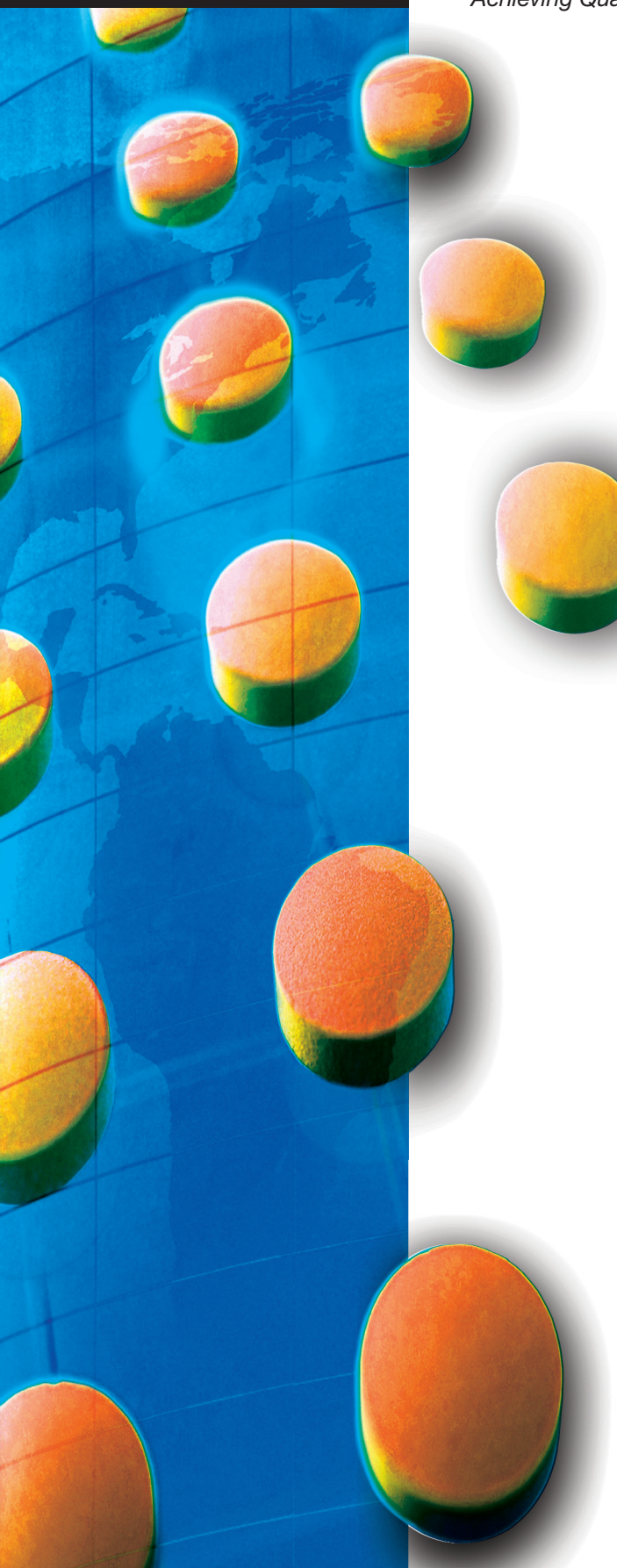
CLARKSTON CONSULTING

INSIGHTS

One More Look at Quality Systems Maturity

Achieving Quality Maturity in a Global Marketplace



A key activity in optimizing product quality is critically assessing your quality systems against proven quality maturity models – such as those described in Quality is Free, by Phillip Crosby. We took Crosby's quality management model and enhanced it based on our experience in the life sciences industry. Using this model, our initial focus was on how organizations can ensure product quality by optimizing the performance of their quality systems.

In revisiting the Quality Maturity Model, our focus is shifting to a key challenge facing pharmaceutical, biotechnology, and medical device manufacturers today – achieving quality in a global market that is constantly under the scrutiny of various regulatory agencies.

In an attempt to eliminate these regulatory hurdles, a network of scientific organizations launched a global initiative to harmonize regulations and legislation. The objective is to encourage convergence among regulatory systems at the global level, facilitating trade while preserving the right of participating members to address the protection of public health using regulatory means considered suitable for their nation. In theory, this will result in a reduction of regulatory differences in submissions/approvals, audits and enforcement.

In order to achieve global harmonization, companies and regulatory authorities need to receive and react to information consistently, something that in the past has proven difficult. So the big question is: how does your company maintain a mature quality system that is still flexible and adaptable enough to meet multiple market needs and regulatory standards?

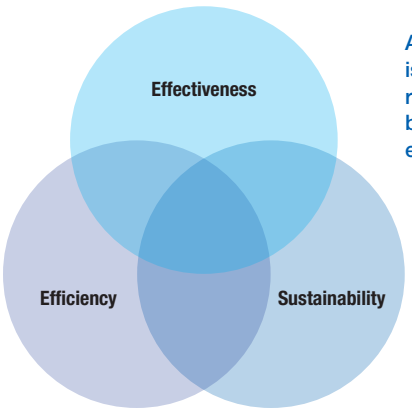
"A key activity in optimizing product quality is critically assessing your quality systems against proven quality maturity models."

