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7 PRINCIPLES OF PRODUCT-CENTRIC QUALITY MANAGEMENT

A GUIDE FOR MEDICAL DEVICE INNOVATORS

ptc

E-BOOK

FOR MEDICAL DEVICE COMPANIES, HAVING A ROCK-SOLID APPROACH TO QUALITY IS A PREREQUISITE FOR SUCCESS AND INNOVATION

The burden on quality and operations leaders to introduce compliant and innovative medical devices to market is great. And as regulatory standards, market requirements, and device complexities have evolved, so too has the weight of the burdens these leaders face.

Unfortunately, traditional tools and staid approaches have not sufficiently lightened the load. Instead, they inadvertently add to it by promoting three key problems:

> Monitoring and measuring product and process performance are key requirements of medical device regulations.
>
> —An Nguyen, Director of Regulatory Affairs & Quality Assurance, IntraOp

1. Disconnected quality and product records
2. Persistent silos of quality, engineering, operations, and related product teams
3. Adoption of static methods to manage complex quality processes

Medical device manufacturers must overcome these issues to eliminate new product development (NPD) and new product introduction (NPI) process delays, reduce compliance risks, and remove barriers that impede innovation.

EXPEDITE READINESS FOR REGULATIONS AND REQUIREMENTS

To ensure patient safety, medical device manufacturers must establish and follow quality systems to meet requirements specified by the U.S. Food and Drug Administration (FDA). Quality systems for FDA regulated products follow current good manufacturing practices (CGMP) as laid out under FDA 21 CFR part 820. Complying with these mandates is a key objective of quality leaders, but many underestimate how significantly their work impacts other teams.

More companies involved with design, production, installation, and servicing of medical devices are expected to demonstrate their quality management processes by following the internationally agreed standard, ISO 13485, which specifies requirements for quality management systems. It's important to note that in the newest version of the ISO standard, it places "greater emphasis on risk management and risk-based decision-making for processes that extend beyond the realm of product realization."

These primary objectives bring us to two important points:

1. Efforts and actions that focus on meeting FDA and ISO standards should not be carried out or managed in isolation
2. To effectively compete, medical device manufacturers need to adopt holistic, connective QMS approaches to provide better traceability

