How to Make Your QMS Work for You

Lean QMS for Medical Devices

May 2019

Abstract & About the Author:

In the medical device industry, every company knows the necessity of a Quality Management System (QMS) for managing internal processes and tracking work to regulatory requirements. Many companies view their QMS as a necessary burden, but we aim to convince those companies to rethink that view and see their QMS as a tool to elevate and accelerate product design and development, not hinder it. We believe a QMS can become an instrument that prevents errors (and delays) by leveraging experience during development.

Velentium's Chief Technology Officer, Randy Armstrong, shows how a company can adapt their QMS to a leaner, more useful model without compromising safety. During his decades of experience designing medical devices, Randy was a U.S. delegate for ISO 14708-3 (neurostimulators) on the committee that authored the original version. He also worked on ISO 14708-4 (infusion pumps), and was the co-chair for two AAMI committees, overseeing neurosurgery and TENS devices.

Contents

Key Takeaways:

- Implementing a lean QMS is not about cutting corners; it is about corporate focus.
- Tools are continually being adapted and improved, so there may be a different “right tool” for the job, depending on the circumstances.
- A product-centric QMS is created and structured based upon the development and production of a specific product or device family.
- Simple is hard, but simple is worth it.

Introduction

In the medical device industry, every company knows the necessity of a Quality Management System (QMS) for managing internal processes and tracking work to regulatory requirements. Many companies view their QMS as a necessary burden, but we aim to convince those companies to rethink that view and see their QMS as a tool to elevate and accelerate product design and development, not hinder it. We believe a QMS can become an instrument that prevents errors (and delays) by leveraging experience during development.

A valuable QMS will not impose rules without reasons. Instead, it will train its users to follow sound principles for design and manufacturing.

With such a QMS, companies can avoid the cultural and performance loss that comes from trapping designers and team members into narrow channels and restraining their creativity. A valuable QMS incorporates all necessary elements while tolerating diversity in approach wherever appropriate. Most importantly, a valuable QMS recognizes where variability is acceptable and where it is unacceptable.

One benefit of design controls is providing processes by which designs and their impacts may be analyzed from multiple perspectives to identify flaws and correct them. A valuable consequence of this is the identification of errors early in the design process (with few exceptions, the later an error is found, the more costly its impact).

Another valuable return, often insufficiently leveraged by most quality systems, is the encouragement toward minimization both in process and in the product. As the process forces us to pick up each piece and analyze it from all perspectives, it consequently forces us to simplify designs by asking ourselves "is this feature or component absolutely necessary, or is it needlessly increasing the complexity of our design?"

The paradox is that while we work to reduce QMS burden, those burdens drive us to reduce device complexity, which will more often than not improve patient safety *and* reduce a company's development and manufacturing costs. A valuable QMS will reduce burden while incentivizing simplicity.

Finally, as connectivity and virtualization move monolithic brick-and-mortar teams into the cloud, where multiple teams or even corporations may contribute throughout the product lifecycle, a valuable QMS will leverage common language and principles (such as those from recognized standards) without emphasizing "regional" dialects, differences, or details. This becomes a critical accelerator for distributed development.

This white paper addresses these and other topics, including:

- How Velentium developed its lean QMS
- How to balance empowerment vs. control within a QMS
- Difference between a standard and a product-centric QMS
- Why "simple is hard but simple is worth it" pertains to quality systems
- How and why these concepts converge

Developing Lean QMS

Implementing a lean QMS is not about cutting corners. It is about corporate focus, which in our case means being risk-driven to create safe and effective devices as quickly and cost-effectively as possible.

When developing its QMS, Velentium made a strategic decision to focus on design controls, manufacturing, and all associated processes. We are very familiar with the requirements for submission to the FDA and EU and are continually able to produce the necessary regulatory materials to satisfy the needs of the process. Our clients generally prefer to maintain their brands and remain the "familiar friendly face" to physicians, patients, other end users, and the FDA, but we provide significant support for their submissions.

We see risk management not only as a process to follow but also as a crucial tool for maximizing value throughout the product lifecycle. Acknowledging the importance of risk management helps us focus our design and our processes around mitigating risk, which ensures that we identify negotiable and non-negotiable aspects of designs.

After all, once a device's therapy or diagnostic is designed, almost all of the remaining work revolves around protecting the patient. We believe that risk management should not be seen *just* as a way to mitigate risk within a design or process, but also as a means to illuminate the real value within the product you're creating and describe the process you will need to achieve it.

Risk management is not just a hoop to jump through; in addition to ensuring a safer device, it can and should be a real money and time saver. A valuable risk management process drives simplification into design and operations, consequently accelerating development and reducing cost.

PROPER RISK MANAGEMENT SAVES TIME AND CAPITAL!

