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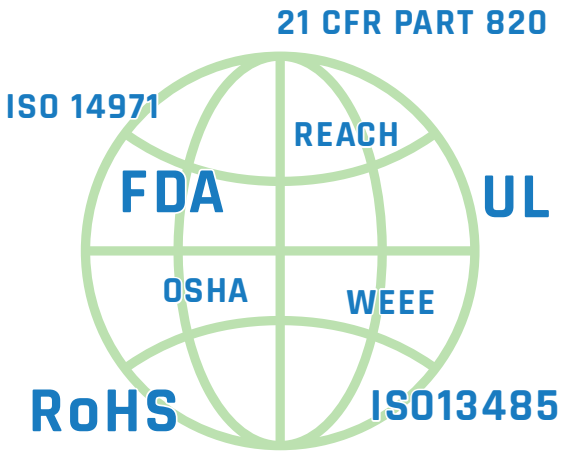
Meet Your Regulatory Compliance Requirements

How a Product-Centric Quality Management System (QMS) Improves Control, Traceability, and Compliance

WHITE PAPER

DELIVERING SAFE AND COMPLIANT MEDICAL DEVICES IS DIFFICULT



Medical device manufacturers and their supply chain partners must get their products to market quickly while facing new technological challenges, global competition, and the need to mitigate risks. Medical devices with electrical, mechanical, and software components introduce even more obstacles as companies strive to navigate the ever-evolving regulatory compliance initiatives for the FDA (e.g., 21 CFR Part 11 and Part 820), ISO (e.g., 13485, 14971), UL, OSHA, and environmental compliance (e.g., RoHS, conflict minerals).

So how can medical device manufacturers keep track of and successfully meet regulatory compliance requirements?

The best way to navigate compliance from early research and development to clinical trials and through commercialization is by keeping all of the quality and product information controlled in a single system of truth. Past approaches leveraging multiple "best of breed" solutions created silos of disconnected information that made it difficult to track the product design, quality issues, and compliance status.

For today's medical device innovators with distributed supply chains, everyone involved in designing, sourcing, testing, building, and shipping devices must have access and

visibility to ensure everyone is collaborating around the latest information. This requires quality records and processes that are linked to the product design for identification, analysis, and quick resolution of issues. Using this product-centric approach to a quality management system (QMS) gives impacted teams the ability to manage new product development and related quality actions in a single system to simplify compliance, reduce audit risks, and get safe and effective products to market.

In this white paper, we explore five keys to success for regulatory compliance:

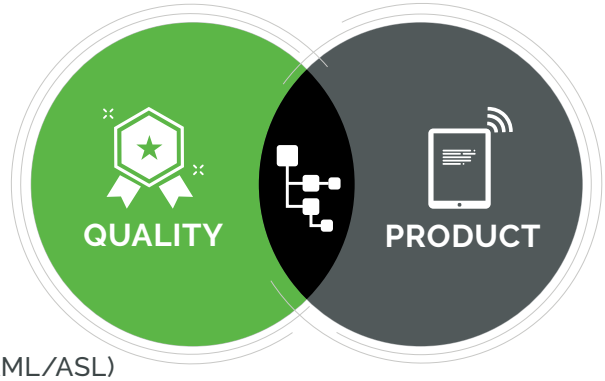
1. Why Product-Centric QMS Is Best
2. Strategic Advantages
3. Strategies for Managing Environmental Compliance
4. How to Reduce Obsolescence Risks
5. Connecting the Customer Feedback Loop

WHY PRODUCT-CENTRIC QMS IS BEST

No matter what type of product you create, you must have a controlled process to document, design, test, produce, and ship medical device products in the United States as stipulated by the FDA Title 21 CFR Part 820. Companies that wish to sell outside the U.S. need to also comply with ISO 13485. In fact, the FDA has agreed to use ISO 13485 as the basis for its quality system regulation as well.

