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White Paper:

Engineering and Quality Teams
in Medical Device Firms:
Can We All Get Along?

Reducing Risk with MasterControl



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Introduction

“Can we all get along?” This was the line made famous by Rodney King, the African-American taxi driver beaten by Los Angeles police officers, in his appeal for calm during the 1992 Los Angeles riots. The violence broke out after the acquittal of four officers charged with using excessive force when they stopped King for speeding. The riots lasted six days, causing nearly \$1 billion in financial losses.

While lack of cooperation between product development engineers and quality professionals in medical device firms doesn't cause nearly as much damage as the L.A. riots, it does cost their firms untold delays and inefficiencies that can translate into millions of dollars during the course of product development.

Product development (PD) professionals, especially engineers, are the innovators in medical device firms and the driving force behind new products. Their overriding goal is to gain competitive advantage by getting to market as soon as possible. On the other hand, quality professionals are responsible for compliance with U.S. Food and Drug Administration (FDA) requirements, as well as with other regulations and quality standards. Sometimes compliance gets in the way of a timely product launch. Oftentimes the product development team equates the role of the quality group as that of a “policeman”; it considers compliance in general as just another obstacle on the arduous road to product launch.

The mission of PD engineers is seemingly at odds with the goal of quality professionals but is discord inevitable? This white paper will show you that the answer is no. Cooperation between the two camps is not only necessary but possible. This white paper will show you how the [MasterControl™ GxP process and document management software solution](#) can facilitate collaboration between product development and quality teams, and among various teams within the firm.

Product Development Professionals

This group is composed primarily of engineers and marketing product managers. Their job is to create the next big thing in medical devices—or at least something better than the closest competing product. Cutthroat global competition and shortened product life cycles bring enormous pressure on this team to create medical devices that offer more features and more benefits in a shorter amount of time.

To appreciate PD professionals, consider some of their responsibilities:

- **Identify Customer and Market Needs:** The team must proactively seek what customers need either by direct communication or by scouring existing studies, surveys, journals, and reports pertaining to the market being targeted.
- **Perform Competitive Analysis and Benchmarking:** It is not enough to identify a customer need. The team also must conduct competitive product analysis using benchmarking methodologies to answer the following questions: Who are our competitors? What are the similarities and differences

between their medical device and what we want to develop? What are the strengths and weaknesses of competing products? What are their prices and how much are we going to charge for our product? How are we going to compete?

- **Concept Generation and Preliminary Testing:** The team will generate as many ideas as possible through brainstorming sessions. Later it will refine ideas through an iterative selection process. After concepts have been narrowed down, the team will test market acceptance of those concepts through focus groups or customer interviews.
- **Taking the Product from Concept to Market:** This is the heart of the product development process, when the team collaborates with the rest of the firm in a concerted effort to address the customer need that has been identified. It is the time to translate the final concept that was developed earlier into a product that meets user requirements and can be sold successfully in the market.
- **Risk Analysis and Ongoing Production Support:** Risks must be mitigated primarily in the inherent product design. If there are design limitations, risks must be reduced through protection mechanisms. A common form of risk analysis is the Failure Modes and Effects Analysis (FMEA).
- **Product Derivatives and Line Expansions:** To maximize return on investment, the team will explore product derivatives, or start derivative development if it was planned from the start. A derivative could be as simple as a product improvement suggested by users, or it could be an entire line of related products that capitalize on the technology or platform developed for manufacturing the original product.

Quality Professionals

The primary goal of the quality team is compliance. This is a daunting task because the medical device industry, like other life sciences sectors, is heavily regulated. Medical device firms are subjected to numerous regulations in the United States ([FDA GMPs](#)) and overseas ([ISO](#), [CE marking](#)). It is not uncommon for the quality group to be divided into various sub-specialties such as quality assurance, quality engineering, supplier quality, and field assurance to achieve the highest level of compliance-readiness. What may be seen by others as the team's police-like role stems from what is known in the industry as FUD—fear, uncertainty and doubt—a natural collective reaction for professionals who must continuously uncover and resolve issues.

Despite the common misgivings about the quality team, nobody can discount the importance of its role in the overall success of any medical device firm. To appreciate quality professionals, consider some of their responsibilities:

- **Manage Company Policies and Procedures:** The team is responsible for managing and in many cases writing company policies and procedures pertaining to all aspects of product quality. It is not enough to write sound quality policies and procedures the team also must make sure that

such policies are in harmony with all applicable regulations, including the FDA's Quality System Regulation or QSR (also known as 21 CFR Part 820) and various ISO international quality standards (ISO 9000, ISO 13485).