Quality systems exist to help the design and development process, but over time they often morph into bureaucratic systems of red tape and myopic complexity. Adverse change occurs when the focus is placed on the quality *system* rather than on the output it's intended to produce. Velentium's stance is that a QMS should benefit the patient: its main reason for existing is to develop a safe and effective product (not job security or infrastructure growth). This meant that the entire QMS had to be stripped down to its fundamentals. We accomplished this by aligning with ISO 13485.

A bit of background: ISO 13485 is an international standard developed from ISO 9001 with special considerations for the medical device industry and its products. ISO 13485 identifies the essential requirements of a medical device quality system; therefore, we structured our QMS around it, directly overlaying and ordering its precepts into our operating procedure. We saw immediate value from this approach because all stakeholders had already validated ISO 13485.

ISO 13485 dictates what a quality system must have, but it is not a law unless a government adopts or recognizes it for that purpose. The European Union has taken this step through its Medical Device Regulation (MDR) whereas, while acknowledging the standard, the US has its own Quality System Regulations (QSRs), which are federal laws which the FDA has authority to enforce. These QSRs align with ISO 13485 concepts, so compliance with ISO 13485 will yield accordance with nearly all related QSRs.

(For details and analysis, download our free whitepaper on Medical Device Standards).

With each QMS development conversation, we consciously and continuously fought the urge to include non-essential procedures that could hinder our goal of getting safe and effective therapies or diagnostics to a patient as fast as possible. Even this goal is about risk mitigation: if a QMS becomes unnecessarily time-consuming and burdensome, product development lifecycles will lengthen, which in turn increases the time and cost to patients for delivery of the new therapy or diagnostic.

LEAN QMS = FASTER TURNAROUND!

Such delays in time and price are contributors to the increase in healthcare costs, which fuels our passion for fighting QMS bloat.

A successful lean QMS requires a delicate balance of knowing where to allow people the freedom to innovate and improve without neglecting principles. It must both:

- Enforce policies without requiring archaic or burdensome processes
- Permit processes and methods to evolve as users discover more efficient ways to carry out those principles.

In other words, an effective lean QMS will focus on and enhance processes, but be less concerned about creating filters to catch defects. By empowering process owners, an adequately executed QMS will create an environment which *creates* fewer errors. Applying energy to prevent mistakes will, in turn, reduces energy spent detecting and fixing defects. Wherever detecting filters are still needed and beneficial, seek ways to automate them; turn to manual filtering and detecting only as a last resort.

Empowerment vs. Control in Lean QMS

How do we empower designers within their current creative process? Tools are continually being adapted and improved, so for many situations, there may be a different "right tool" for the job depending upon circumstances. As a specific example, traceability can be done using a text document, a spreadsheet, or a more sophistical tool, e.g., JAMA, but it is crucial that the proper tool is selected at the right time to achieve the desired result.

We also need to adapt as new tools come into the industry, and the QMS should not over-burden these transitions. A quality manager must have the humility to admit when he or she may not know the best method to accomplish a goal and learn to lean on the team's knowledge. While QMS principles are always enforced, the mechanics of execution should remain flexible wherever possible.

Empowerment during the design stage enables our engineers to keep re-evaluating, simplifying, and reducing overall risk, in order to achieve the safest, most effective design. It is imperative we place a high

amount of effort into this iterative process before design completion and production begins.

Control becomes more critical as we move toward the manufacturing side of the product realization process. In general, manufacturing needs more filters and allows less variability than the design process. There are many reasons for this, including a need for production efficiency and the speed of manufacturing. But a more direct goal is that filters and reduction in variability are testing tools correctly used to ensure product conformance to specification.

Once a company confirms that its design is safe and effective, the production process needs to be able to reproduce that design with zero departures from the original blueprint. If you view the manufacturing process as a kitchen, the recipe is the Device Master Record (DMR), the ingredients are the Bill of Materials (BOM and SBOM), and the manufacturing staff are the chefs. Chefs do not need to know all of the nuances (Device History File – DHF) that went into creating the recipe, only how to follow the method to create the desired result.

Manufacturing can also be considered one of the last lines of defense for patient safety. QMS protection becomes all the more critical when increasing the quantity of production (magnifying the potential breadth of impact of a safety or security event) or completing repetitive activities within manufacturing. It is critical that all process improvements have been appropriately validated before greenlighting full production. Reducing variability at the manufacturing stage provides the double benefit of patient protection and improved yield for cost savings (again, consistent with our passion for reducing healthcare costs).

QMS Scales with Production Size!

Overall, we want to emphasize how important it is to dedicate the time and energy to ensuring that proper control is applied in the right places. Problems (both practical and cultural) can arise when rigorous manufacturing controls are uniformly applied throughout an organization.

