MasterControl Risk™

A consistent approach in assessing and managing risk is crucial to successful quality management. An integrated software solution can help companies identify and mitigate long term systemic risks by tracking and analyzing the recurrence of issues.

How can MasterControl help you?

MasterControl Risk™ is a "one-stop shop" that unifies all risk-related activities and documentation in a single, centralized repository. The MasterControl Risk solution provides a complete and accurate picture of the risk landscape across product lines, business processes, and business units, precluding reputation damage from recalls or regulatory action.

These examples demonstrate how MasterControl Risk helps companies efficiently manage consistent risk evaluation and mitigation processes:

Challenges	MasterControl Solution
Disjointed Systems: A lack of standard risk analysis methodologies and assessments results in enterprise-wide waste of time, money, and resources.	**Integrated System:** MasterControl brings together all risk-related documentation in a single location. MasterControl's scheduled reporting and full search capabilities provide insight and easy access into risk assessment and mitigation activities.
Inconsistent Risk Assessments: In environments where risk assessments are performed but are not standardized, risk evaluations may vary from one assessor to the next. Whether an appropriate action is taken depends on the particular assessor, meaning that similar issues may end up being treated differently.	**Standardized Risk Analysis Process:** MasterControl insures that a single system is being used to collect and manage risk- related activities. The system guarantees that corporate risk tolerance thresholds are employed and followed for risk-related activities across the enterprise. When used in tandem with MasterControl Process™, standardized risk calculation tools and methodologies can also be implemented.
Disconnected Processes: The use of manual systems typically results in the creation of separate data repositories (e.g., risk analyses and corresponding CAPAs), making it difficult to track and record comprehensive documentation.	**Connected Processes:** MasterControl provides employees from different departments with a simple and efficient method for participating in risk assessment and mitigation activities. MasterControl Risk offers electronic workflows and signatures for execution, review, and approval of risk activities and documentation. Personnel can leverage a risk-based approach in multiple processes including CAPA, non-conforming material disposition, protocol development, supplier qualification activities, etc.

Features and Benefits

- **Uniformity:** MasterControl gives quality and regulatory departments uniform methods to perform consistent risk analyses. Engineering and manufacturing personnel can easily document and store risk mitigation activities in product and process design.
- **Risk Assessment Capabilities:** Users can configure multiple risk types for evaluating different categories of operational risk. Risk assessments can be launched from anywhere within the MasterControl system to analyze hazards associated with any process or activity. MasterControl's best practice process also includes risk mitigation and reassessment.

- **Reporting Tools:** MasterControl's analytics reports allow analysis of risk files and risk assessments. The system's scheduled reporting capability and intelligent threshold rules also increase management awareness.

- **Risk File Management:** A single collection point for all risk-related activities pertinent to a given project, process, or supplier brings together risk assessments, documentation, and other risk management processes (FMEA, FTA, surveys, etc.). Risk files may be routed for approval and electronically authorized in accordance with 21 CFR Part 11.

- **Integration Points:** Keywords are used to launch risk assessments from any MasterControl Process™ form (e.g., CAPA, NCMR, etc.). Risk files are associated with vendors stored in the MasterControl Supplier™ module to track risk-related activities. Risk assessments launched from an item (document, process, project, BOM, etc.) in any MasterControl module are automatically linked to related InfoCards in the MasterControl system.

- **Increased Management Oversight:** The software's standard methodology simplifies the application of resources in the most risk-prone areas. The MasterControl Risk solution insures that organizational risk tolerance is not exceeded.

About MasterControl Inc.

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit www.mastercontrol.com, or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 6801 6147 (Japan)