

QUALITY MANAGEMENT SYSTEM GOVERNANCE TO ENSURE EFFECTIVENESS AND GUIDE QUALITY IMPROVEMENTS



The quality management review (QMR) serves as a process for top management to periodically review and evaluate the effectiveness of a quality management system (QMS), determine its continued suitability and effectiveness, and address the need for changes to policy, objectives and other elements to further improve quality.

AssurX Quality Management Review software provides an automated process for conducting QMRs and managing the changes that may result from findings.

REGULATIONS AND STANDARDS

Life science companies including pharma, biotech, medical device and diagnostics manufacturers must show proof that quality management reviews have been executed. In addition, manufacturing and service-driven companies that adhere to ISO Standards are required to conduct QMRs as well. Examples include:

- [FDA 21 CFR Part 820](#) requires medical device firms to conduct essential reviews periodically and document the results.
- [International Conference on Harmonisation \(ICH\) Q10](#) guidance for pharmaceutical companies require QMRs as a part of management responsibility and commitment to quality.
- [ISO 13485](#) provides a list of management responsibilities for medical device firms, including conducting QMRs to demonstrate commitment to medical device quality.
- [ISO 9001](#) requires a management review ensure that a company's QMS continues to meet ISO standard requirements.

IMPROVE QUALITY PROCESSES

AssurX Quality Management Review software provides significant benefits beyond satisfying external audit requirements. QMRs are opportunities to adopt a culture of continuous quality improvement. Automated workflows guide the review of all available data to confirm that the best processes are in place for an optimized quality value chain.

Management can review inputs and data and make improvements that align with corporate quality objectives.

AssurX guides the review process based with best practices workflows to insure a thorough review of all quality inputs. Each review culminates in tasks for improvement and changes to quality policies.

The AssurX platform seamlessly integrates quality processes to help accelerate ROI, ensure compliance, increase efficiencies, and advance quality excellence. AssurX connects the quality management review process with [CAPA](#) and [audit management](#), and can be integrated with any other core process in the AssurX platform.

QUALITY MANAGEMENT REVIEW SOFTWARE BENEFITS

Compliance

Provide proof that a quality management system is effectively updated, fit for purpose, and capable of adjusting to changes within the company. Show the current status of changes and corrective action outputs.

Collaboration

A closed-loop system helps end departmental silos by connecting people, tasks, and processes for greater collaboration. Engage representatives from all functional areas in the quality management review. Tasks are automatically assigned to specified roles, groups, or people for shared ownership in product quality and customer satisfaction.

Data Integrity

The FDA and ISO focus on quality management guidelines that focus on data, documentation and risk-based decisions. AssurX solutions provide rapid access to reliable data that can be pulled into QMR records. All records within the Quality Management Review software become permanent with an unbreakable audit trail and electronic signature compliance.