ADDITIONAL RESOURCES

Driving Quality Across Supply Chain to Highest Levels

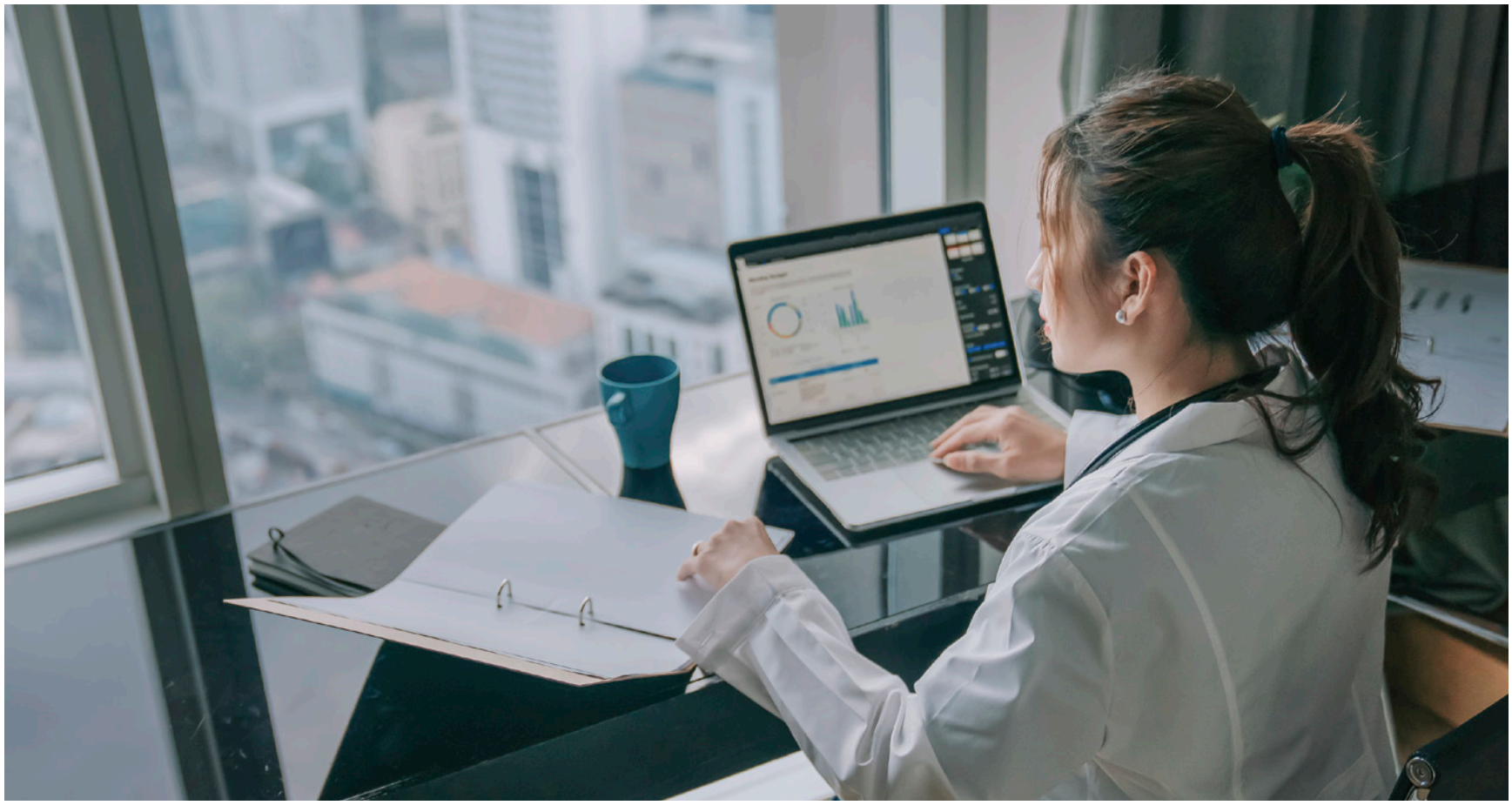
FDA – Quality System (QS) Regulation & Medical Device Good Manufacturing Practices

ISO 13485 – Medical Devices

Orthopedic Design & Technology – A Risk-Based Approach to QMS

Organizations that exemplify these points see quality as important beyond just compliance—setting the stage for continuous improvement, a learning culture, supply chain collaboration, and greater customer satisfaction.

Let's look closer at how quality and operations leaders can help their teams and their organizations realize these rewards.



GO BEYOND THE LIMITATIONS OF DOCUMENT-CENTRIC QMS APPROACHES

Simply Put, Document-Centric QMS Falls Short

For medical device companies, document control is critical to success. Despite that absolute, traditional stand-alone QMS systems address only a subset of what's needed, focusing only on two fundamental areas of FDA compliance:

1. Documentation control for SOPs, specifications, and other files
2. Process enablement and tracking for auditable processes (including CAPA, requirements management, and training records)

While the automation of paper-based processes is helpful, that function alone fails to capture or connect quality management processes to the comprehensive product record often comprised of hundreds if not thousands of mechanical, electrical, and software components; assembly and test procedures; and other documents specified in a product's bill of materials (BOM).

Traditional document-centric QMS approaches may suffice for some life sciences companies that don't have complex products. However, medical device companies that develop products with a mix of electrical, software, and mechanical components must bring cross-functional teams and designs together to prevent product issues from arising too late in the NPI process.They must also provide traceability between all aspects of the design and quality elements and be able to track, control, and release product design changes to market quickly and effectively. And, they must be able to address product failures to identify, analyze, and resolve issues. Let's look deeper.