Managing the quality and compliance processes in context to the entire product record enables a product-centric QMS approach. This keeps internal and external teams on the same page and accelerates design reviews, corrective actions, and resolution. Product-centric QMS provides better visibility, traceability, and control in these areas:

- Product record and bill of materials (BOM)
- Component compliance information
- Device master records (DMR)
- Design history files (DHF)
- Corrective action requests (CAPA)
- Design reviews
- Engineering change orders (ECO)
- Validation and verification records
- Training records
- Approved manufacturers and suppliers (AML/ASL)



Many traditional QMS solutions provide a document-centric approach, but these solutions must manage more than just documents. QMS applications must manage the complex product record and hierarchal BOM with links from every component and document to every associated quality and product record. This provides full context among the design, quality, and manufacturing teams, as well as greater access and traceability between disparate teams that engage throughout the development and commercialization process. And because this information is controlled in a single system, internal and external auditors can quickly and easily verify compliance.

STRATEGIC ADVANTAGES

With increased specialization, outsourcing, and regulatory compliance initiatives, a single unified solution to manage product and quality information provides key benefits:

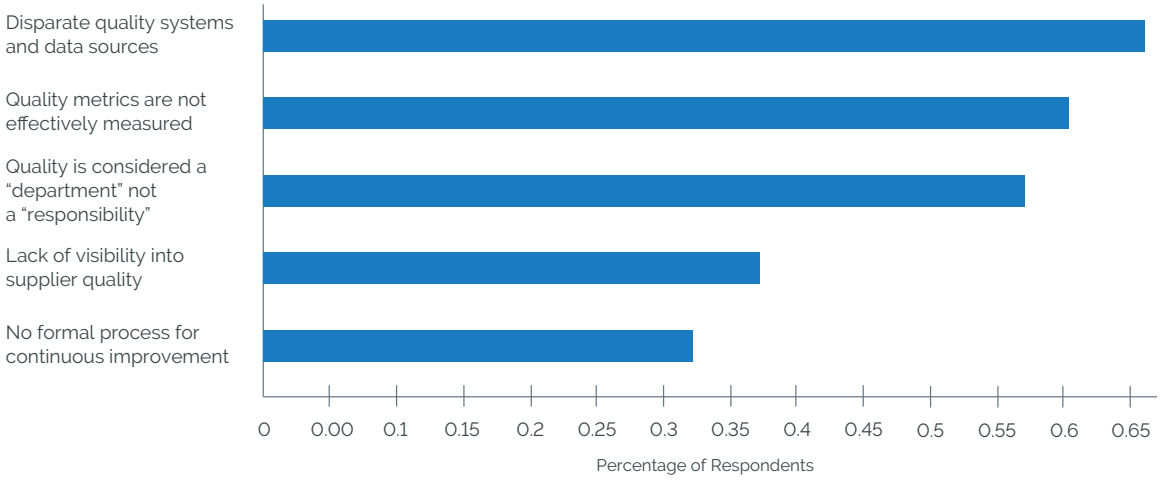
Improved Compliance
Medical device design and equipment manufacturers (ODMs/OEMs) must factor compliance throughout the new product development and introduction process. Otherwise, impacted teams will lose sight of, or have a difficult time addressing, the myriad of changing regulatory requirements.

Better Collaboration
Manufacturing, engineering, quality control, and compliance teams can more easily collaborate anytime and anywhere to reduce issues, control costs, and shorten the NPI process to gain first-mover[1] advantages in the market.

Continuous Improvement
With a single unified system, internal teams and external partners can offer critical feedback at every stage, ensuring product issues are resolved as early as possible.

Underscoring the importance of compliance, LNS Research published the results of their quality management survey. In this survey, medical device company executives ranked the ability to "better manage operational risk" and "ensuring compliance" as their top two quality management objectives. The majority of executives also noted that having disparate quality systems and data sources was a key challenge to reach their quality management objectives (see chart below).[2]

Top Quality Management Challenges



When organizations rely on disparate systems to manage quality and product development processes, they struggle to identify, analyze, and resolve quality issues in a timely and accurate manner. With a product-centric QMS solution, medical device companies eliminate confusion and silos to improve knowledge sharing, support better design processes, and provide increased visibility across all teams.

The benefits are clear, but there is more you can do to help reduce additional challenges and risks with complex medical device manufacturers.

