How to Build Your Quality Nirvana

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Introduction

Quality management is an integral factor in the development, approval and commercialization of medical devices. With the 2016 American Medical Device Summit quickly approaching, we took a moment to sit down with one of the summit presenters, Kari Miller, Vice President of Regulatory and Product Management at Pilgrim Quality Solutions, to gather her insights on the challenges and opportunities in quality management and explore some best practices to create a Quality Nirvana.

About Kari Miller

As Vice President of Regulatory and Product Management, Kari Miller is responsible for driving strategic product direction and delivery of industry best practice solutions to Pilgrim's customer base. Working with customers, industry analysts, and regulators, as well as Pilgrim's Development, Professional Services, and Support groups, Kari and her team are responsible for translating market and industry trends, along with customer and regulatory requirements, into industry- leading enterprise quality management solutions that meet the needs of the heavily regulated Life Sciences market. Additionally, Kari leads the development of user documentation and solution presentations. Working with Pilgrim's Customer Product Advisory Board, Kari is responsible for the company's product roadmap, product partner relationships, and overall product direction.

What is the current state of the regulatory and quality landscape for Life Sciences organizations?

Life Sciences organizations, including Medical Device, as well as Pharmaceutical, and Biotech manufacturers, are experiencing unprecedented levels of change in the regulatory and quality landscape.

In this global economy, value chains (which include the demand chain and the supply chain) are getting longer and longer. Achieving quality and regulatory compliance in this environment can be quite overwhelming. To focus in, we can look at some of the most recent changes in regulations and standards that have either been initiated/implemented, revised, or are in the process of revision, and that affect Quality Management Systems for Medical Device companies.

Unique Device Identifier (UDI)

The first change is the introduction of Unique Device Identifier (UDI). UDI often generates a lot of discussion regarding "ownership" within an organization: does ownership lie with Quality, Manufacturing, Engineering, etc; but at a minimum the Device Identification (DI) – which identifies the labeler and the specific version or model of a device - needs to be captured on Nonconformances, CAPAs, and Complaints.

If the Production Identifier (PI) - which is the variable portion of the UDI and identifies one or more of the following: batch or lot number, serial number, expiration date, and/or manufactured date - is available for Nonconformance, CAPA and Complaints, all the better. This new requirement from the FDA also impacts labeling and submission to the FDA's Global UDI Database (GUDID).

ISO Revisions

Then we can look at ISO. Let's start with ISO 9001:2015. This revision took three years and the input of more than 90 participating and observing countries to complete. The new standard is less prescriptive than its preceding versions, and focuses on performance, risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organization. ISO 13485:2016 also emphasizes risk management and risk-based decision making, and it places additional regulatory requirements on organizations in the extended supply chain. The revised regulation aims to strengthen supplier control processes and increase the focus regarding feedback mechanisms. It also prescribes improved alignment of global regulatory requirements. Organizations will have three years to transition from ISO 13485:2003 and the associated European Standard EN ISO 13485:2012, to ISO 13485:2016.

Medical Device Single Audit Program (MDSAP)

There's also the Medical Device Single Audit Program (MDSAP) that aims to develop a single audit program that applies internationally and will serve as "THE Audit". The aim of the initiative (the pilot concludes at the end of 2016) is to minimize the regulatory burden on Med Device companies and achieve global alignment of regulatory approaches. The EU is currently an observer of this initiative, and there is concern that it will be difficult to obtain agreement from all EU member states; with the exit of Britain from the EU, there may be added complexity in achieving complete participation in Europe. However, regulatory bodies around the world are driving towards global standards, efficiency, and improving the safety and efficacy of medical devices.

