Quality Audits

Streamline your quality audit processes

Effective audits are the foundation for quality and compliance throughout your organization.

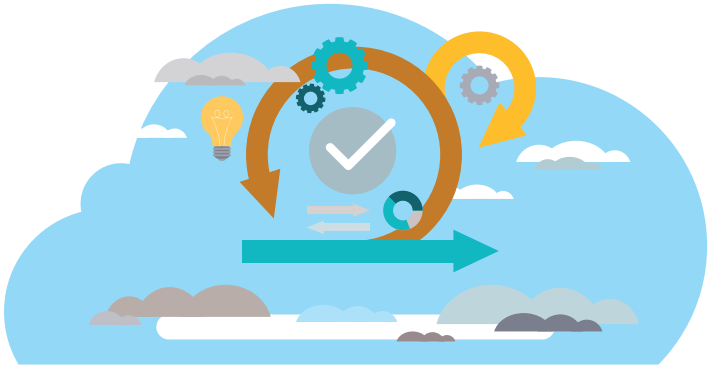
With Quality Audits in Merit for Life Science, you can streamline the processes required to plan, manage, and conduct internal audits (such as raw material, employee certifications, and testing/retesting) as well as supplier, and regulatory audits.

Quality Audits is an integrated part of the quality management processes within the Merit for Life Science platform which includes processes for managing quality incidents like complaints, non-conformances and deviations as well as implementing and managing corrective and preventative actions (CAPAs).

Situation: Planning, conducting, and tracing audits after the fact can be a real challenge for pharma, biotech, and medical device manufacturers. These tasks can be especially daunting for anyone relying on a paper-based system, or even a partially electronic system.

Common challenges include:

- Cumbersome document control
- Traceability issues
- Communication and accountability across multiple departments
- Untimely or difficulty accessing historical audit details



Benefits: Merit for Life Science helps streamline quality audit processes so that you can:

- Simplify audit planning
- Save time and effort with automatic scheduling
- Seamlessly integrate with Quality Incident processes for tracking / managing audit issues
- Ensure consistency across processes and divisions
- Improve overall audit management
- Centralize audit trails for easy access in the future
- Audit history automatically integrated into review processes across the enterprise
- Easily share results

Request a Demo

info@MeritSolutions.com

What's New in Quality Audits

- **Audit frequencies** – Determine how often new audits will be created, at which time frame and in which moment
- **Audit plans** - Link everything together including audit frequencies, audit processes and standardized audit questions for different types of audits
- **Audit scheduler** – Use audit frequencies and plans to drive the creation of audits through the Audit Scheduler
- **Workflow** – Leverage the standard D365 workflow engine to coordinate and track review and approval processes across the organization
- **Audit trails** - Provide full history for audit activities (including electronic signatures where needed)

Why Merit Solutions?

Cloud ERP

- Advances Microsoft Dynamics 365 for life science
- Purposely tailored for biotech, pharma, and medical device manufacturers
- Support for complex compliance requirements including FDA, DEA, ISO, OSHA, GAAP, Sarbanes Oxley
- Designed to connect and support external partners like CDMOs, CMOs, CROs, Cell Banks, Clinical Trial Sites, 3PLs, IV&V

Microsoft Cloud Platform

- Familiar user experiences
- Native application integration
- Microsoft Trust Center (GAMP, SOCS, FDA, etc.)
- Disaster recovery and system redundancy
- Zero trust foundation
- Secure hybrid workforce

Life Science Specialists

- More than 20 years' experience implementing and developing ERP software for life science organizations
- Experts for the implementation and on-going support of your FDA-compliant solution
- Demonstrated proficiency, skill set and expertise