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How Quality is Your System?

What to Consider in your Quality System Lifecycle

Organizations create processes but the question is how effective are they? How robust are these processes? Are they able to adhere to management's near and long term goals?

Organizations need to continuously examine what is in place and what is needed to meet regulatory and industry expectations. They need to ensure they can expand to meet these expectations and/or streamline to avoid complexities that impact compliance.

Medical Device companies require a range of Quality Systems elements and processes that change throughout their product lifecycle.

Product development and design phases:

- During initial product development and design phases, a company's focus on innovation and technology to create advanced life changing devices requires a focus on design control.

From concept to commercial production:

- As products move from concept to commercial production, Good Manufacturing processes (GMP) must be in place to meet regulatory expectations.

Just as we look to improve health care efficiencies through medical devices, so must we seek efficient methods to implement the Quality Systems that drive safe and effective products to market. Emerging and early growth enterprises, whether medical device, diagnostic, or medical information system focused, must accelerate the build and robustness of a compliant quality system.

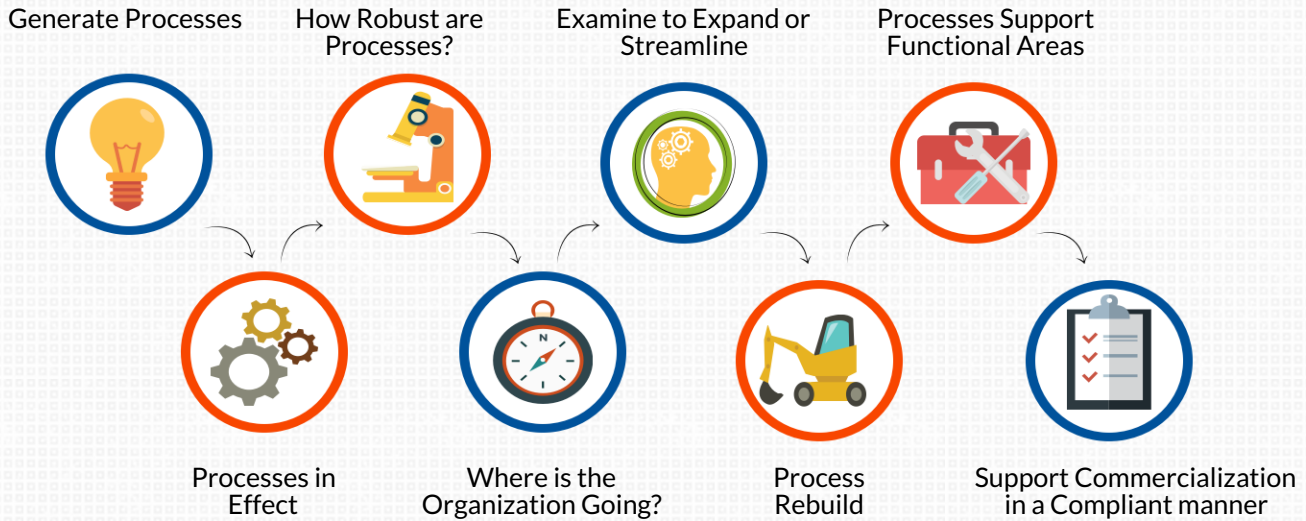
Rapid deployment of new or systemic improvements to the Quality System in a modular approach reduces costs and time of development.

Assessing the maturity of a Quality System against Quality Management System (QMS) requirements and regulatory expectations at each lifecycle stage promotes Quality Systems Planning and Prioritization.

Quality Systems Planning and Priorities

Late stage, pre-commercial companies are universally busy. Making the transition from product development to commercial is an exciting yet challenging time. Current employees must wear multiple hats and stretch their skill sets. The company is likely hiring more talent to help with the transition, resulting in an increasingly diverse set of perspectives and experiences. The priorities of these companies are typically product development, trial completion, product/process validation, regulatory preparation, and commercial launch preparation, all while ensuring the necessary finances to support it all.

