

White Paper:

Automating Electronic
Engineering Change
Management (ECM) Systems

Reducing Compliance Risk
and Improving Product Quality

The Power of an Integrated Quality Management System



View Customer Video Now
Click here to launch



If you like our white papers, you'll love our products.
See what our customers say about MasterControl products.

Introduction

From medical devices to car parts to forklifts, all products undergo design changes at some point. Manufacturers of every stripe face the common challenge of the unexpected change. Modifications may stem from unavailability of parts, or safety reasons, or because of government regulations. They may be minor, affecting only a single component, or they can be complex, involving several assemblies.

Every manufacturer needs an **Engineering Change Management (ECM)** process for initiating and controlling change. An effective ECM process ensures the safety and reliability of products by using current, approved, and released documentation for a specific change. An electronic or web-based ECM system offers reduced risk of non-compliance and the potential of increased product quality by providing the following:

- A secure electronic login to the document control system
- A secure process of electronic approvals
- E-mail notifications to all participants
- Integrated task tracking
- A configurable automated workflow processes
- A means for attaching/linking documents to the ECM process
- Current status reports on the document in question
- A process to find/read/print documents within the database
- Electronic engineering change notice/request/order template forms
- Capability for all participants to add comments and read everybody's input
- A process for creating external reports using current data

A change initiated from a customer complaint or through a corrective action process that was meant to fix a simple mistake could potentially affect the design team, the manufacturing team, suppliers, and subcontractors. A redesign in the product itself could affect all of those people and may even include personnel in sales and marketing, contract administration, purchasing, inventory control, training, quality, and technical publications.

Process changes, updates in equipment, or new setups all pose challenges in change management, but the overriding factor is usually the lack of control in engineering and other referenced drawings, bill of material (BOM), and submission to vendors. Keeping track of approved engineering change notice (ECN) and engineering change requirements (ECR) can also be a major issue.

For example, a company that produces medical device XYZ finds out that a change is necessary to fix a defective pump. The new pump, produced by another vendor, has different mounting holes, as well as electrical connections. This single change in the pump has affected two other assembly pieces manufactured through other vendors. Drawings must be updated to accommodate the new pump. This change will affect several vendors (old pump, new pump, fabrication, and electrical wiring vendors) and entail updating instructions and BOM, installation of new pump, and new packaging. All of these will probably mean additional costs.

This shows how an engineering change is affected by different factors. Manufacturers that depend on outside vendors require a higher degree of control than those using in-house processes. Companies that run 24/7 operations could potentially experience more issues if changes are happening every hour. In a nutshell, dealing with an engineering change can be simple or complex. There's no foolproof formula for doing it, but you should consider the ECM process as an important tool in helping you execute the change successfully.

Typical ECM Process

The ECM typically provides everything needed to set up a fast, effective, and secure change process. There are three major components to the process meant to ensure data accuracy, security, and consistency: Engineering Change Notification (ECN), Engineering Change Request (ECR), and Order Change Management (OCM).

An engineering change usually begins with either an internal or external user report about an issue, or an update to a document or drawing or process through ECN. The change task notification is then sent to the responsible parties through specific routes/workflows. They use the change notification to check the issues and/or updates and to decide on the appropriate action.

If the decision is made that an engineering change task is necessary, an ECR is created on the basis of the change notification and both documents are linked. The changed engineering documents are prepared. Responsible parties check all parts and items being changed. A good ECM provides a collaboration process that allows everybody affected to redline the changes in the document.

After everybody has approved the changes, the ECR can then be converted into an Engineering Change Order (ECO) for the affected parts. The responsible parties proceed to make the changes, which become effective only after they release the ECO. The release can be made either in one step or as a general release or through a multi-step process.

If changes are released for running production orders, the Order Change Management (OCM) process may optionally be triggered to adopt changes in a controlled process.