A crucial part of developing an effective lean QMS is understanding *how* applying controls will benefit the patient or end user. During design, controls should ensure *principles* are satisfied while allowing *methods* to be optimized. During production, controls should likewise ensure *policies* are met, but also *methods* where control and invariability are necessary. It is not about how *much* control is applied overall, but rather *where* and *how* it is used to maximize the *patient benefit* from each control to result in timely and cost-effective delivery of a safe and effective device.

Standard-Centric vs. Product-Centric QMS

A product-centric QMS is created and structured based upon the development and production of a specific product or device family. This is an intuitive approach because that product or device family is typically what the company that created it knows best. It *feels* (and often is) efficient, as long as that product or device family remains consistent – a growing rarity in today's fast-paced and merger/acquisition environment.

A product-centric QMS needs to demonstrate compliance with applicable standards, which is accomplished by mapping the QMS elements to the standards and performing gap-analyses to ensure that every nuanced aspect is addressed.

Companies may have this type of QMS because they have designed and manufactured their product for a significant amount of time, even well before the creation of the standards. In specific scenarios, as suggested previously, this process can and does work out well for many companies within the industry. However, some of these companies can get into a bind when they acquire or pivot to a new product line and are forced to either revamp their QMS or figure out how to integrate their new product with another product's QMS. Such integration from a product-centric approach can inadvertently apply methods, guidelines, or rules – particularly those who have become culturally ingrained – which may be unnecessary or even burdensome for newly introduced products.

In contrast, at Velentium we created a standards-centric QMS. Our quality procedures are based upon and structured by adherence to industry standards, specifically ISO 13485, ISO 14791, and IEC 62304. Our approach ensures comprehensive mapping to the standards, which regulatory bodies appreciate, and also equips us with a common language to use with our clients and diverse associated teams. Not only do we adhere to definitions and terminology in the standards, but we also successfully resist creating new lexicons of Velentium- or team-specific jargon.

If every company creates its QMS with a different organization, conditions, divisions, sub-documents, and procedures, it causes confusion or delay among teams – a needless inefficiency in today's rapid distributed development culture. Because we leverage these standards, our clients know exactly where to find and how to understand detailed technical information within our QMS and within the Design History Files (DHFs) we provide or co-develop with each client. This allows for easy identification and avoids the need for deciphering and translating content.

Everything is structured around the standards – they've become our *lingua franca* of medical device development. Many of our clients are startups or small businesses which do not have an established QMS, and our QMS provides an inexpensive way to hit the ground running while retaining flexibility and portability to pivot as-needed within the development cycle.

Ensure All Elements Map To Standards!

We also work with large, well-established clients who have mature, product-centric QMSes. Because our system is standards-centric, our QMS is easily overlaid onto the client QMS' applicable standard map. This allows smooth interaction, bridging, and translation because the client has already performed that task.

Moreover, we create and support a diverse *range* of products, including varying stages within the product lifecycle based upon a client's needs. This would be challenging for a product-centric QMS. Since we did not create our QMS around existing product processes, but around industry standards instead, each new project can be completed according to its essential needs and not those of an unrelated design. This boosts efficiency and provides added benefits in the form of increased privacy for our clients: because quality for each project is managed according to that

project's specific needs, we eliminate risk from unintentional cross-pollination.

At the same time, we fully understand the necessity for product-centric QMS aspects at the appropriate levels. While the top level of our QMS is based around ISO 13485, the products we help design or manufacture may have product-centric components. But even then, we utilize standards-centric approaches wherever beneficial, such as developing neurostimulators with the validated risk mitigations of ISO 14708-3, a *product* standard. Standards are becoming ubiquitous and continue to improve with time and use, being refined by stakeholders for efficiency. So once again, we encourage everyone to leverage validated standards to accelerate time-to-market and reduce healthcare costs.

Simple is Hard, but Simple is Worth It

Frustrations can build when excessive energy is spent on a feature that is not essential to the safety or efficacy of the device, and even more significantly, not beneficial to the patient. Frustrations multiply if the energy spent is due to a complicated process. But while simplicity is an objective, remember that there may be a decreasing return in pursuing it. As Albert Einstein is credited with saying, "Everything should be made as simple as possible, but no simpler." When the simplified object or process no longer meets its requirements (which have already benefited from simplification), that threshold has been breached.

The ultimate goal for a design team should not be a complete simplification of the device; rather, the goal should be to provide the safest and most effective equipment for the patient in the most efficient way possible, while still meeting all stakeholder needs.

FOCUS ON SAFETY AND EFFICACY OVER SIMPLIFICATION!

Appropriate simplification demands that designers understand the difference between user *needs* and *preferences* to prioritize functionality and ensure that essential facets of design and usability are not left out. The same holds for internal process developers. The responsibility for simplification should be distributed, not carried by system engineers alone; nonetheless, they can be internal champions for simplification, which will work in their favor because complexity is likely to be heaviest on their shoulders. Yet simplification should be sought and applied across all disciplines in design, production, and processes.