Trying to establish the necessary Quality System to govern regulatory compliance in this environment, although critical from a regulatory approval perspective, is often very difficult.



What Are the Challenges and How Can You Overcome Them?

1 Establishing a Compliant Framework

The Challenge

Companies often do not have enough hours in the day to put together a clear, well-defined strategic plan/framework around their QMS.

A lack of a comprehensive QMS increases the risk for regulatory action, including denied/delayed approval of new products.

Within the Medical Device industry, the number of FDA-issued warning letters nearly doubled from 2007 to 2012, with the overall volume of issued warning letters having increased 78% from 2007 – 2013.

How to Overcome

Leverage an accelerator to mitigate the regulatory risks:

- ✓ Establish a necessary framework
- ✓ Ensure the required documentation is in place in case of an inspection
- ✓ Provide a Lifecycle perspective for the company

Creating a QMS does take time and resources. However, investing in a Quality System accelerator decreases the time and resources required to implement a compliant QMS.

2 Consistency in Process and Direction

The Challenge

Another challenge many medical device companies experience is rapid growth, thus leading to an influx of ideas and assumptions. If an organization does not have defined singular processes, individuals and teams often use their past experience and assumptions.

This leads to ambiguity and process assumptions as an organization makes the transition to commercial.

How to Overcome

Adding a Quality Systems accelerator to your toolkit allows a facilitated discussion around key processes to draw out these assumptions.

Using industry standardized processes as a starting point, the organization can discuss how to operate as they move forward. This helps Business Unit heads understand and visualize the resource demands necessary to meet required QMS expectations and define where in the organization these resources will be needed.

An accelerator expedites having key Standard Operating Procedures (SOPs) in place to cover quality elements that the regulatory agency inspectors will be looking for before approving commercial sale of a product. Having these processes in place keeps the organization focused, aligned, and moving in one direction.

The Benefits of the Lifecycle Approach

When your Quality Plan considers a Quality Systems Lifecycle approach and accelerator you can:

- Prioritize your SOP development to align with the organization's current stage and plan for the next.
- Initially, many companies may only require limited Quality System elements. Additional Quality Systems elements will be required as they transition to preparation for the commercial world.
- Support your response by showing a defined and well-thought-out approach to developing your QMS instead of receiving an observation for a missing procedure and just scrambling to fill the gap.
- Articulate known gaps and the plan to remediate.
- Provide management with a discrete project plan for QMS implementation.

Quality Acceleration and Overwatch

Often organizations develop quality processes during their preparation for commercialization which takes away precious time from preparing to commercialize product. Having a quality accelerator helps establish the basic QMS framework and can minimize regulatory authority requests for additional SOP development during the pre-approval phase.

With a Quality System accelerator they have a collection of industry-proven templates at their disposal to adjust and customize to meet their requirements allowing them to a have proven process in place with ease and little time requirement. Now, instead of focusing valuable time on recreating the wheel they can quickly create the basic framework of a Quality Management System which meets current needs and provides a basis to grow as they do.

Through years of experience working with client partners and helping to develop and strengthen their Quality Systems and processes, Clarkston Consulting has developed Overwatch. Built upon the challenges faced by our clients and their need to accelerate the build and robustness of a compliant quality system, Overwatch provides a fresh perspective to your QMS growth and development and delivers significant improvements in operational efficiency and compliance position. Providing Overwatch as your organization grows through the Quality Lifecycle stages, along with the ability to modify the Quality System as needed, results in a compliant customized solution.

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Clarkston Consulting provides management, operations, and implementation consulting services for life sciences and consumer products companies. Within the life sciences industry, we deliver solutions for sales and marketing, quality and regulatory, serialization and traceability, supply chain management, and enterprise systems. Clarkston has achieved a 15-year average client satisfaction rate of 95% by continuously pushing for success for our clients, our consultants, and our company.

To learn more about Clarkston's services in quality, compliance, medical device, and more, please contact:

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