ECM Functions

The ECM process is inherently complex; automating the process can greatly expedite engineering changes. Change forms, such as ECN, ECR, and ECO, can be electronically created and routed individually or combined with a template and attached documents for review and approval. Some e-forms can be integrated processes in themselves – providing a form template, background process, and an integrated document process allowing data retrieval and record analytics that give direct feedback online. Here are some of the main functions of ECM:

- **Routing/Change Control** - The ECM process is critical in controlling routing of drawings, specifications, formulations, process documents, etc. . . . Changes made in certain operations may require detailed change justifications and descriptions of changes, listing of products/processes affected, disposition of affected product, and updates to affected documentation, personnel, and equipment... Through the ECM process, new training courses can be initiated using timed, notified, and dated SOPs for all affected employees. This may include new machine setups or material handling instructions. The ECM can also be used to track changes made to engineering drawings. The relationships between current and previous drawings can be shown using attached and/or linked documents.
- **Collaboration and Approval Steps** - An ECM process may include multiple collaboration and approval sequences. E-mail notification should be sent automatically to members of each review/approval step. Approvals are made based on the pre-structured routing order. Tracking is easier if members of each step have the ability to approve and sign off electronically. Members' review comments, approval, or rejection can similarly be tracked.
- **Quality and Regulatory Control** - Most quality control programs use ECM to help meet stringent standards set forth in FDA's 21 CFR 820 regulations and in ISO/QS certification programs to help reduce the number of items that are scrapped or returned.
- **Engineering Audits** - An ECM provides an audit trail for tracing a product backward or forward throughout the engineering lifecycle. It's also essential in tracking changes in different versions of engineered parts and in comparing multiple versions of routings and BOMs.

- **Management of Change** - An ECM provides the MOC a mechanism to initiate and control the:
 - technical basis for the proposed change
 - possible impact of change on safety and health
 - modifications to operating procedures (SOP)
 - control of a necessary time period for a change
 - authorization requirements for the proposed change
 - employees affected by change that need to be informed and trained prior to startup
 - updating of drawings, if affected
 - updating of procedures, if affected

Controlling Change

The ECM process is crucial in maintaining the consistency of products because it defines and controls the change task process. An effective ECM should be flexible and workflow-process driven. It should log, record, and track the history of all change tasks, including BOMs. All affected personnel should receive timely communication about a change task and they should have the capability to give input and/or approval.

The size of a manufacturer does not affect the nature of an ECM as much as the complexity of a design change, the corporate policy on change, and the extent of compliance requirements involved. It's critical for a manufacturer's ECM process to do the following:

- Configure an effective Change Control Management process that works within existing manual system and automate the notification and approval process.
- Prepare company processes to effectively control and document changes in:
 - Engineering drawings
 - Manufacturing processes
 - Product redesign
 - Vendor product changes
 - Other changes
- Integrate and complement manufacturer's Change Control Management processes to fully utilize computerized systems.
- Configure system to a variety of types of change tasks.
- Fit into different levels of change tasks (major, minor, critical)
- Decentralize the roles and responsibilities of approvers and administrators
- Provide the company with formatted templates for Change Control SOPs and Form revisions

Advantages of Web-Based ECM Processes

Advanced ECM systems now include Web-based applications that give users access to documents, processes, workflows, collaboration, and e-signature approvals via the Internet. One of the advantages of a Web-based system is its ability to let traveling or off-site employees participate in change management processes.

Many companies also take advantage of controlled Web access to improve supply chain and customer involvement in their change management process. With controlled Web access to ECM, suppliers and customers can be added to change processes with limited users' rights, such as review and approval rights.

When organizations decide to switch from manual or hybrid to an automated system, they start by establishing an electronic data management (EDM) process to manage the whole engineering change process. EDM provides efficiency and security through a controlled environment and allows a circular flow of information within the teams. It captures the entire change process electronically. Here are some of the things the EDM does:

- Provides pending change notifications for engineers and production personnel.
- Tracks approvals for changes.
- Provides engineering changes to in-process work orders for manufactured parts.
- Prevents certain transactions against in-process work orders when changes are pending.
- Maintains a comprehensive audit trail of changes and approvals.
- Allows secure manufacturing repeatability
- Allows traceability of ECN/ECR/ECO documents
- Maintains drawing and product specification revisions
- Maintains parts and materials lists
- Provides product change notifications
- Provides flow charts

Automating the ECM Process

The initial review process can be automated in a number of ways. For example, an engineer could initiate an ECN by getting an electronic copy of the document that needs to be changed (e.g., a drawing or specification). ECNs (Engineering Change Notifications) may be improvements — not a full-scale revision — to a previously approved specification. After proposed changes are made to the document, it could be sent on a collaboration route to those who need to review it and/or provide feedback.