STRATEGIES FOR MANAGING COMPLIANCE

When introducing a new medical device, ODMs and OEMs must initiate well-defined risk analysis and evaluation phases. Establishing risk management assessment processes is critical to ensure that manufacturers take into account the necessary risk analysis, evaluation, control, and corrective actions throughout new product introduction (NPI) and post-production.

Medical device companies must comply with both industry-specific and universal standards and regulations for marketing product. Industry standards and regulations include International Standards Organization (ISO) 13485, ISO 14971, Food and Drug Administration (FDA) 21 CFR Part 820, and FDA 21 CFR Part 11. Environmental standards and regulations include Restriction of Hazardous Substances (RoHS), Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Waste from Electrical and Electronic Equipment (WEEE), and conflict minerals.

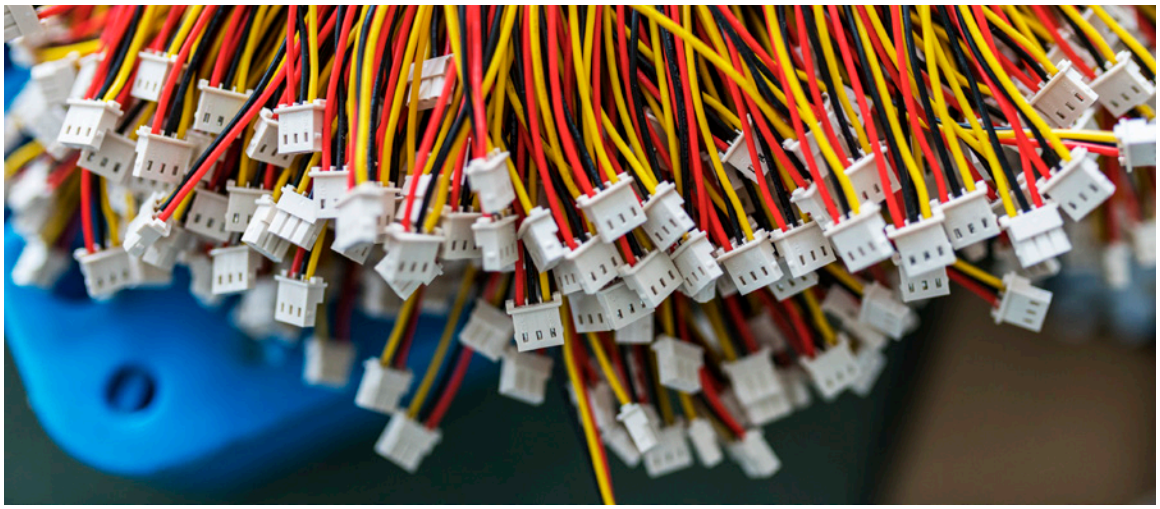
Medical Device Specific Compliance

Each medical device regulation introduces the need to establish and manage current good manufacturing practices (CGMP) to reduce risks.[3] Problems identified during the design, development, and use of a device can often be eliminated with the review of a medical device company's multidisciplinary team. A product-centric QMS solution simplifies compliance by providing every team visibility to all processes, and enabling them to collaborate in real time to address design or production issues.

Teams participating in the risk assessment and management evaluation process should consider these questions:

- What is the intended use of the product?
- Is energy or a substance delivered to or extracted from the patient?
- Is the device to be routinely cleaned or disinfected by the user?
- Are measurements taken? Is maintenance or calibration necessary?
- Is the medical device susceptible to environmental influences?
- Does the medical device have software?
- Does the product have a shelf life, and what determines its useful life?
- Does product installation or use require special training?

Once the risk elements and hazards of the product design are identified, an analysis of each element can be performed.



Environmental Compliance

RoHS, REACH, WEEE, and conflict minerals

Any business, including medical device companies, that sells applicable electrical or electronic products, equipment, sub-assemblies, cables, components, or spare parts directly to RoHS (Restriction of Hazardous Substances) countries, or sells to resellers, distributors, or integrators that in turn sell products to these countries, is impacted if they use any of the restricted 10 substances. A component database integrated with their product-centric QMS solution helps medical device companies dramatically reduce environmental hazard compliance risks.