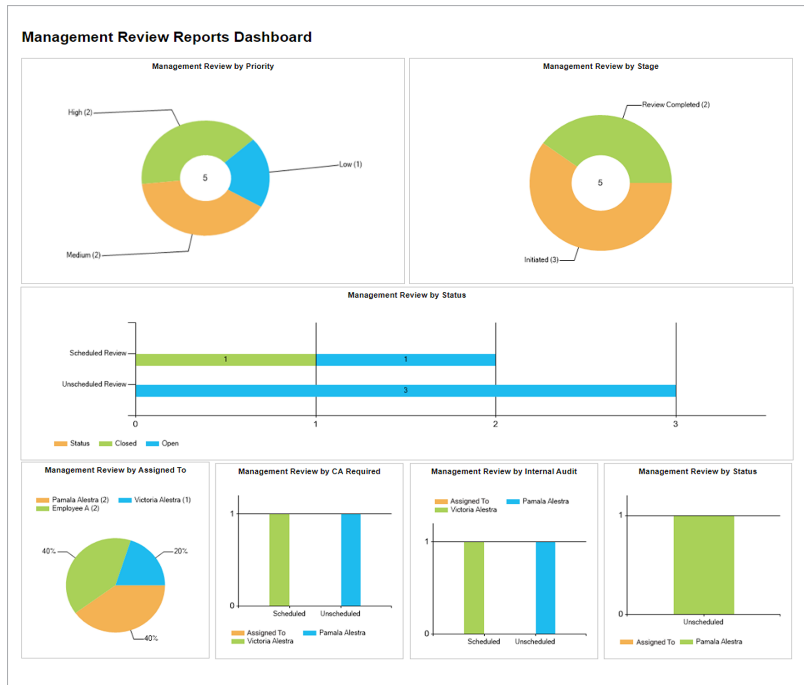
Proactive Approach

Whether your meetings are annual, quarterly, or segmented by focus area, AssurX helps automate planning and set expectations in advance. Create detailed agendas with input from all stakeholders to make sure all topics are covered (a requirement for FDA and ISO). Set automatic reminders to keep participants on-pace and accountable.

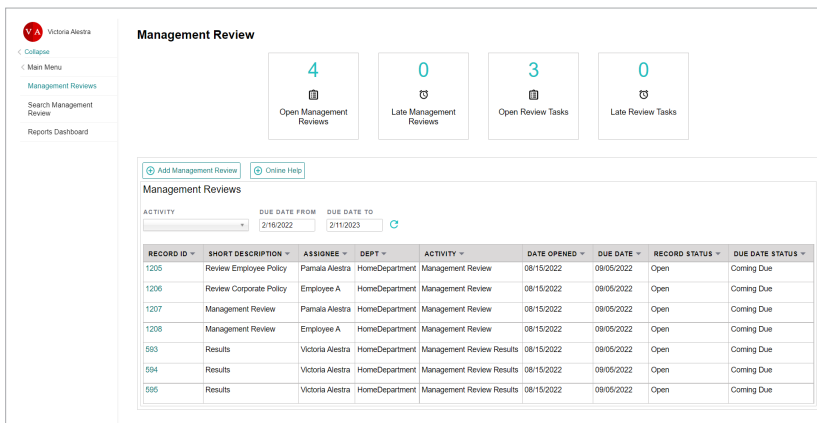
Quality Improvement Effectiveness

AssurX helps you identify the KPIs most relevant to the quality value chain in your organization (reasons for downtime, time to resolution of critical issues, supplier performance, etc.). AssurX Quality Management Review Software allows you to define the most important key performance indicators (KPI) for your QMR and use them to pinpoint areas for improvement.

A fully configurable reports dashboard provides high-level details of pending tasks. Clicking on any dashboard widget drills-down to detailed reports.



Pending tasks can be sorted using multiple selection criteria and rich query functions. Dashboard cards provide an overview of KPIs, which can be configured based on user identity, role, or group.



ASSURX FEATURES AND FUNCTIONALITY

- ▶ **Unmatched Configurability:** The QMR solution follows industry best practices and can be used either out-of-the-box (as installed) or as a starting point for configuration to align with your specific business needs with extensive configurability. Configuration is accomplished without having to modify any source code, ensuring compatibility with all future core service packs and upgrades.
- ▶ **Paperless Automation:** AssurX automates and streamlines the QMR process, from preparation and scheduling to data collection (inputs), to results and objectives (outputs). Actions such as CAPA, audits, or other quality tasks can be launched from the quality management review for seamless issue resolution.
- ▶ **Dashboards:** Equip your team with robust dashboards that provide drill-down visibility into KPIs, status, and metrics in a secure environment.
- ▶ **FDA-Compliant Audit Trail and Electronic Signatures:** AssurX provides full audit trail and e-signature capability designed to comply with [FDA 21 CFR Part 11](#) requirements.
- ▶ **Robust Analytics and Reports:** Generate customizable reports for and data-centric KPIs for review inputs.
- ▶ **Enterprise System Integration:** AssurX can be [integrated with other systems](#), including ERP, CRM, LIMS, and LMS systems to maximize available enterprise data for even greater collaboration and decision-making.