In initiating ECRs (Engineering Change Requests), the workflow drives the users directly to the associated documents and their markups. ECRs define the acceptance of an engineering change notification that is approved. An automated system allows the recipient to collaborate with the originator and resolve questions immediately. The recipient can easily check out the document for changes, make the changes using the native application, and then check in the revised document. When the changes are complete, the work can be automatically routed to the designated participants for review and approval and the continuing release process.

After all the responsible parties have approved the changes, the ECR can be converted into an Engineering Change Order (ECO). Only then can the physical change of the affected parts be made. The ECM process could also include implementation steps to ensure that approved changes are incorporated, documents are released, training has been completed, bill of materials (BOM) has been updated, etc. Implementation steps ensure that the original intent of the approved ECR has been effectively followed through.

Conclusion

An effective engineering change management system is critical to maintaining quality standards and ensuring FDA and ISO compliance. Companies that rely on a “work-around” — an alternate process used when problems arise — may get the job done, but runs the risk of compromising product quality. By using a work-around, it is easy for employees to break rules and policies. The result: an entire organization’s product quality may be jeopardized.

Implementing a Web-based ECM not only allows manufacturers to streamline workflow processes, but establishes control over these processes. An electronic ECM sets a standard for the workflow, so enforcement is not the sole responsibility of the manager. The entire system (not just the manager) will ensure that every step of the process is performed accurately and consistently.

When choosing a Web-based software solution, find a system that’s flexible enough to configure a variety of change tasks and decentralize the roles and responsibilities of approvers and administrators. It should be able to automate the notification and approval processes, tracking, reporting, and provide a secure audit trail. Select an integrated system that will connect all of your quality data, processes, and teams to ensure compliance.

Glossary

- **Engineering Documents** - Documentation relating to the design, manufacture, procurement, test, inspection (if applicable), of an item or items or system as well as procedures that may be required to support the program’s hardware procurement, build, test and site delivery phases.
- **Released** - Released engineering documentation is data that has been reviewed and approved by project review process.
- **Effective** - Effective engineering documentation is data that has been released and approved and is available to all users.
- **Expiration** - Expiration engineering documentation is data that has met a defined archive date and/or is replaced by a newer revision.
- **Approval** - Program designated members review and approve, engineering documentation, and changes thereto, prior to use in procurement, manufacture, assembly, installation, test, or inspection of an item or system intended to be delivered to a site or retrofit or repair an item or system previously delivered to a site.
- **Redlines** - The markup of drawings to show how portions of the engineering documentation are to be revised. These markups may be made on hardcopies of the drawings and electronically scanned and linked to Web ECO documentation package. Markups may also be done electronically with Adobe Acrobat and other such Web markup/viewing programs for CAD and word-processed documentation.
- **PDF Format** – A document-viewing format (portable document format) that may be viewed and printed with its original appearance preserved with Acrobat Reader (Adobe Systems Incorporated). It is available free from their Web site. An Adobe Acrobat application may be purchased which includes modules that allow a user to electronically markup a document in the PDF format, and then distribute it for viewing and printing on any system, to streamline workflow.
- **Database** - An SQL data management application that maintains data and generates reports about parts, bill-of-materials, drawings, software code, files, and specifications used in the SMA project. Users may search this information system and produce reports that may be viewed with a web browser and printed.

- **Drawing Library** - A hierarchical computer filing system where all electronic files of engineering drawings, software code, and documentation are stored.

The MasterControl Solution

The MasterControl[™] quality management software solution offers a holistic approach in improving the ECM process. It interconnects data, processes, and people to promote efficiency across an organization. MasterControl's integrated software modules are configurable, easy to use, and designed to help companies maintain compliance by effectively managing change control, training control, audits, corrective/preventive action (CAPA), and other forms-based quality processes under a single Web-based platform. MasterControl offers comprehensive technical and customer support, including product training, installation, implementation, and full-cycle validation services.