- **Conduct Internal Audits for Compliance:** The team conducts regular compliance audits to ensure that activities have been performed properly and in accordance with approved procedures.
- **Perform Statistical Analysis and Risk Management:** The team implements quality control through statistically driven testing and analysis, such as statistical process control (SPC), statistical quality control (SQC) or other methods. Statistical analysis, however, is but a small part of a medical device firm's risk management system, which is responsible for identifying, controlling, and preventing product failures that can result in health hazards for users or patients.
- **Coordination of Recall Efforts:** When a product is recalled, the quality team will spearhead all activities pertaining to the initiative, including generating appropriate explanation for the recall, communicating such information to customers, and reporting results of the recall and other pertinent information to the FDA and other regulatory agencies involved.
- **Customer-Complaint Handling and Reporting:** The reporting of customer complaints, especially side effects or adverse events, is incorporated in FDA regulations. Customer-complaint handling and the requisite reporting to the FDA constitute an important responsibility for the quality team.
- **Manage Corrective and Preventive Action (CAPA) Efforts:** In both FDA and ISO environments, a CAPA program is required to address noncompliance in a timely manner and to avoid future problems. The quality team typically manages the program, which has direct impact on regulatory compliance.
- **Manage Material Review Board (MRB) Activities:** The FDA's Quality System Regulation requires medical device firms to maintain an MRB primarily to make decisions pertaining to the use of any nonconforming products. The quality team must develop written procedures pertaining to the review and authorization of the use of nonconforming products. It must ensure that the MRB is composed of individuals knowledgeable about the nonconforming product and that the board is operating according to written procedures.

Bridging the Gap

A cross-functional team approach allows a medical device firm to bridge the gap between the product development and quality silos, with the ultimate goal of bringing new products to market faster, more efficiently and more economically. In a cross-functional team environment, efficiencies are gained and decisions are made in a timely manner by bringing together representatives from key disciplines as early as possible in the product development process. For example, PD professionals who need to work with quality procedures must be involved in developing those procedures. They must be part of the creation of quality structures to ensure that such structures are compliant but not so rigid as to hinder

product development.

While there are no hard and fast rules for implementing the cross-functional model, software solutions can facilitate collaboration among various teams. The MasterControl GxP process and document management software solution provides a system that is flexible and efficient for PD engineers and at the same time ensures compliance for the quality team.

MasterControl allows the PD and quality teams to pursue their individual expertise, and also achieve their cross-functional goals. Below are some of the benefits of using MasterControl in a multidisciplinary environment.

Provides Transparency: MasterControl Documents[™] and MasterControl Process[™] are key applications that provide transparency between PD and quality so they can collaborate, even as they pursue their separate functions. PD is concerned with project timelines, while quality is primarily concerned in ensuring that proper documentation is in place for design control. MasterControl links these two camps by automating many tasks that affect each other's work. In addition, it provides transparency beyond these two groups. Marketing, manufacturing, regulatory and sales—all part of the multidisciplinary team—can benefit from a transparent electronic system by allowing them to participate easily in all cross-functional processes.

The following are some of the features of MasterControl that allow engineers to spend more time on actual product development, and simultaneously allow the quality team to keep track of compliance-related documents without unnecessarily involving engineers:

- **Centralized Electronic Repository:** MasterControl Documents[™] provides a centralized electronic repository for all documents related to the manufacture of a product, including all PD and quality documentation. This means either group can easily search and retrieve documents. MasterControl's Organizer, similar to Windows Explorer, allows each department to maintain its documents, but at the same time allows documents to reside in multiple Organizers.
- **Internet-Based Platform:** MasterControl's Internet-based platform gives employees in different locations or time zones access online. It makes cross-functional review and other documents-based and forms-based collaboration possible from virtually anywhere.
- **Automatic Routing, Escalation, Approval:** MasterControl Documents automates all documents-based tasks, while MasterControl Process automates all forms-based tasks. Automation includes routing, tracking, escalation, review, and approval of documents and forms. The capability to review and approve documents electronically speeds up the approval process significantly.
- **Advanced Tracking:** MasterControl Documents tracks documents by status or history and MasterControl Process does the same with forms. If tracked by status, a document or form will show either as "in process" or "complete." If tracked by revision or approval history, it will identify

the people who have reviewed it and when.

Makes Collaboration Easier: The earlier PD and quality collaborate, the better. While quality's role is deemed critical toward the middle and the end of the product development process, getting the team involved with risk assessment early on, such as analysis of complaints and field data of similar medical devices, will greatly benefit PD in its work. In the same vein, getting PD involved with quality efforts during the post-market stage means any complaints from the field will be addressed immediately.

With MasterControl, cross-functional work is easier because it provides a virtual workspace for collaboration among different teams. Team members can review, revise or approve documents or forms at their convenience, without having to be physically present with the entire team. The system is integrated to connect not only PD and quality, but also marketing, manufacturing, regulatory, and sales teams. The following are some of the features of MasterControl that facilitate multidisciplinary collaboration throughout the product development process.

