Industry Brief

MasterControl™

6 Must-Haves for a Quality Management System (QMS)

MasterControl™

Introduction

How much does quality cost? Most companies would be hard-pressed to translate "quality" into a monetary value – that is, in real dollars and cents. What they do realize, however, is that a lack of quality could cost millions of dollars in rework, scrap, recall, or even liability lawsuits. An equally important, but more positive question is, how much does quality earn? Better quality reduces costs, but it also increases sales, brand equity, and productivity.

In regulated environments, such as those under the jurisdiction of the U.S. Food and Drug Administration (FDA) and/or International Organization for Standardization (ISO), quality is closely incorporated into regulations and standards. Quality, therefore, isn't just good business sense, but also a matter of compliance.

The FDA explicitly states that the overarching philosophy of the pharmaceutical current good manufacturing practice (CGMP) regulations is this: "Quality should be built into the product, and testing alone cannot be relied on to ensure product quality." Similarly, the ISO 9000 series of standards articulate the importance of making quality an integral part of a manufacturer's daily operations.

Six Must-Haves

The best way to build quality into a product is with an effective, connected quality management system (QMS), which serves as the foundation for long-term regulatory compliance and market success. However, not every QMS has the same capabilities and connectivity. A QMS that isn't connected to other areas of the enterprise still slows down quality processes and introduces the possibility of more human error.

The MasterControl Platform™ connects quality to every step in the product life cycle — including development, manufacturing, supplier, clinical, regulatory, and postmarket. The optimal QMS provides a level of connectivity that reduces human error and increases efficiency.

1. Enables Automation.

Even in today's business environments, where technology is ubiquitous, many companies in regulated industries continue to rely on paper-based or hybrid quality systems. While a paper-based system can be compliant, it requires more time and effort to maintain that compliant state. Every task that is automated in an electronic QMS has to be done manually when dealing with paper. That

includes routing documents for signatures, updating standard operating procedures, and locating documents for an audit or inspection.

Quality systems are complex, but manageable with a QMS that automates all quality-related tasks such as routing, tracking, escalation, review, and approval of documents and forms. This applies to standard operating procedures (SOPs), training records, electronic production records, and anything else that requires review and approval. Since these documents are all stored in the same system, a company can be constantly prepared for an audit with the most up-to-date version of each document, fully automated change control, and an electronic signature trail.

With MasterControl, this means that every time a user updates an SOP, training tasks are sent out to affected employees. Those records are also connected to MasterControl Manufacturing Excellence™, ensuring every operator on a line is fully trained.

"We're all [on] one site, and so everybody around the world is together. Now I can see the documents that Poland is working on and vice versa. We haven't had that flexibility until now."

- Matt Seitz-Paquette, North America Quality Specialist, Fagron

2. Connects All Areas of Quality Management.

If putting a dollar value on quality is difficult, breaking the concept of quality into separate compartments is even more challenging. Consider the example of a defective medical device, in which a new glucose monitor shows erroneous readings during testing. An investigation of this product would cover the entire product life cycle. The manufacturer would investigate the root cause of the problem through its corrective action/preventive action (CAPA) process.

In this example, what if the CAPA investigation showed a weakness in product design? A design change would be initiated and managed through the change control process. When the change is approved and successfully tested (and proven safe), a new training on the approved design changes would be implemented for all employees concerned, and this activity would be documented and managed through the training control process. All updates in the documentation for this product would be managed through the document control process. From this perspective, it is virtually impossible to manage each aspect of quality as a differentiated process.

MasterControl Quality Excellence™ provides connectivity on multiple levels:

- It connects the different quality processes critical in compliance, such as document control, training management, change control, CAPA, quality audit, nonconformance disposition, customer complaints, and other processes.
- It can integrate with electronic repositories that are good for storing critical documents but are incapable of controlling quality processes like training or CAPA. It enables companies to leverage their existing repositories by integrating them with robust applications without expensive custom coding.
- It allows the exchange of files and data between MasterControl applications

that control specific quality processes and enterprise systems such as enterprise resource planning (ERP) and manufacturing execution systems (MES) that are not connected to the QMS.

- Its cloud-based platform connects different departments and people – even vendors, consultants, and other authorized third parties – involved in quality control, regardless of location.

3. Provides Robust Analytics and Reporting Capabilities for Effective Management.

90% reduction in investigation cycle time for deviations and nonconformances when companies use advanced analytics.[1]

In today's competitive manufacturing environment, organizations must not only ensure product quality, but also have insight into all quality processes. Those in regulated environments, especially, need all the support they can get to see trends and understand quality issues to proactively solve problems. Their ability to adapt to changes and problems in a timely manner can make all the difference between a simple CAPA or a product recall.