- **MasterControl Portal[™]** – Provides a Web-based foundation for all MasterControl applications. It offers easy access through the Internet for all authorized users. It ensures security through encrypted passwords, automatic password expiration, intruder lockout, and dual signatures for login and approval.
- **MasterControl Documents[™]** – This core module within the MasterControl suite provides control for all types of documents regardless of the software used to create them. It also offers capabilities for: revision control to ensure current version of a document is used, advanced routing, automatic e-mail notification, time-based escalation of tasks, secure and time-stamped audit trail, tracking, reporting, and business analytics.
- **MasterControl Forms[™] and MasterControl CAPA[™]** – These closely related applications offer out-of-the-box configurations that can be used as is or customized to help manage forms-based quality processes such as audits, out of specifications, nonconformances, deviations, customer complaints, and corrective/preventive action (CAPA).
- **MasterControl Training[™]** – This innovative module provides the tool for managing role-based training requirements that are critical to compliance. It allows deployment of simple or extensive training courses that will require users to learn their duties and demonstrate their proficiency through exams. When integrated with MasterControl Documents, it can trigger training tasks related to engineering change or any modification in SOPs, policy, and other quality-related documents.
- **MasterControl Collaboration[™]** – A solution that connects people and teams, regardless of their location. MasterControl Collaboration is an effective tool for sharing ideas. It allows users to view everybody's input to avoid duplication of corrections. This module simplifies teamwork and strengthens collaborative initiatives.
- **MasterControl Submissions[™]** – This product has all the necessary features for submission of electronic records and signatures to ensure compliance with FDA 21 CFR Part 11. It offers templates that conform to formats approved by various FDA centers. With just a click of a mouse, you can format submissions for New Drug Applications (NDA), Biologic Licensing Applications (BLA), Common Technical Document (CTD), and Investigational New Drug (IND).

Other MasterControl White Papers

In addition to this white paper, other complimentary papers can be downloaded by contacting MasterControl Inc. at 800-825-9117. A few of these include:

- Corrective and Preventive Actions (CAPA) – Does your CAPA system need a CAPA?
- Automating Paper-based Document Control and Change Management Processes
- Automating Paper-based Training Control Processes

- Validating Software Systems in FDA GxP Environments

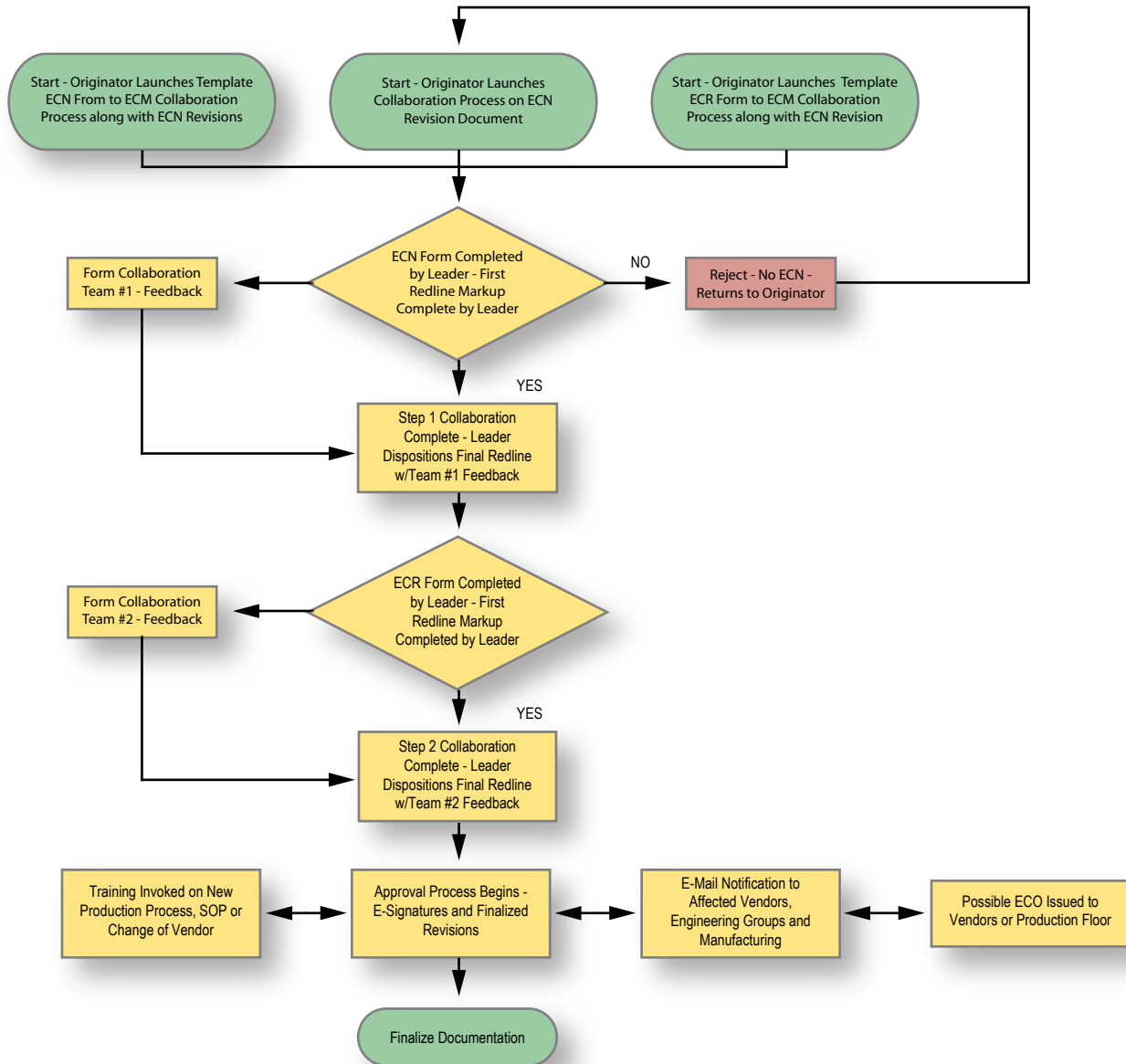
Related Acronyms Used in the Engineering Industry