READ MORE

Determining the right type of quality management system for your needs

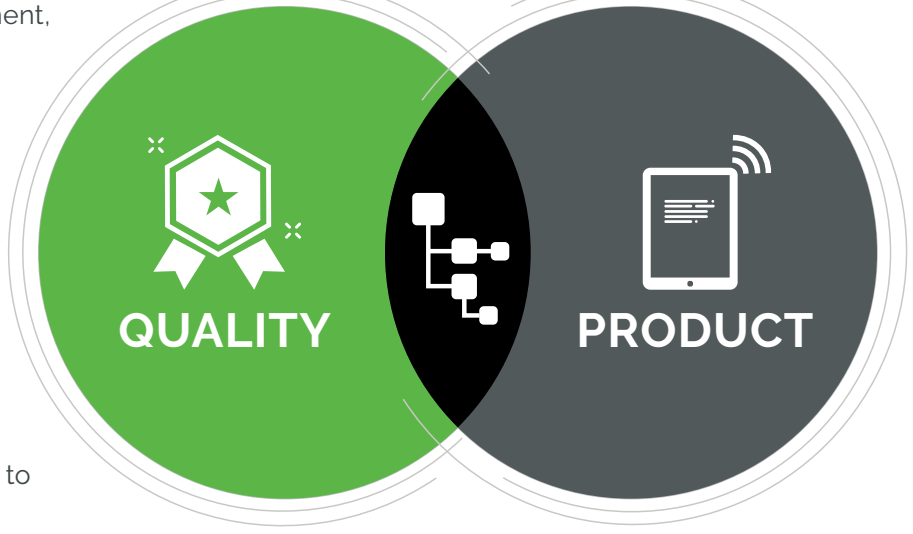
Realize the Benefits of Product-Centric QMS

While still providing the benefits of automated document management, a product-centric approach to QMS is advantageous because it enables complete control throughout your new product development and introduction (NPDI) process.

Arena QMS achieves this by aggregating the entire product record and connecting it to quality processes within a single system. At the heart of every medical device company's product is a complex, relational BOM specifying hundreds or thousands of interrelated components, subassemblies, and associated documents required to test, build, and ship your products to market. This approach addresses quality system requirements in a more traceable, controlled, and connected manner allowing all teams to view the design and related quality records without having to refer to multiple disconnected systems.

The benefits are significant:

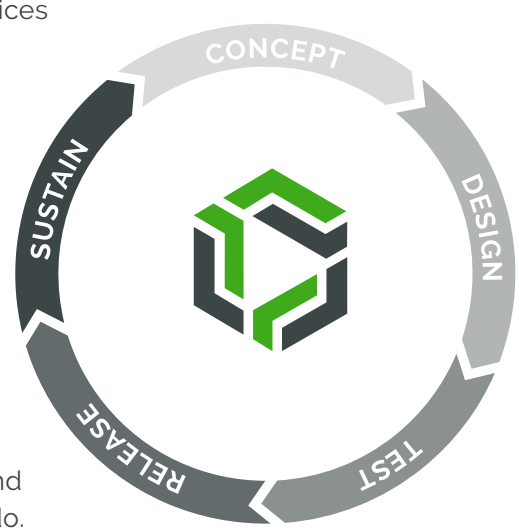
- Acceleration of your product launch process
- Streamlined regulatory compliance
- On-time shipment of reliable, high-quality products
- Tighter control of your product design
- Reduced costs and improved compliance
- A common platform enabling cross-functional team collaboration and continuous improvement



> A product-centric QMS solution enables complete control and traceability throughout the new product development and introduction (NPDI) process with unified quality and product record management.

ASSURE QUALITY AND PRODUCT-CENTRICITY THROUGHOUT NPDI

Quality should never be considered something that ceases upon initial compliance to regulations or even upon delivery of products to market. Continuous improvement is key to improve processes and products. Establishing practices that ensure devices are safe and effective requires a multidisciplinary approach spanning design, development, production, installation, and servicing of all finished devices. Product-centric QMS provides the BOM foundation necessary to manage quality and training records in context with the product record throughout the entire NPDI process.