RoHS specifies maximum levels for the following 10 restricted substances. The first six applied to the original RoHS while the last four were added under RoHS 3.

- **Cadmium (Cd):** < 100 ppm
- **Lead (Pb):** < 1000 ppm
- **Mercury (Hg):** < 1000 ppm
- **Hexavalent Chromium (Cr VI):** < 1000 ppm
- **Polybrominated Biphenyls (PBB):** < 1000 ppm
- **Polybrominated Diphenyl Ethers (PBDE):** < 1000 ppm
- **Bis(2-Ethylhexyl) phthalate (DEHP):** < 1000 ppm
- **Benzyl butyl phthalate (BBP):** < 1000 ppm
- **Dibutyl phthalate (DBP):** < 1000 ppm
- **Diisobutyl phthalate (DIBP):** < 1000 ppm

Source: RoHS Guide Compliance[4]

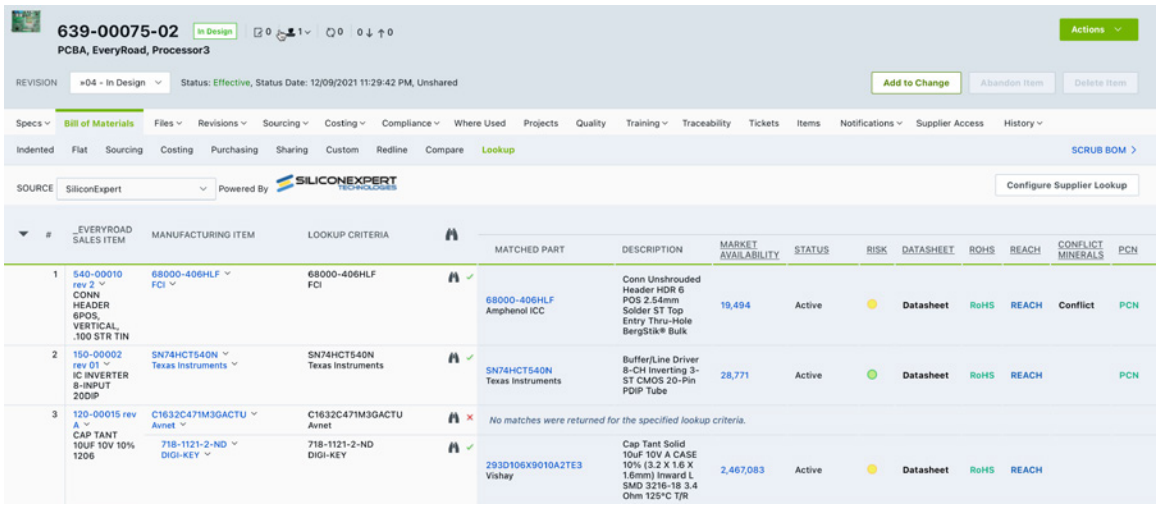
Types of hazards can include energy, biological, environmental, software, user error, labeling, complexity of use, and functional failure. In addition to the chemicals regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), medical device companies that want to sell their products globally must report on the use of certain hazardous substances per the RoHS directive.[5]

RoHS applies to a wide array of medical devices including:

- Radiotherapy equipment
- Cardiology
- Dialysis
- Pulmonary ventilators
- Nuclear medicine
- Laboratory equipment
- In-vitro diagnostic devices
- Other appliances for detecting, preventing, monitoring, treating, or alleviating illness, injury, or disability

The WEEE Directive aims to minimize the impact of electrical and electronic goods on the environment by increasing reuse and recycling to reduce the amount of waste of electrical and electrical equipment going to landfills. WEEE dovetails with RoHS efforts to reduce hazardous materials in electronics products. Category four and five medical devices are subject to recovery and recycling targets under WEEE.