ATD	Available-to-Deliver	ECO	Engineering Change Order
ATO	Assemble-to-Order	EDM	Electronic Data Management
AVL	Approve-Vendor List	EDMS	Electronic Data Management Systems
BOM	Bill of Materials		EDMS Engineering Document Mgmt System
BTP	Build-to-Order	EIM	Enterprise Information Management
CAD	Computer-Aided Design	EMD	Engineering, Manufacturing, Design
CAE	Computer-Aided Engineering	FCO	Field-Change Order
CBT	Computer-based Training	MCAD	Mechanical Computer-aided Design
CGMP	Current Good Manufacturing Practices	MOC	Management of Change
CM	Configuration Management	MRP	Materials Requirements Planning
COTS	Commercial Off-the-Shelf	OCM	Order Change Management
CRB	Change Review Board	PCM	Product Change Management
DM	Document Management	PLM	Product-lifecycle Management
DMS	Data Management System	PDM	Product Development Management
ECM	Engineering Change Management	PSM	Process Safety Management
ECR	Engineering Change Request	SOP	Standard Operating Procedure
ECN	Engineering Change Notice	TQM	Total Quality Management

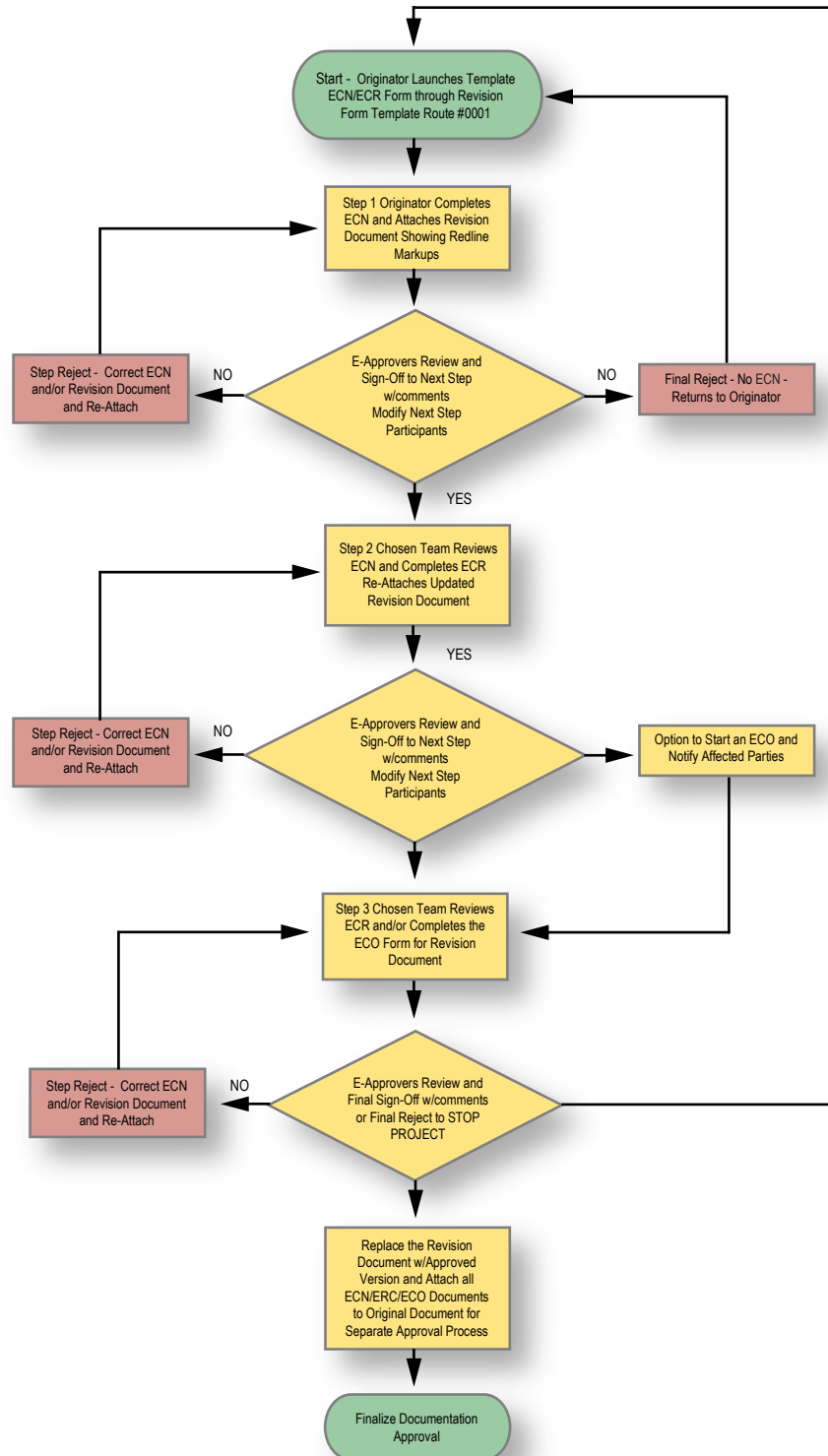
Typical Flow Processes for ECM

These flow diagrams represent two typical scenarios that can be used in the Web-based ECM system environment, the first is an e-document control flow, with or w/o e-collaboration and the other is using an integrated e-forms process that consolidates all of the interactions within the process, where departments, vendors, and linked revision changes are managed