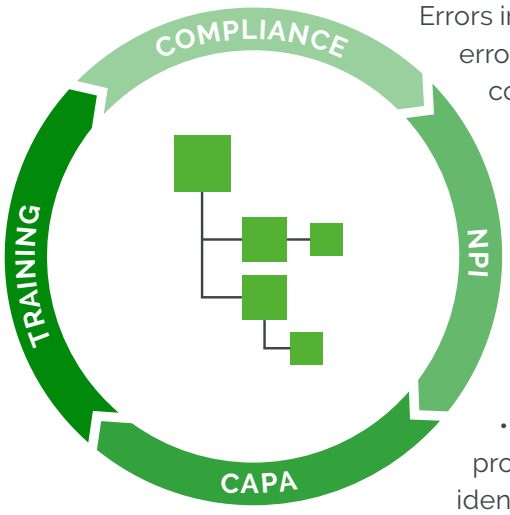


For an organization to deliver high-quality products that 1) meet regulatory and market demands and 2) lead in innovation—quality, operations, and related teams must be able to:

- Seamlessly advance their respective objectives in a shared environment
- Maintain constant traceability, control, and visibility of the product record
- Quickly understand and address the impacts that actions in one area may have on another

It's important to remember that quality issues can arise during any and all phases of a product's lifecycle. Successful organizations maintain persistent connection between the product record and quality at all times to prevent issues from arising in the first place or accelerate resolution if they do.

DRIVE CLOSED-LOOP CAPA PROCESSES THAT TIE TO THE PRODUCT RECORD



Errors in medical devices can bring about harmful and sometimes fatal consequences. Preventing such errors from occuring was the impetus for the FDA's requirement of medical device manufacturing companies to establish and document corrective and preventive action (CAPA) processes as detailed in 21 CFR 820.100.

Most medical device manufacturers have closed-loop CAPA processes in place. However, they are often poorly defined, inconsistently applied, and/or are dangerously disconnected from the product record. Here's why having a solid closed-loop CAPA process is important:

- Inconsistent, incomplete CAPA processes leave organizations vulnerable to undesired risk and audit impacts—FDA warning letters, 483 observations, legal consequences, and customer satisfaction issues.
- A single quality issue may affect many products and stakeholder groups. Disconnected CAPA processes mean repetition of actions and reliance on tribal knowledge and ad hoc processes to identify, address, and correct issues.

ANALYZE
INVESTIGATE
IDENTIFY
VERIFY & VALIDATE
IMPLEMENT
DISSEMINATE
REVIEW
RECORD

HOW CAN YOU OPTIMIZE CLOSED-LOOP CAPA PROCESSES?

- Provide easy access and traceability to all teams to streamline the investigation of issues and speed resolution.
- Link quality records and CAPA processes to the affected product record, providing a unified quality and product process to identify, analyze, and resolve issues quickly and effectively.
- Ensure that issue resolution can be launched and referenced directly from the quality issue with a corrective action request (CAR). The ability to spawn engineering change orders (ECOs) at the end of the CAPA process creates a unified system approach to closing the loop on changes to design, documentation, packaging, or manufacturing processes.

LEARN MORE

How connected closed-loop CAPA processes help ensure safer devices

BRING DISCONNECTED TEAMS AND SILOED SYSTEMS TOGETHER

Many companies develop or implement systems as they grow from young start-ups to more mature companies. This approach typically involves use of point solutions like Microsoft Word, Google documents, email, spreadsheets, network servers, file services, CAD design systems, or other homegrown solutions. This creates a patch-quilt system of silos to manage product and quality records. And, these systems lack a single controlled place to manage all related records by impacted teams.

What does working in disconnected silos look like?

- Mechanical, electrical, and software engineers design in different tools that are used by their individual teams
- Quality teams use document management or other quality management tools that are controlled and accessible only within their workgroup
- Manufacturing and customer support teams use a variety of systems to handle planning, sourcing, and service
- All of these teams have to rely on passing or sharing information via email, shared servers, or cloud storage

These disconnected silos make it difficult, if not impossible, to identify the latest design and track quality or manufacturing issues. Furthermore, executive management teams cannot get a complete picture regarding NPDI process performance and risks.

TEAM AND SUPPLY CHAIN SYNERGY

Medical device companies today rely on distributed teams of experts to design, manufacture, and support their products. These experts can be direct employees, design partners, contract manufacturers, suppliers, or other contractors. Keeping these distributed teams aligned requires a single, connected solution. Without a single unified system, you will experience:

- Difficulty identifying the latest revision of designs and confusion about which system has accurate information
- Lack of visibility regarding product changes, compliance, sourcing issues, and manufacturing challenges

This disconnect typically results in product design delays, production problems, and increased product costs caused by scrap, rework, and resolution late in the NPDI process.

