ASSURX RISK MANAGEMENT

A systematic approach to managing risk across the quality ecosystem.

AssurX Risk Management utilizes a workflow-driven process for the identification, assessment and control planning of risk. Using quality risk management is a continuous process that minimizes risks to product quality throughout the life-cycle in order to balance benefit and risk.

AssurX facilitates risk-based thinking into the deployment and management of an enterprise quality management system (EQMS). Risk Management is incorporated into the following AssurX solutions:

- Audit Management
- Change Management
- Complaints Management
- Corrective Action
- Deviations / Nonconformances

The AssurX Risk Management solution supports companies in their compliance objectives with the following standards and guidance:

- ICH Q9 Quality Risk Management guidance for pharmaceuticals
- ISO 9001 Guidance for Quality Management Systems
- ISO 14971 Guidance for Application of Risk Management to Medical Devices
- ISO 13485 Standards for Medical Device Quality Systems

The core methodology of risk management is consistent across industries and can be used by all Life Sciences (Medical Device, Diagnostics, Pharmaceutical, Biotech), Food & Beverage, and any other manufacturing or service enterprise (High-Tech, Consumer, Industrial).

FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

The AssurX Risk Matrix is used to identify and manage risks within the AssurX Platform. The FMEA (Failure Mode Effect Analysis) measures the three key ratings:

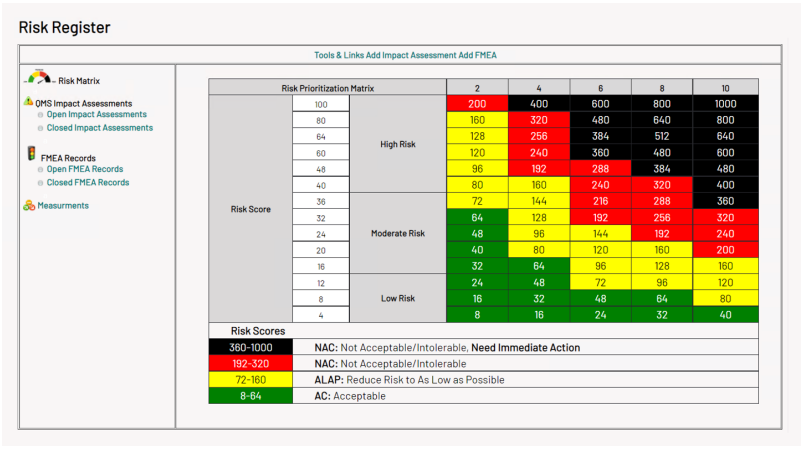
Frequency of Occurrence x Severity of Occurrence x Chance of Detection

When the three ratings are defined, an RPN (Risk Priority Number) is calculated. The RPN represents the level of risk, and helps you prioritize activities based upon the RPN.

When failures are entered into the Risk Score Matrix, AssurX enables easy reference to level of attention to be applied to each FMEA based on the total RPN. When an RPN value meets or exceeds a defined threshold, the solution launches a Deviation.

In addition, the FMEA searches for CAPAs in the system to trace current preventive actions. AssurX further facilitates risk awareness by automating alerts and review tasks to expedite approvals of risk activities.

AssurX displays a heat map graphic incorporating the risk matrices. The color-coded heat map creates visibility into high risk at-a-glance, and tasks are subsequently assigned based on time frames and values you select.



Risk matrix using a four-point scale. Different values, including compliance risk, requirement maturity, internal audit effectiveness, and other criteria can be utilized to determine risk acceptance threshold.

This level of clarity enables you to:

- Identify, prioritize and limit failure modes.
- Demonstrate real-time risk management.
- Proactively identify risk trends.
- Utilize historical information for analyzing potential product failures.
- Assign RMRs based on integrated quality data including complaints, customer ratings, supplier performance metrics, CAPAs, NCRs, management reviews and audit findings.
- Efficiently route tasks down the appropriate path for actions, escalations and exceptions.
- Gain visibility into open records and actions.
- Assign issues based on your defined criteria (risk level, roles, product, etc.).
- Utilize a harmonized approach for consistent review and reporting of risk.

CONFIGURABILITY AND CONTROL

The AssurX Risk Management Solution is highly configurable, ensuring that your custom configuration meets the needs of your organization and your users. Configuration is accomplished without having to modify any core source code, which ensures compatibility with all future core service packs and upgrades.

Risks initiated from any source or system are automatically associated with related product records across the system, forming an enterprise level approach for rapid mitigation.

BUILT FOR ENTERPRISE COMPLIANCE

All activities are systematically managed and recorded in a closed-loop to meet requirements for FDA and other regulations for validation, audit trail, electronic signatures, retention and traceability. Once added to a record, signatures cannot be modified, copied, transferred, or deleted. AssurX automatically maintains a secure, time-stamped record (audit trail) of all changes to records.

IMPLEMENTATION, SUPPORT & MAINTENANCE

AssurX provides expert services for system implementation, validation and training through its Professional Services and Validation Services teams.

AssurX no-code configurability enables your internal resources to independently develop, configure and deploy processes based on your organization's expertise and resources (which can be broadened with AssurX Training Services). Validation services can be purchased for creating customized documentation and authenticating the installed solution.

BENEFITS AT A GLANCE:

- Strengthen and substantiate your organizational risk posture.
- Demonstrate a proactive compliance posture based on regulatory standards and industry guidance.
- Monitor, identify and streamline remediation for products, components, services and customers.
- Make decisions faster with custom reporting and dashboards to access detailed data.
- Manage product quality risk and visibility in a multi-layer supply chain.
- Manage risk across the organization using comprehensive quality data from complaints, customer ratings, supplier performance metrics, CAPAs, NCRs, management reviews and audit findings.

Want to learn more?
Connect with AssurX today