MasterControl Risk Analysis™

Risk management is one of the central goals of quality operations. Whether reporting a nonconformance, a deviation or a CAPA, each process is intended to evaluate and mitigate the immediate risk posed by an issue. Long-term systemic risks are then exposed by tracking and analyzing the recurrence of similar issues. A consistent approach in assessing risk is an important factor for successful quality management.

How can MasterControl help you?

MasterControl Risk Analysis™ establishes risk evaluation as a separate process. The output is a risk score based on a consistent process, which enables quality departments to reduce the oftentimes subjective nature of quality decision making.

Here are some examples of how MasterControl Risk Analysis is helping companies efficiently manage a consistent risk evaluation process as an input to different quality-related processes such as nonconformance, deviation, CAPA, and more.

Challenges	MasterControl Solution
Lacking Support for Decisions: Actions taken, or not taken, on quality issues are often challenged by internal employees, in customer audits or in FDA audits. Without a formal risk assessment it can be difficult to defend your decisions.	**Introduce Objective Metrics:** Many of MasterControl's quality solutions include triggers to perform a risk analysis. This enables a methodology that establishes objective risk metrics. These can then be used as thresholds for decision-making.
Risk Assessments are Inconsistent: In environments where risk assessments are performed but are not standardized, risk evaluations vary from one performer to the next. Whether an action is taken on a quality issue depends on the particular assessor and similar issues end up being treated differently.	**Create a Standardized Risk Analysis Process:** A team of risk experts is designated in your company and automatically involved in every risk analysis. MasterControl supplies the risk metrics which can then be further defined in your program to match your specific needs. This results in consistent, objective and defensible quality decisions.
Disconnected Processes: Manual systems create separate data repositories (e.g. a risk analysis and its corresponding CAPA), making it hard to locate complete documentation later.	**Connected Processes:** MasterControl integrates different quality processes for more effective and efficient quality management. For example, a deviation might trigger a risk analysis. Based on the results from the risk analysis, a CAPA may be launched. All this is coordinated from the deviation form, and data on the forms stays associated electronically for easy traceability and reporting.

Features and Benefits

- **Best-Practice Form:** A pre-configured, multi-page form prompts participants to collect and track all relevant data and guides them through the process while allowing responsible personnel to make decisions appropriately. The form is automatically routed to the appropriate personnel and can be escalated if not processed in a timely manner.

- **Best-Practice Process:** MasterControl incorporates a two-step process that guides users through the process, including Risk Analysis Performance and Risk Analysis Approval.

- **Analytics Reporting Tool:** This built-in tool comes with a standard set of pre-configured reports that can be adjusted and customized by the end user. Risk Analyses can be analyzed by source and other parameters. These data-mining capabilities can give important insight into systemic quality issues and serve as yet another starting point for CAPA.

- **Audit Trail and Electronic Signatures:** MasterControl provides time-stamped audit trail, reporting, and electronic signature capabilities that fully satisfy FDA's 21 CFR Part 11 and other global regulatory requirements.

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)

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