within the document system via a closed controlled work flow process. Here, forms are filled on-line, attachments and linked revisions become part of the final forms data collection and recordkeeping. Both have major advantages over paper documentation with the e-forms having the most attributes and advantages. This is where the true power of e-forms works to control every step of the ECM process.

Web-Based ECM COLLABORATIVE PROCESS (not using e-forms)



Web-Based ECM PROCESS (using e-forms)



Related Videos



MasterControl as a Company-Wide Solution



Gaining a Competitive Advantage with MasterControl

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).



MasterControl Inc.

Corporate Headquarters:

MasterControl Inc.

6322 S. 3000 E. Ste. 110

Salt Lake City, UT 84121

United States

Phone: 800.825.9117

Fax: 801.942.7088

www.mastercontrol.com

Asian Headquarters:

MasterControl KK

Aios Akihabara 702

3-2-2 Ueno Taito-ku

Tokyo 110-0005

Japan

Phone: +81 (3) 6801 6147

Fax: +81 (3) 6801 6148

www.mastercontrol.co.jp

European Headquarters:

MasterControl Global Limited

First Floor North Wing

Matrix House

Basing View

Basingstoke

RG21 4FF

United Kingdom

Phone: +44 (0) 1256 325 949

Fax: +44 (0) 1256 325 289

www.mastercontrolglobal.co.uk

Germany Office

Mendelstrasse 11

48149 Muenster

Germany

Phone: +49 (0) 251 980 2140

Fax: +49 (0) 251 980 2149

www.mastercontrol-global.de

Email: info@mastercontrol.com