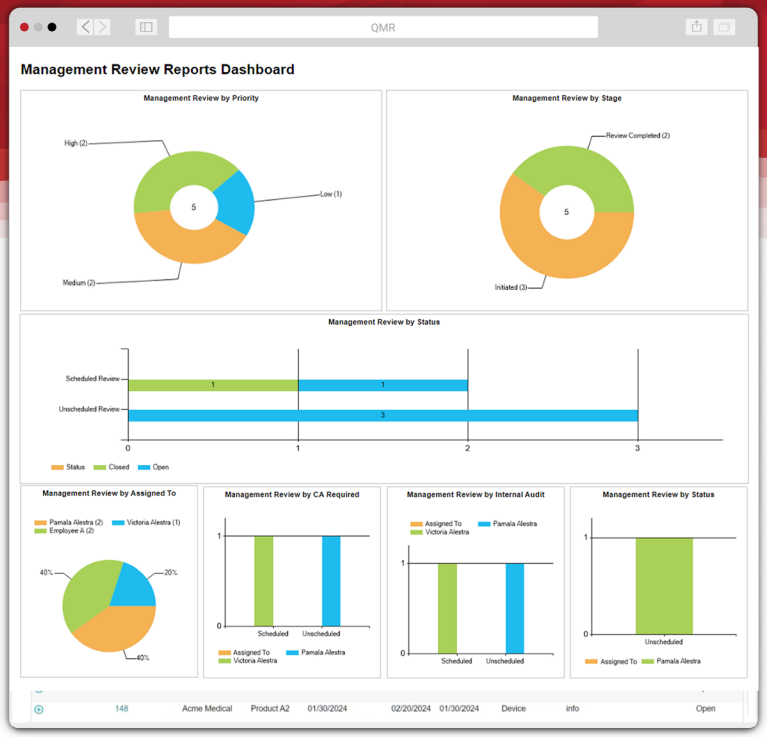
DATASHEET

Quality Management Review Solution

Accelerate ROI, ensure compliance, and advance quality excellence

AssurX Quality Management Review software provides an automated process for conducting QMRs and managing the changes that may result from audit findings. QMRs are opportunities to adopt a culture of continuous quality improvement.



Global Compliance Regulations & Standards

Life Science, Manufacturing and service-driven companies need to adhere to global regulations and standards. AssurX provides proof that quality management reviews have been executed. Some examples include FDA 21 CFR Part 820, International Conference on Harmonization (ICH Q10 guidance), ISO 13485 and ISO 9001.

Compliance

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

Collaboration

A closed-loop system connects people, tasks, and processes for greater collaboration. Engage representatives from all functional areas in the QMR. Tasks are automatically assigned to specified roles, groups, or people for shared ownership in product quality and customer satisfaction.

Data Integrity

With a focus on data, documentation and risk-based decisions, the solution provides access to reliable information that can be pulled into QMR records. All records become permanent with an unbreakable audit trail and electronic signature compliance that adheres to FDA and ISO guidelines.

Proactive Approach

Automate planning and set expectations in advance. Create detailed agendas with input from all stakeholders to cover all topics (a requirement for FDA and ISO). Use reminders to keep participants on-pace.

Quality Improvement Effectiveness

Define the most important key performance indicators (KPIs) for your QMR and use them to pinpoint areas for improvement. Implement and test the effectiveness of your changes.

Assurx Quality Management Review at a Glance

Unmatched Configurability: Based on industry best practices and used with either out-of-the-box (as installed) or as a starting point for configuration to align with your specific business needs. Configuration is accomplished without having to modify any source code, ensuring compatibility with all future core service packs and upgrades.

Paperless Automation: Automate 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.

Robust Analytics and Reports: Generate customizable reports for and data-centric KPIs for review inputs.

Systems Integration: Connect the quality management review process with CAPA and audit management and integrate with any other core process in the AssurX platform. Ability to integrate with enterprise applications, including ERP, CRM, LIMS, and LMS systems to maximize available enterprise data for even greater collaboration and decision-making.