At Velentium, we routinely use a technique called "kill, keep, or combine" to reduce the complexity of any topic across the company. For example, when brainstorming a list of features needed for improvement, the uninhibited list may be excessive and need filtering. The technique is simple: Apply one of the following to each item.

- Kill the item from the list (when not found to be necessary or useful)
- Keep the item on the list until next round
- Combine the item with one or more others; if necessary, creating a new item encapsulating them

This process is repeated until no further items can be removed or combined, and only the key entries remain. But simplification is not just a matter of perpetual kill, keep, combine; it is asking the right questions in the proper order.

It's valuable to mitigate business risks (which often relate to patient risks) as early as possible. A big question answered too late can be tragic.

This is well understood by venture capitalists, who ask questions like, "Is the device going to be clinically effective?" or "Does a known path for regulatory approval and reimbursement exist?"

For many startups, device development may not be the most significant risk. Teams must prioritize according to patient risk and business risk, with the former taking priority. As a final reminder, the simplification process is not corner-cutting; it is ensuring that essentials are achieved as thoroughly and flawlessly as possible. Deliver an effective risk control is much more critical than providing voluminous uninformative risk analysis documentation (a.k.a. "risk management theatre"). Documentation must not obfuscate the critically important analyses and mitigations but instead must shine a spotlight on actual risks. This requires clarity in thinking and in the presentation.

Four Goals of Valuable Lean QMS

The principal objective of a QMS for a medical device company is patient safety. Patient safety is well understood and communicated throughout the medical device industry, leading to an almost single-minded passion for preventing defects. However, if we lose sight of the **urgency to deliver a medically-effective and cost-effective device**, we can allow the concern for **safety** to go beyond what is *necessary* and turn into a bureaucracy. It is crucial to be able to balance without compromising any of these **four goals**. Remember, a valuable QMS should be optimized and risk-driven to deliver a **safe** and **effective** product **rapidly** and **cost-effectively**.

While we continuously emphasize the benefits of simplicity, we conversely underscore the importance of not "cutting corners." If a design or process has been optimized and simplified, what remains is essential and necessary. Each remaining step has value toward our four goals. In the same way, we strongly encourage fixing problems immediately at the root cause. While fixing problems seems intuitive, the process meets resistance when the root cause is in a long-lead item (e.g., an ASIC). There's immense pressure in such cases to find workarounds and "bandages."

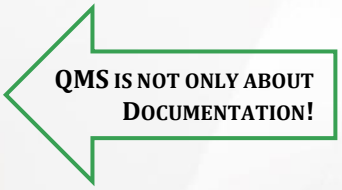
While there may be situations in which these are acceptable, they must be done with great caution and consideration. We have observed many instances in which the long-term impact of the workarounds negatively affects one or more of the four goals.

Taking this 4-goal approach allows us to appropriately size our QMS for a variety of products and stages within the development lifecycle. While the QMS principles remain consistent, the methods and relevant components may change. One size does not fit all, but safety, efficacy, speed, and cost-effectiveness are consistent common denominators.

Overt efficiency can also be enjoyable, not only for us but also for our clients. Productivity can accelerate the device's time-to-market, meeting patients' needs sooner. We'll go so far as making this bold claim: a QMS can be fun. Many people perceive QMSs negatively due to unfortunate past experiences. Recognizing the value of positive culture, we actively seek to overcome those negative perceptions.

We understand the importance of QMS checks and balances, while simultaneously celebrating successes produced by efficient processes, enhanced quality, and accelerated projects. After the foundation of a lean and effective QMS has been laid down, the satisfaction comes the first time – and every time – we realize that a significant delay was avoided due to the processes we prescribed.

A valuable QMS will be used as a *tool* rather than as an *afterthought*, the latter being recognizable when a QMS is seen as primarily a *documentation* process. (Note: if true in your company, it's time to hit the brakes!) Alternatively, and more nobly, many consider a QMS to be just a safety system. What if a QMS wasn't *just* a safety system like a seat belt, but actually helped us drive better? Then it becomes a *valuable* QMS.



Every medical device company has to create a QMS, expending energy and resources to do so. Why not make it productive instead of a deterrent? A well-thought-out QMS can be a tool used to roll out products faster, speed up design and development, and give the engineering team more freedom in which to do their work. The principles are mandatory, so why not create a process which is competent, efficient, and enjoyable at the same time? Seize the opportunity: don't make it a hindrance, but a boon!

We've said it throughout this paper: a valuable QMS should be optimized and risk-driven to deliver a **safe** and **effective** product **rapidly** and **cost-effectively** (our 4 goals). Or, in a simple mnemonic, a valuable QMS makes a product **RISE** (**R**apidly and **I**nexpensively be **S**afe and **E**ffective).