In addition, responsible sourcing and reporting of conflict minerals is necessary to demonstrate due diligence. Environmental regulations are an integral part of medical device product design. Documenting and tracking the components and raw materials that are used for production must occur throughout the entire lifecycle. Because of this, OEMs, distributors, and contract manufacturers rely on component databases like SiliconExpert and Octopart to manage substance declarations. A component database is the only practical and cost-effective way to comply with ever-changing compliance mandates and frequent updates. Linking your product-centric QMS solution to these types of component databases allows you to leverage the single source of product truth and maintain environmental compliance data.[6]



Arena's Supplier Item Lookup provides regulatory and material availability information to eliminate risks to ensure compliant parts can be sourced when needed.

A component database improves product risk management and provides instant access to component documentation. When integrated into a QMS solution, component databases help medical device companies dramatically reduce environmental hazard compliance risks.

HOW TO REDUCE OBSOLESCENCE RISKS

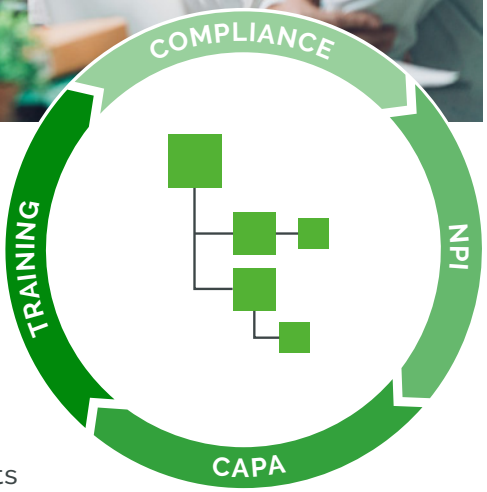
Component databases can also help with obsolescence. Choosing the right components is critical to ensure parts can be sourced locally and globally as needed. Unfortunately, many medical device companies still don't have a scalable method to identify electronic parts for functionality, availability, and compliance. Modern component databases can help gain visibility when components are going end-of-life, and thus avoid part shortages during volume production.

Being caught unaware on a part going EOL can be catastrophic, causing production and shipping delays.

Imagine having a medical device that you expect to last for three to four years. It's working well in the market and its components are readily available, but suddenly one part goes obsolete. Because of a single component, your ability to produce and ship products is at risk.

Now, you might need to find a similar part that meets your cost, compliance, and functionality goals—which is not always possible. So, you are almost certain to increase costs, delay shipments, and/or build products that are not capable of meeting the performance objectives of your original design. For regulated medical device companies that produce Class II or Class III devices, the latter is not going to be an option.

CONNECTING THE CUSTOMER FEEDBACK LOOP



We've discussed many aspects of NPD, NPI, and manufacturing. But what happens after your products ship to customers is critical as well. Many medical device companies today have processes and systems in place to identify product issues and customer complaints. However, few have integrated those systems (e.g., CRM) to capture complaints and issues and actually initiate a closed-loop CAPA management process that is tied directly to the product record.

Depending on your product, connecting the customer feedback directly from systems like Salesforce and Zendesk can help you accelerate the analysis and resolution process to save time and money. More importantly, if your product has a greater effect on patient health—then linking your complaint systems to your QMS system can save lives. Smart thermometer company Kinsa is helping to stop the spread of illness, especially during the Covid-19 pandemic, by linking their customer feedback system (Zendesk) to Arena to speed the customer feedback loop.[7]

ANALYZE
INVESTIGATE
IDENTIFY
VERIFY & VALIDATE
IMPLEMENT
DISSEMINATE
REVIEW
RECORD

CONCLUSION

Companies that rely on disparate, siloed systems face greater obstacles and risks when faced with FDA audits or, worse, with legal liability caused by shipping defective products. The volume and complexity of regulations is not going away and will likely continue to increase over time. The need to create high-quality, low-risk medical devices is crucial to success. Any impediments during the new product introduction process can impact quality, profits, or even human lives.

As you consider the best way to compete in today's global market with changing regulations, having a single source of quality and product truth is the best hedge against product realization and regulatory compliance pitfalls. So, consider Arena's cloud-based product-centric QMS as a key advantage to help you not only deliver innovative products that change the world—but also improve the quality of your customers' lives.

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