> When quality records are connected to the product record, the result is a shared, controlled, and unified view throughout the NPDI process. This fosters effective collaboration and faster iterations to deliver high-quality products on time and under budget.

READ MORE

Connecting distributed teams in an era of accelerating innovation

MAINTAIN TRACEABILITY AND TRANSPARENCY AT ALL TIMES

Addressing Quality Issues Quickly and With Confidence

With products that focus on patient health, it is imperative to be able to identify, track, analyze, and resolve issues quickly and effectively. Many companies rely on tribal knowledge and manual or siloed processes that introduce communication delays or risk of human error. The best approach is for companies to be proactively prepared to:

- Confidently and efficiently trace issues back through design
- Quickly identify causes and remedies of the immediate issue
- Prevent issues from recurring with other patients or markets
- Avoid the impacts of recalls, field service repairs, and elevated risk exposure

Avoiding the Agony of Audits

Audits are a constant reality for medical device manufacturers and drive the critical need for traceability and transparency. How well a team performs during internal or external audits can determine not only the success of the product, but sometimes a company's very existence. Having the full product design history and all quality records tracked in the same system gives everyone the confidence to respond to audits effectively.

REDUCE THE PAINS AND PRICE OF SOFTWARE VALIDATION

Medical device companies are required to validate enterprise software that is part of the quality system to ensure all functionality meets the software's intended use. Detailed in 21 CFR 820.70(i) and 21 CFR 11.10(a), these multilayered requirements can have a major impact on business operations in the form of high costs and significant time demands on team members.

Many organizations find the process so punitive, in fact, that they choose not to install updates, upgrades, and bug fixes at all. Those decisions lead to a dangerous mismatch of cutting-edge technologies being managed by old, outdated enterprise software.

CHALLENGE:

How can medical device companies benefit from software updates and make the validation better?

Arena Validate simplifies validation so that organizations can reduce costs and the work required by internal quality and regulatory teams. This straightforward approach is comprised of three steps:

STEP 1

Each Arena release is thoroughly validated against a predefined set of intended uses common to all medical device manufacturers.

STEP 2

Arena distributes the full results of the validation testing to all validation subscribers.

STEP 3

Arena customers can then leverage 100% of the enhancements to yield additional benefits.

Arena Validate Benefits

- ☑ Reduces time and costs associated with developing and executing test cases
- ☑ Provides customer time to evaluate the scope of upcoming release to assess the impact—no surprises on Arena releases
- ☑ Continuing benefits of validation documentation for ongoing Arena releases
- ☑ Ensures ongoing validation support

LEARN MORE

Learn more about Arena Validate

SETTING THE STAGE FOR SUCCESS AND INNOVATION

The burden placed on quality and operations leaders to introduce compliant and innovative medical devices is significant. Medical device manufacturers can reduce this burden and at the same time improve quality and product realization by following two principles.

Efforts and actions that focus on meeting FDA regulations and ISO standards should not be carried out or managed in isolation.

To effectively compete, medical device manufacturers need to adopt holistic, connective approaches and tools for managing quality processes.

Regulated companies around the world are reaping the rewards of product-centric QMS to:

- Accelerate NPDI processes and get high-quality products to market fast
- Expedite readiness for regulations and requirements
- Go beyond the limitations of document-centric approaches to QMS
- Assure quality and product-centricity throughout NPD and NPI
- Drive closed-loop CAPA processes that tie to the product record
- Connect systems and eliminate disconnected teams and silos
- Maintain traceability and transparency at all times
- Reduce the pains and price of software validation

HELPING INNOVATIVE COMPANIES CHANGE THE WORLD

At Arena, we help you design, produce, and deliver complex medical device products to market by connecting your product record, quality processes, and supply chain partners. This helps you create innovative, safe products to change the world.

For more on Arena and to discover a wealth of product-centric QMS resources and best practices, visit ArenaSolutions.com.

> Arena provides everything we need in one place—product lifecycle control, quality system control, collaboration, and more. We appreciate Arena's focus on our product development and quality system needs.
>
> —Penny Dalton, Sr. Quality Systems Specialist, Nativis

SEE ARENA QMS IN ACTION

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