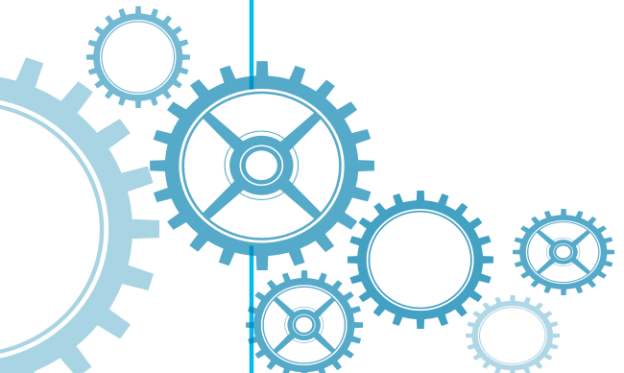
There are many other changes on the horizon as well:

- EU directives are becoming law and will extend regulatory scope with 2012/0266 and 2012/0267.

- Regulatory bodies around the globe are focusing more and more on change control within Life Sciences companies, so much so that production could be shut down until appropriate documentation of the change is submitted.

However, it is not just regulations that are changing the Medical Device landscape. With the move towards personalized medicine and personalized devices, Cybersecurity is an increased concern. New technologies such as 3D printing, that enable the move to point-of-care manufacturing, will certainly expand the scope of regulatory body oversight.

Navigating these regulatory and compliance changes will require Medical Device manufacturers, and all Life Sciences companies, to rethink their approach to regulatory reporting as well as their Quality Management System (QMS).



Pilgrim assists companies in achieving a "Quality Nirvana." What is a Quality nirvana and why should life science organizations strive to achieve it?

Quality nirvana is the realization of a global Enterprise QMS which aids in the identification, diagnosis, and ultimately, the prediction and prevention of quality problems across an organization's value chain.

This is achieved through operational consistency and compliance. A global Enterprise QMS creates a common language across an organization, through harmonization and the creation of a single source of quality truth. This, in turn, facilitates communication between groups globally, and builds a cooperative, collaborative environment within the organization's value chain. This value chain extends to suppliers, external service providers, and yes, regulatory bodies around the globe.

With the changing regulatory and compliance landscape Life Science organizations are experiencing, having a common language across the organization and around the globe is more important than ever. Organizations operating with silos of quality data will find it very difficult to keep up with the evolving standards and regulations, and to demonstrate consistent, controlled quality processes. The ability to communicate, and therefore collaborate, within the value chain will be key to an organization's ability to achieve global compliance. More importantly, it will be critical that they consistently meet their requirements and enhance their customers' satisfaction through improved efficacy of their treatment and their quality of life.

What are the most common hurdles that organizations have to overcome to achieve this nirvana?

The most common hurdle an organization will encounter when implementing a global enterprise quality management system and achieving quality nirvana is culture; every organization has a quality culture, pro or con. Too often, organizations see quality as a department, and an overhead department at that. It is often seen as the "police" that stifle innovation and efficiency. To those who fall into that camp, John Wooden, legendary basketball coach and leadership mentor would ask, "If you don't have the time to do it right, when will you have time to do it over?"

The definition of Quality is widely accepted as the achievement of customer expectations through conformance to their requirements. In today's global economy, only the reliable will survive. Organizational management and quality groups both have a responsibility to instill a quality culture throughout their organization's value chain. However, changing culture is not an easy task. Change is one of the constants in life; it is also that which most resist. To cultivate a quality culture, quality professionals must be able to position and communicate the value that extends beyond compliance to regulations and guidances. A quality culture is participatory and extends quality awareness and practice beyond the QA department.

GENERIS

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In your opinion, how can companies best enable cultural change to achieve a quality driven/focused culture?

An entire industry has been built to support companies that desire to make a cultural shift in their organizations. However, there is also a stream of consciousness that declares you can't fix culture; rather, that cultural change is a result of fixing the business. Harvard Business Review's April 2016 cover declared boldly, "You Can't Fix Culture, Just Focus on Your Business and the Rest Will Follow." So how does an organization make the shift to a quality culture? Focus on changing behaviors through inclusion, new processes, and structures to manage quality. Implementing a harmonized, global Enterprise QMS plays a key role.