- **Integrated Framework for Project Management:** MasterControl Projects[™] unites everybody in a cross-functional team under a standardized and integrated framework that allows the coordination and tracking of all tasks, schedules and resources related to a project. MasterControl connects a project plan with corresponding tasks, so the system automatically updates the plan as soon as a document is approved or a process is completed. Furthermore, the design history file (DHF) can be populated automatically as project tasks are completed, easing the burden on product development and quality groups alike.
- **Allows Collaboration with External Parties:** MasterControl Process[™] provides electronic forms with best-practice features that prompt users with select data, making it easier to collaborate with suppliers, customers, consultants and other external parties involved in forms-based processes. MasterControl Organizers facilitate sharing of certain documents with external parties, as well as gathering their input. They will immediately find what they need in Organizers specifically created for external collaborators instead of searching the system blindly.
- **Simple and Efficient System for BOM:** MasterControl Bill of Materials[™] provides an electronic system for accurate lists of all components required to manufacture a product, a function that encompasses different teams within a firm, and therefore a key to collaboration. The system consolidates and controls all BOM iterations generated during the design process for easier exchange of data with suppliers. By giving suppliers restricted access to the system, they can make markups to design files and related BOMs.

Leverages Existing PDM Solutions: Most medical device firms use product data management (PDM) solutions to control their computer-aided design (CAD) files, but these solutions may be inadequate for their quality management needs. MasterControl PDM Connectors provide a seamless interface for effective communication and collaboration between PD engineers who use the PDM system and the

quality specialists who use MasterControl for document management. MasterControl PDM Connectors maintain regulatory compliance by ensuring that data is kept consistent between systems.

Here are some of the benefits offered by MasterControl's PDM Connectors for [Solidworks' PDMWorks™](#), [PTC's Pro/Intralink™](#) and [PTC's Windchill™](#):

- **Collaborative Redlining:** MasterControl PDM Connectors allow redlining on PDF drawings while ensuring that the PDF copy in the MasterControl system stays in sync with native files in the PDM solution.
- **Simplified Process:** MasterControl provides engineers with a straightforward tool for applying document control to CAD data in the native PDM solution where they manage CAD files. MasterControl creates PDF copies of CAD files for document control purposes such as routing, tracking, and approval.
- **Automated Process:** A MasterControl InfoCard is automatically created for every new or revised drawing at a user-defined state in the native PDM solution. The InfoCard allows automatic routing of drawings for collaboration and approval.

Offers Alternative for Small- and Medium-Sized Firms: [MasterControl DHF Jumpstart™](#) offers the best of MasterControl features in an out-of-the-box solution that is ideal for small- and medium-sized companies. It offers a configuration that jumpstarts a company's electronic design control system, drastically reducing implementation and training time, but concurrently ensuring regulatory compliance. The following are some of the features of this solution:

- **Electronic DHF:** MasterControl provides a preconfigured DHF based on industry best practices and regulatory guidelines, making it possible to quickly generate documents for design review, or an FDA or ISO inspection, or other needs.
- **Automatic Routing, Tracking, Approval:** The system automates routing, tracking, escalation and approval of design control documentation. Its electronic signature capability greatly speeds up any review process.
- **Analytics and Reporting Capability:** The system provides standard and customized reports. Design control documents can be summarized in multiple levels such as product, department, and document type.

Conclusion

In today's competitive global market, medical device firms realize that the days of a "silo" mindset are long gone. Collaboration between PD and quality, and also among marketing, manufacturing, regulatory, and sales in a cross-functional environment, is a key to more effective working practices and competitive advantage in the market.

A strong commitment from management, coupled with a willingness to invest in appropriate tools, is essential to the success of any cross-functional model. Choosing software such as MasterControl can greatly facilitate collaboration by making it easier and more efficient for all stakeholders to participate. More importantly, MasterControl can unify stakeholders as early as possible by providing a single electronic environment where good ideas are expedited and potential issues are identified immediately.

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About MasterControl

MasterControl Inc. is a global provider of GxP process, quality audit, and document management software solutions for life science companies. MasterControl[™] products are easy to use, easy to deploy, easy to validate, and easy to maintain. They incorporate industry best practices for automating and connecting every stage of the product development cycle, while facilitating regulatory compliance. By combining an integrated platform with a continuum of risk-based software validation products and services, MasterControl drives down the total cost of ownership and enables customers to extend their investment across the enterprise. Hundreds of companies, including 50 percent of the top 20 pharmaceutical enterprises, currently use MasterControl solutions for easier compliance, faster validation, and better process management. For more information about MasterControl, visit www.mastercontrol.com, or call 800-825-9117 (U.S.) or +44 118 9812838 (Europe).



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