MasterControl™ Quality Management Suite

Your Foundation for Continuous Compliance

While market globalization has vastly increased the potential for profit for manufacturers and other businesses, it has also intensified competition and the pressure to produce faster and at a lower cost. The situation is doubly challenging in the FDA and ISO environments, where companies must contend not only with cutthroat competition, but also stringent regulatory requirements.

How can MasterControl help you?

With more than a decade of experience in the rigorous FDA and ISO environments, MasterControl has developed an integrated software solution that combines industry best practices with the flexibility to meet every customer's unique needs.

The MasterControl™ quality management suite consists of configurable, easy-to-use, and connected applications for automating, streamlining, and effectively managing document control, change control, training control, audits, corrective/preventive action (CAPA), customer complaints, and other documents- and forms-based quality and business processes under a single Web-based platform. Hundreds of companies worldwide rely on MasterControl to facilitate compliance with FDA regulations (e.g., 21 CFR Parts 11, 210-211, 820, 606), ISO quality standards (e.g., ISO 9000, ISO 13485, ISO 14000, ISO/TS16949), and Sarbanes-Oxley Act requirements.

There are three key factors that distinguish MasterControl from other software providers:

Compliant: Sustained Compliance

MasterControl believes that compliance is a state, not an event. The MasterControl solution is designed not only to help companies attain compliance, but to sustain it year after year by optimizing quality and business processes and fostering efficiency, both of which help lower compliance costs and increase competitive edge.

Connected: Integrated Quality Management Suite

MasterControl is integrated, effectively connecting people with data and processes for a holistic approach to quality management. This connectivity gives managers the "big picture" — allowing them to view and monitor the entire quality system to continuously improve it and to proactively reduce, if not prevent, quality problems that could lead to product recalls, returns, waste, and rework. MasterControl's integrated solution increases efficiency, resulting in a faster throughput process and a shorter cycle time. For FDA-regulated companies, implementing an integrated solution also means system validation can be performed just once.

Complete: Enterprise-wide Solution

MasterControl believes that quality initiatives must be integrated into an organization's corporate culture. Its platform is powerful enough to meet the needs of every department in an organization and to ensure that quality standards are enforced across the enterprise. MasterControl offers robust software, plus the appropriate tools and services necessary for successful implementation and validation. For FDA-regulated companies, MasterControl offers a line of validation products and services addressing different levels of validation needs based on individual risk assessment. They are designed to allow "continuous validation" by significantly reducing the time, cost, and pain involved in software validation.

The MasterControl suite consists of the following integrated applications:

- **MasterControl Documents™** automates task assignment/routing, scheduling, follow-up, tracking, escalation, review, and approval of all documents-based processes. It provides a single repository for all documentation, making search and retrieval easy. MasterControl tracks all document changes and provides automatic revision control to ensure that only the current version of a document is available. This core application integrates other quality processes such as training control, change control, customer complaints, corrective/preventive action, and audits for a closed loop solution.

- **MasterControl CAPA™** interconnects different quality subsystems and tracks incidents that can escalate into a corrective action. It includes a best-practice "8D" process to guide the quality team through every step of CAPA implementation, from problem identification through corrective action. A CAPA form can be launched directly from another form (e.g., nonconformance or deviation report), automatically entering relevant data into the CAPA form. Through the Internet, customers, vendors, and others outside the company can submit customer complaint or other forms that could lead to CAPA.

- **MasterControl Training™** automates assignment and monitoring of training tasks and grading of online exams. It allows sequencing of training courses, so after a prerequisite course is completed, the next one is automatically launched. It provides group sign-off feature for verifying training of large groups of employees. Training control can be integrated with the rest of the quality system, so any change to a document or process that warrants new training will automatically invoke training tasks upon approval of the change.

- **MasterControl Forms™** automates routing, notification, escalation, and approval of any forms-based process for faster turnaround. This solution offers best-practice features that prompt users with selected data to reduce data entry and avoid mistakes common in manual data entry. Forms created in Microsoft Word, Excel, or PowerPoint can be converted to PDF as is, so users will see the same form and won't need new training. A company may also improve existing forms or design new ones to suit its needs. MasterControl is Web-based, so employees, customers, suppliers, and others can participate in forms-based processes from virtually anywhere.

- **MasterControl Change Control™** streamlines the change control procedure for faster turnaround. It offers a best-practice form that incorporates priority level and prompts risk assessment and classification of the change as low, medium, or high. For FDA-regulated companies, any high-level change implies great impact on the product and is likely to require regulatory filing. Customizable reports provide real-time status not only of change control tasks but of the entire quality system.

- **MasterControl Audit™** automates, streamlines, and effectively manages the audit process. It provides advanced tracking capability, from scheduling and planning to execution and completion. MasterControl offers best-practice forms for tracking basic audit information and audit findings. It automates scheduling of all recurring audit-related activities and provides advanced analytics and reporting capability, so managers get a real-time view of the audit process.

- **MasterControl Customer Complaints™** streamlines the complaint-handling process and reduces the lifecycle from submission to resolution. A simple, three-step process is incorporated in a pre-configured, multi-page form that starts with the processing of a customer complaint, automatically moving to internal investigation, and culminating with resolution of the issue. MasterControl's advanced reporting capabilities increase management oversight and demonstrate appropriate controls to regulatory agencies. Customers can submit complaints from virtually anywhere because MasterControl is Web-based.

- **MasterControl Nonconformance™** is a robust solution designed to automate, manage, and streamline the process for identifying, evaluating, reviewing, and handling of nonconforming materials, components, parts, and finished products. The solution's best-practice form and five-step process connect all responsible personnel for effective and timely disposition of a nonconformance. This solution offers the choice of maintaining a stand-alone nonconformance process for small-scale, localized incidents, or you may connect it to the CAPA process for automatic escalation when the situation warrants it.

- For companies seeking compliance with the Sarbanes-Oxley Act, **MasterControl SOX™** is a complete and easy-to-use solution that automates and effectively manages business processes, including voluminous documents, records, and SOPs. It includes a pre-configured form that documents and collects data pertaining to risks, internal controls, and tests. It links every risk with its control and test through pre-built workflows. It allows testing to be automatically scheduled and incorporates escalation to ensure that tests are completed.

- **MasterControl Submissions Gateway™** facilitates electronic delivery of FDA applications (such as IND, NDA, and BLA) by providing control in assembling and tracking necessary documentation. It provides appropriate templates to streamline the dossier-creation process. MasterControl can be integrated with leading e-submission applications, connecting approved documents and forms-based content with the dossier assembly process, to accelerate submissions.

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: 800-825-9117 (U.S.); +44 1256 325 949 (Europe); or 03-6801-6147 (Japan)

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