With a global Enterprise QMS, quality will come out from behind the walls of Quality Assurance and into the organization. With this comes transparency and increased opportunities for collaboration and knowledge transfer, achieved via harmonization and a Single Source of Quality Truth. Harmonization is different than standardization because it also takes into account regional/local needs, and considers that which is unique to a process or product. When a process, whether a CAPA, a complaint, or a Change Request (to name only a few QMS components) is truly harmonized, at its heart is a DNA strand that is consistent and measureable. It means that wherever the process is in use, the core of the process is common and based on industry best practices such as ISO 9001 or GMP for compliance. By engaging in consistent quality processes, an organization achieves synergies that will strengthen the organization. It also will improve the flexibility and agility of the organization due to the ability to flex resources across and among sites and divisions. There are more tangible benefits as well: a reduction in the overall cost of quality through the reduction of rework, scrap, returns, penalties, and fines.

What is a "Single Source of Quality Truth" and how does it help to mitigate risks or identify opportunities?

Once an organization has made the decision to think globally about quality management, and the strategy for harmonization is agreed upon, the foundation for your organization's common language has been established. While establishing a global QMS, common definitions will be required for all system users to share and visualize the quality data generated, and then to act upon it. This means thinking through organizational structures, including virtual entities in your value chain such as your suppliers, as well as your data structures.

In this age of big data, structuring your QMS data is imperative. Properly structured quality data will allow for the aggregation and disaggregation of all that quality data. The goal of properly structured data sets? Turning data into actionable information through its transformation. Data may be transformed into key performance indicators (KPIs), metrics, and measures that can be used consistently at a site, division, or business unit level. Whether for products or product families, or for customers and suppliers around the globe, this data is essential within a global QMS. These data definitions and measurements become the common language for the organization: the Single Source of Quality Truth.

The Single Source of Quality Truth then acts as a risk mitigation and opportunity identification process. With a common language, sites with common operations/processes and or products can "see" and understand (due to common definitions) when issues are trending, and what was done to correct that trend, and they can respond accordingly (risk mitigation). In fact the Enterprise QMS will act as an early warning system through notifications, dashboards, and metrics. The opposite side of that coin is true as well. When improvements to products or processes/operations are made, that knowledge is available to all, and all can act accordingly (opportunities for improvement).

If you had to give one piece of advice to someone looking to implement an Enterprise QMS what would it be?

When implementing an Enterprise Quality Management System, the best advice is *inclusion.*

A global implementation team is imperative to successfully implementing a global Enterprise QMS. A designated team also builds global organizational buy-in and ownership to the process. It also ensures that everyone's voice is heard and that regional or product-specific requirements are considered. Additionally, acceptance of the harmonized global process is more easily achieved because global communication and collaboration are demonstrated from the start.

A siloed approach will adversely result in one of two things:

When implementing an Enterprise QMS, often organizations will use one site as the model for the rest of the organization. The result is a lack of consideration for regional and product-specific requirements. This typically results in multiple reconfigurations, or worse yet, modification of the solution in future phases. For Life Sciences organizations, this can mean additional policy, procedural, and work instructions updates. It will also require additional project overhead, re-validation of the solution, and re-training of personnel. Do this too often and project fatigue can set in, and time-to-value is significantly elongated.

Another adverse result of a siloed approach is risk of the appearance of "acceptance." This leads to multiple work-arounds, back-door processes, and spreadsheets and other documents to support how it "really" works. When this occurs, there is no longer a "Single Source of Quality Truth," and the organizational synergies, efficiencies, and flexibility, as well as the global visibility and common language of the organization, are not achieved.

This doesn't mean a complete big bang approach has to be taken during the implementation of a global Enterprise QMS. Many organizations cannot support that level of resourcing.