Enterprise systems hold all the data you need to make smart decisions for quality and manufacturing. Unfortunately, getting that data together and analyzing it takes time, especially if you have to do that manually. Even if you're working with a digital system, Excel data dumps are a fact of life. It doesn't have to be that way, though. With connected quality data that is always up to date, all the information you need is immediately available to you.

MasterControl offers features to track, trend and report on the data within your MasterControl solution and your other enterprise solutions. MasterControl comes with out-of-the-box reports, but users can also use a simple drag-and-drop interface to build their own. The level of granularity is also flexible, allowing you to see a broad overview or drill down into the details of the data. MasterControl can even use predictive and prescriptive analytics to tell you how to improve the quality on a line or the root cause of a problem.

4. Flexible and Scalable to Support Change and Growth.

Automating a quality system is a major endeavor in terms of time, effort, and cost. Rather than be forced to revamp their system often, organizations choosing a QMS should take into consideration how the system would support future growth at three individual levels: users (by the dozens, hundreds, or thousands); business units (domestic and/or overseas); and operations (new products and services). The system must be able to adapt to changes in the market and in the regulatory environment.

The MasterControl Platform offers the flexibility and scalability for enterprise quality management across the entire enterprise — different sites and facilities, multiple business units, and different departments — no matter the organization's size.

- MasterControl's modular approach allows small startups to automate their quality processes using core applications, and then enhance the system by

adding modules as the company grows.

- For midsize companies past the startup phase, the full MasterControl Platform can help them cope with changes in the market and respond to growth opportunities.
- For large-scale enterprises that have invested in electronic repositories and point solutions, MasterControl can integrate with these external applications to complement their functionality.

Because it is cloud-based, MasterControl can support a company with nationwide or worldwide operations, and its scalable infrastructure makes it easy to add more users and increase storage as business needs grow or change.

5. Integrates Training Into Quality Management for Continuous Improvement.

50% improvement in training cycles since UCSF Health implemented Quality Excellence.

CGMP regulations require all those engaged in product manufacturing to have the education, training, and experience necessary to do their jobs properly, including ongoing training in CGMPs. Training is similarly important in the ISO sector: the sixth quality management principle of the ISO 9000 series refers to "continual improvement."

Despite training requirements, many companies fail in this aspect, which is why training is among the top reasons for receiving an FDA Form 483. There are two reasons for this. One is that a lack of efficiency, visibility, and connectedness means company personnel are unable to perform according to industry standards. The second is that, even when employees are trained, it is difficult to find the associated paperwork that proves they were trained.

MasterControl Training™ makes continuous training easy with automated assignments, monitoring, and verifying of training tasks, as well as grading of online exams. Test results and related documentation that serve as proof of personnel competency are always ready for inspections and audits.

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.

6. Makes Continuous Validation a Strategy for Staying Compliant.

45 minutes, average upgrade validation time for MasterControl VxT users.

Companies operating in FDA-regulated industries are required to provide documented evidence that their computer systems consistently produce results meeting predetermined specifications, a practice known as validation. The FDA also requires companies to be in a constant state of validation, which generally means they must re-validate every time they upgrade or change their systems. In most cases, validation requires months to complete and produces stacks of paperwork to prove validation occurred.

MasterControl is a trailblazer in simplifying and expediting validation for our customers. The patented Validation Excellence Tool (VxT)™ uses a risk-based

approach to validation, which is what the FDA itself suggests. VxT lets users assess the risk to their business based on their individual usage of the software. By relying on MasterControl-provided documentation and only doing additional testing for high-risk features, validation can be a matter of hours or even minutes.

Even better than the idea of rapid validation is software that validates itself. The next generation of MasterControl products will have this ability. This will mean all the validation work is done on our end using the automated testing we run on the software. With testing built into every feature, the software is validated immediately as users complete their configuration. MasterControl also prepares the associated documentation, meaning users can demonstrate their validation to regulators with no additional work on their part.

Conclusion

Quality can be a "slippery" concept, but a solid quality management infrastructure will make it concrete and easier to attain and sustain. An effective QMS is the foundation of any regulated organization's compliance efforts. A QMS that has the above features will help companies realize maximum value for years to come.

Sources

1. "Making quality assurance smart," Tacy Foster et al. McKinsey & Company. Jan. 29, 2021.

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality, compliance, and production management software for life sciences and other regulated industries. Our mission is the same as that of our customers — to bring life-changing products to more people sooner. The MasterControl Platform helps organizations digitize, automate, and connect critical processes across the regulated product development life cycle. Learn more at www.mastercontrol.com.

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