

Audit Management and Control

Effectively managing audits is essential to any quality management program. Good audit management helps to proactively ensure quality by measuring and improving processes, procedures, and marketed services and products. In addition, supplied products and services can be audited to ensure quality adherence throughout the entire value chain. Early detection and prevention through audit activities is the key to lowering product defects, thereby resulting in higher customer satisfaction.

Audit Process Management and Control

Good audit management programs begin with a clear definition of audit processes and metrics. In compliance with current regulations, the system should be able to track progress against previous audit deficiencies and identify potential root causes in a timely manner. Integrated CAPA processes ensure that corrective actions are implemented in a timely manner to eliminate potential root causes.

Audit Management Best Practices

Effective audit management requires a combination of people, processes, and technology to achieve maximum results. Technology-based audit programs are in and of themselves, insufficient. The best practices summarized below highlight the essential requirements for automated audit management systems and the required processes and human resource requirements to ensure sustained compliance and reduce regulatory risk.

1. **Obtain top-down management support and commitment.** A fundamental requirement of any compliance initiative that impacts the entire organization is support from senior management. Top-down support ensures that compliance is treated as a corporate mandate versus a departmental challenge. It also ensures that resources will be available as needed to ensure success.
2. **Establish clear policies, procedures, and metrics.** You cannot measure the effectiveness of something that is not defined. Audit management programs should incorporate defined policies, procedures, and metrics as performance benchmarks. These elements should be reviewed periodically for continuous improvement.
3. **Integrate essential quality management processes.** To ensure success, an effective audit management system should automate the entire audit process and include integration of the following processes:
 - Corrective and preventive actions
 - Change control
 - Non-conformance tracking and management
 - Regulatory document/content management
 - Custom reporting, analysis and analytics
 - Training
 - Compliance intelligence dashboard

CAPA is central to all the audit process. Audits may reveal a number of issues and process deficiencies. The corrective action process insures that these matters will be identified, tracked, and monitored in a controlled manner.