An organization might start with one end-to-end process, maybe for a particular product family, with a global team leading the charge. Consider the end-to-end process for managing a nonconformance. This won't be inclusive, just enough to depict the reason for implementing an end-to-end process rather than a siloed process. First, take into account the sources of nonconformance; suppliers, product, processes, etc. The first consideration in an end-to-end nonconformance process is to ensure all types are identified. To peel this back a bit more, look, for example, at a supplier nonconformance which will illustrate why an end-to-end process is key to avoiding missed integration points. At receiving inspection, a material nonconformance is created due to out-of-specification inspection results. The nonconformance investigation reveals that the material cannot be used or even re-worked for use. As a result, the material is dispositioned, an ERP inventory status update is submitted and an ERP return material authorization is potentially triggered.

Additionally, the nonconformance investigation indicates that this is a trend for this supplier, and therefore a CAPA is issued. The CAPA investigation uncovers the fact that a design change was not considered in the material the supplier shipped. In turn, this triggers a supplier audit to determine why the supplier QMS processes missed the change notice, or if something changed in the suppliers' process capabilities. Yet another possibility may be that the CAPA investigation reveals that change notices are not getting sent to this supplier because Engineering was using an outdated SOP. This will initiate a change request to update the SOP, and additional training is triggered for the Engineering group.

The point for choosing an end-to-end process is this: there are both internal QMS integration points as well as external integration points that will be missed without a complete process view. Additionally, the global team needs to participate in this process to ensure regional reporting requirements are not overlooked, thereby creating the need for "rework" later.

Through the discussion above, the necessity of a global voice (inclusion) during implementation is clear if an organization is to achieve a successful implementation of an Enterprise QMS. That global voice not only ensures a harmonized process; it also drives organizational synergies, efficiency and flexibility that work for all sites around the world. It will improve organizational acceptance, and shorten global time-to-value.

How do you see the quality needs of the Life Sciences industry evolving over the next 5 years?

The pace of change experienced in 2016 from a compliance perspective is very likely to continue. This is partially being driven by technology. With the growth of social media, not only has the speed of information greatly increased, so has the speed of response from the consumer. Consumers are more informed, more educated, and therefore, more demanding than ever before. They expect more: more value, more quality, and more service. From a quality perspective, that means more requirements to meet in order to achieve customer satisfaction, the mantra of Quality.

As technology evolves, so will the face of manufacturing and business in general. The workforce is more mobile than ever, so security concerns will continue to grow. In Life Sciences organizations this is of paramount importance as the likelihood of patient information being part of that mobile data record is high. Technologies like 3D printers will move manufacturing to point-of-care facilities. As the price of 3D printers continue to come down, and the demand for personalized medicine increases, the opportunity for manufacturing to move out of the realm of "traditional" manufacturing to manufacturing at the point of care, including hospitals, dental offices, and other healthcare providers, increases as well. These are just a few of the new frontiers for quality and compliance Life Sciences organizations will face in the upcoming years.

About Pilgrim Quality Solutions

Pilgrim Quality Solutions is the leader in quality compliance management software and services for Life Sciences. For more than 20 years, our solutions have automated thousands of processes across global company sites to manage the quality and compliance of life's most important products. Our cloud-based and on-premise solutions include in-the-box best practice workflows, document and process management, dashboards, electronic signatures, audit trails, and automated validation – helping companies more easily achieve quality system compliance and pass regulatory audits. Pilgrim Quality Solutions is majority owned by Boston-based private equity firm, Riverside Partners LLC. With Pilgrim Quality Solutions as your partner, you are prepared to succeed. For more information, visit www.pilgrimquality.com.

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Gain an in-depth understanding of quality system transformation by joining Pilgrim Quality Solutions at the American Medical Device Summit!

American Medical Device Summit 2016

Oct 5-6, Chicago, IL

THE CASE FOR QUALITY SYSTEM TRANSFORMATION

October 5, 11:45 am – 12:20 pm

KARI MILLER
VP of Regulatory & Product Management
Pilgrim Quality Solutions

- The value of thinking globally: identify, diagnose, predict and prevent quality problems across the organization's value chain
- Harmonization: the process DNA strand that is at the heart of every quality process - consistent and measurable
- Creating a single source of quality truth: properly structuring data sets to establish a common language for the organization
- Making the case for transformation: securing executive support for an enterprise-wide quality system

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