management needs of life sciences companies dealing with industry-specific quality challenges, incorporating best practices into common quality processes.
- Quality Document Management System (QDMS): a full set of capabilities including authoring, review, approval, distribution, tracking, storage, access, controlled printing and reporting.
- QualityAnalytics™: a range of standardized dashboards and reports, which meet critical tracking, trending, reporting and analytical needs while providing necessary business insights.

QualityExpert™ works in tandem with Amplexor's holistic Regulatory Information Management (RIM) platform, which enables life sciences companies to drive, manage and control the processes of releasing new products or maintaining existing products on the market while ensuring regulatory compliance.

Amplexor QualityExpert™ process management comprises:

- Quality Event Management through different types of Quality Events (Deviations, Complaints, Non-Conformances, Out of Specification, etc.)
- Investigation and Root Cause analysis process
- Extension Request process
- CAPA process and Effectiveness checks
- Creation of Audit Plans, Audits, Audit Activities
- Creation and approval of documents like Audit Agenda and Audit Report
- Automatic creation of Quality Events from Audit findings
- Change Control process linked to every other relevant process
- Supplier Qualification process
- Dashboards providing actionable QMS insights

This equips businesses with the ability to:

- Harmonize and standardize quality management processes.
- Achieve oversight and control of the quality processes, content and other meta-information to minimize the risks of non-compliance.
- Eliminate paper based and uncontrolled workflows.
- Improve inspection readiness.
- Support compliance requirements through a validated solution.
- Increase efficiency through a consistent and user-friendly enterprise collaborative environment regardless of the user's physical location.

Amplexor QualityExpert™ document management covers:

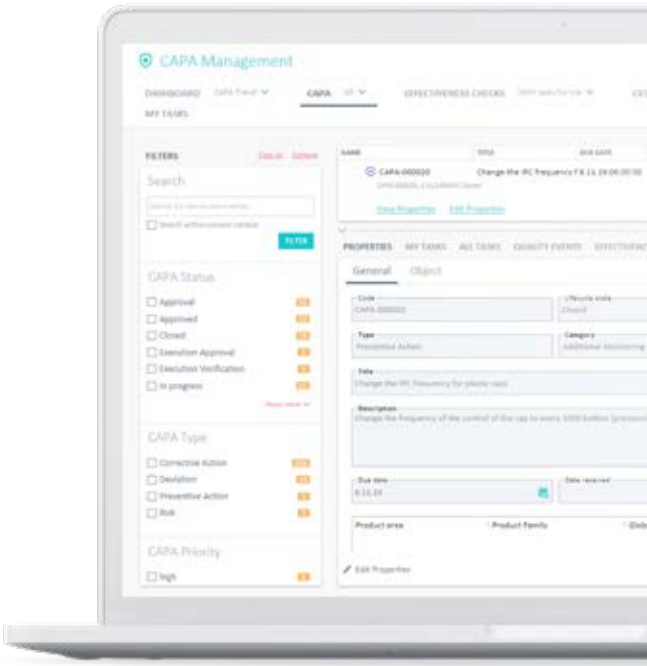
- SOP management (includes Quality Manual, Policies and Guidelines, as well as training documentation)
- Quality Control documentation management
- Technical Agreement management
- Validation Documentation management
- Product Quality Review management
- Site Master File management
- Dashboards providing actionable QDMS insights

This brings businesses the following abilities:

- Using controlled templates for all quality-related documents – from high-level policies and guidelines, through process specific instructions and procedures to lower-level records
- Predefined workflows, metadata, versioning policies, roles and permissions
- Document management for quality assurance, quality control, manufacturing and R&D including SOPs, analytical procedures, flow charts, working instructions, specifications etc
- Content reuse for internal and external purposes (e.g. same product information being used in laboratories and in a technical agreement or contract)
- Controlled printing with the use of additional overlays for offline track record
- Periodic review and document validation processes, including automatic notifications
- Automatic document expiration notifications to responsible users

QualityAnalytics™ focuses on the quality domain, consisting of a preconfigured set of standard dashboards and reports addressing common quality tracking, trending, reporting and analytical needs:

- Predefined set of business relevant reports that can be extended
- Interactive components
- Flexible pagination
- Crosstabs and hierarchical structures
- Embedded charts
- Exporting reports consistently to PDF and MS Excel formats



In addition, the self-service analytics allows for:

- Ad-hoc reports - exploring and analyzing data from multiple perspectives
- Faster business insights
- Custom reports & visualizations
- Security - users can only see what they are supposed to see
- Collaboration and sharing tools for team work

By supporting quality management and compliance processes, Amplexor QualityExpert™ enables companies to reduce regulatory risks and improve product safety and quality.

Please get in touch to find out more or visit us online.

solutions@amplexor.com **amplexorlifesciences.com/quality**

ABOUT AMPLEXOR LIFE SCIENCES

Amplexor Life Sciences is a global provider of regulatory, quality and safety software solutions, serving and trusted by pharmaceutical, biotechnology and medical device companies for over 25 years. Its holistic Life Sciences Suite solution helps life sciences organizations to be efficient with launching products and breaking into new markets quickly while ensuring quality, efficiacy and safety through end-to-end support to product lifecycle processes, data and content management.

AMPLEXOR
AN ACOLAD COMPANY

solutions@amplexor.com

www.amplexorlifesciences.com