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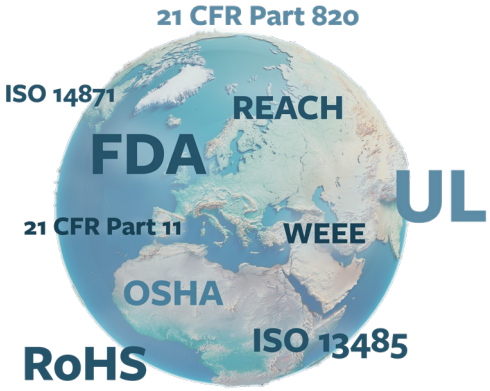
White Paper

Meeting Regulatory Compliance Requirements in Today's Global Market

How product-centric QMS increases control and visibility for medical device teams, products, and regulations

Delivering Complex Medical Devices Is Harder Than Ever



Medical device manufacturers and their supply chains 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 landscape including FDA (e.g., FDA 21 CFR Part 11 and Part 820), ISO (e.g., 13485, 14791), UL, OSHA, and environmental compliance (e.g., RoHS, REACH, conflict minerals) initiatives.

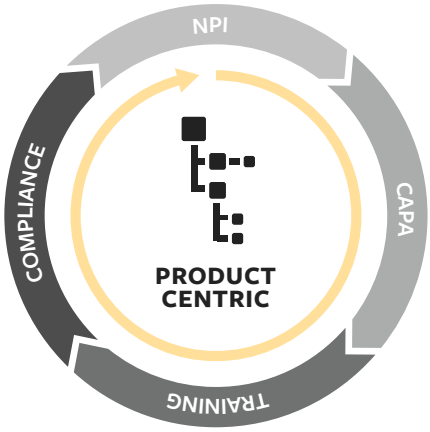
So how do medical device manufacturers address regulatory compliance?

The best way to navigate compliance from early concept phases through commercialization is with a single system of truth for all product and quality information available to internal teams and partners. Past approaches leveraging multiple "best of breed" solutions create silos of disconnected information that make it difficult to track quality and product processes.

For today's complex solutions and highly distributed supply chains, everyone involved in designing, sourcing, testing, building, and shipping medical devices must be connected in a single system. Ensuring that quality processes are linked to the product design and manufacturing process is critical for identification, analysis, and resolution of issues. This product-centric approach provides the ability to manage new product introductions in context to quality while maintaining regulatory compliance.

Competing in the global marketplace requires a modern product-centric quality management system (QMS) solution to weave the entire supply chain together, ensuring you can ship high-quality products on time and under budget. We will explore five keys to success for medical device companies:

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 design and build, you must have a controlled process to document, design, test, produce, and ship products.

Managing the entire product lifecycle and change process with a centralized product definition and automated sign-off process serves as the foundation to shorten new product development (NPD) and new product introduction (NPI) cycles.

With a centrally controlled product record, teams can work together throughout the product lifecycle. But, the effectiveness of the product launch is significantly improved when quality, corrective action preventive action (CAPA), training, and regulatory compliance can be managed in context with the product record in a single system. Product-centric QMS provides better visibility, traceability, and control over your quality and product process information including:

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

QMS solutions today must manage more than documents; they must manage the entire 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 NPD and NPI process. And because this information is tracked and visible by all key stakeholders, 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 NPD and NPI 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 addressed as early as possible.

The results of a quality management survey published by LNS Research showed medical device executives ranked the ability to "better manage operational risk" and "ensuring compliance" as the 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 top quality management objectives (see chart below).[2]

When organizations employ 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 single product-centric QMS solution, medical device companies have a unified system for product and quality. This streamlines product realization processes to improve knowledge sharing, support better design processes, and provide increased visibility from engineering to quality to operations and partners.

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 Environmental Compliance

When introducing a new medical device, ODMs and OEMs must initiate a number of 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 and post-production.

There are several industry standards and regulations to consider, including ISO 13485, ISO 14971, FDA 21 CFR Part 820, FDA 21 CFR Part 11, RoHS, REACH, WEEE, and conflict minerals. Each of these regulations introduces the need to establish and manage current good manufacturing practices (CGMP) to reduce risks.

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. Providing every team greater visibility to all processes, while also enabling them to collaborate in real time to address design or production issues, is easy with a product-centric QMS solution. 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.

Various 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, Authorization and Restriction of Chemicals), medical device companies that want to sell their products globally must now report on the use of certain hazardous substances per the RoHS directive (Restriction of Hazardous Substances).

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

Any business that sells applicable electrical or electronic products, equipment, sub-assemblies, cables, components, or spare parts directly to RoHS countries, or sells to resellers, distributors or integrators that in turn sell products to these countries, is impacted if they utilize any of the restricted 10 substances.

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.

- **Lead (Pb):** < 1000 ppm
- **Mercury (Hg):** < 100 ppm
- **Cadmium (Cd):** < 100 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 [3]

Today, environmental regulations are an integral part of medical device product design. Because of this, OEMs, distributors, and contract manufacturers now rely on modern 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 truth and maintain environmental compliance data in context to the entire product record. [4]

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.

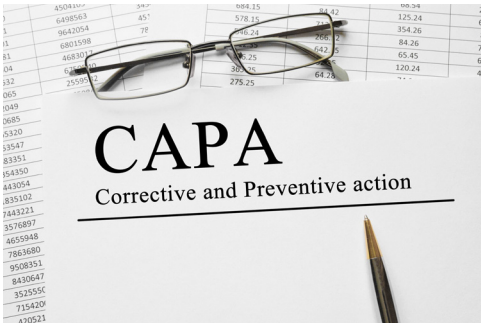
How to Reduce Obsolescence Risks

Component databases 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 loop might help you accelerate the analysis and resolution process to save time and money. But, if your product has a greater effect on patient health, then linking your complaint systems to your QMS system can save lives.

Conclusion

Companies that rely on disparate 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 a myriad of regulations, it should not surprise you that having a single source of quality and product truth is the best hedge against product realization and regulatory compliance pitfalls. So, consider Arena's leading 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.

References

[1] https://www.investopedia.com/terms/f/firstmover.asp

[2] https://www.mdtmag.com/article/2014/01/5-reasons-medical-smbs-leverage-plm-enterprise-quality-management

[3] http://www.rohsguide.com/

[4] See https://www.arenasolutions.com/pdfs/products/plm/SiliconExpert-Datasheet.pdf, https://www.arenasolutions.com/pdfs/products/plm/Octopart-Datasheet.pdf, and https://www.arenasolutions.com/pdfs/products/plm/arena-green-data-exchange.pdf

About Arena

Arena Solutions helps innovative electronic high tech and medical device companies create products that change the world. Arena unifies product lifecycle (PLM) and quality management (QMS) processes, allowing every participant throughout the product realization process from design to manufacturing to work together. With Arena, teams accelerate product development and delivery to increase profits. For more information, visit ArenaSolutions.com.

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