Summary

Quality is a measure of a product's ability to satisfy the patient's stated or implied needs. Quality systems are a company's formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product quality requirements, customer satisfaction, and continual quality improvement. A mature quality system has quality, safety, and effectiveness designed into the system and built into the product. Quality is not tested into the finished product, nor is the product tested into compliance in a mature quality system. Each step in the process is controlled to maximize the probability that your product meets all pre-established quality and design specification limits. A mature quality system is designed to assure overall compliance with cGxPs, internal procedures, and specifications.

In a mature quality system, your company's Quality Control Unit (QCU) will review and approve all critical steps in your product's process, including all product defect evaluations, returned product evaluations and salvaged products. The QCU must assure that all errors have been fully investigated, approve changes before they are implemented, and provide feedback regarding the appropriateness of those changes. Essentially, a mature quality system:

- Will improve customer loyalty, leading to repeat business; enhance customer satisfaction; and increase your company's speed and agility in taking advantage of market opportunities.
- Ensures your product does not adversely impact patient/user safety.
- Has the resources and flexibility to adapt to global regulatory changes.
- Is harmonized to global regulatory standards because it is efficient, effective, and sustainable.



A mature quality system is harmonized to global regulatory standards because it is efficient, effective, and sustainable.

> "A mature quality system has quality, safety, and effectiveness designed into the system and built into the product."

Clarkston's Quality Maturity Model identifies effectiveness, efficiency, and sustainability as key components of a mature quality system.

- Effectiveness is the capability of producing a desired result. When something is deemed effective, it means it has an intended or expected outcome.
- Efficiency describes the extent to which time, effort, or cost is well used for the intended task or purpose.
- Sustainability is the capacity to endure social, environmental, economic, and resource changes.

Looking Back at Looking Ahead…

In 2011, we published "Looking Ahead with Quality *Systems; The importance of knowing where you are–and where you need to go..." The paper focused on the FDA's goals and strategic priorities, and how organizations could improve their product quality efforts. Despite the increased complexity surrounding quality systems and global harmonization, our approach is still the same. To identify the strengths and weaknesses of your quality systems, and to develop a plan for moving forward, use our assessment method below.*

1. *Determine your organization's current quality management maturity.*
2. *Go through the assessment process to analyze your organization's quality systems in detail, identifying opportunities, and developing an optimization plan to address the opportunities identified.*
3. *Create a plan for implementing the changes identified in the assessment.*

For more information, visit ***http://www.clarkstonconsulting.com/publication/looking-ahead-with-quality-systems****.*

Considerations and Impact

While regulatory standards may vary, what is consistent across all regulatory agencies is public health and safety monitoring. To determine if your quality system is effective, efficient, sustainable and harmonized to global markets, you must consider the following questions:

Does your quality system have the ability to respond to quality incidents with speed and agility?

- Review the average completion time for these events and strive to continuously improve completion time and effectiveness:
  - CAPA
  - Complaint investigation
  - Product Recall
  - Product Market Withdrawal
- Establish a Speed & Agility Index (SAI) with specific metrics.
- Benchmark how your company compares against peer companies and examine industry best practices.

Is your quality system proactive?

- Establish a tracking and trending program to ensure consistent, repeatable quality results, reduce mistakes, improve customer satisfaction, and move towards quality sustainability.
- Measure and track your company's organizational effectiveness, or how effective your organization is in achieving intended outcomes and successfully executing strategies.

Do all of your quality subsystems use risk assessments as an evaluation tool?

- Make sure that your risk assessments include the probability of occurrence of harm and the consequence of that harm (i.e., how severe it might be). A mature quality system has a risk assessment program that includes risk analysis, risk evaluation, risk control, and production and post-production information.
- Establish a risk management file that assesses risk in terms of patient/user, risk to employees, property and environment. Document the estimation of risks for each hazardous situation in the risk management file and prioritize in order of inherent safety by design, protective measures in the manufacturing process, and safety information.
- Verify each risk control measure and evaluate any residual risk.
- Reduce any unacceptable risk to acceptable levels. Define and document acceptable and unacceptable risk levels, ensuring that changes made to eliminate or minimize hazards are captured. It is also important to document actions taken, which ensures changes did not introduce new hazards.
- Understand your product and process risks, which better prepare your quality systems for regulatory compliance without compromising the ability of your system to meet future requirements.

Does your quality system track your product through commercial distribution?

- Define metrics, establish a tracking system and risk assessment tools, and integrate speed and agility to change with new requirements.
- Track operational and quality data and evaluate key operational metrics; this can be a useful method to determine if your quality system is effective.

Does your quality system trend quality incidents across time, product lines, and batches?

- Review complaints at occurrence and reexamine them over time to see if a pattern or trend is present, which may result in escalating the associated series of complaints to a CAPA.
- Include tracking and trending strategies that are triggered by process monitoring, risk assessments, rework/reprocessing, deviations, complaints, audits, and new equipment qualifications. The tracking and trending strategies associated with these triggers should have an extensive post-implementation follow-up duration. Post-implementation follow-up should include similar product lines.

Are you conducting thorough root cause investigations and determining causal relationships?

- Ensure that your company's design, R&D and quality teams meet routinely to discuss root causes and associated causal relationships determined during quality investigations, and jointly communicate issues to management. Design/R&D departments have important product knowledge and experience that can increase the effectiveness of root cause determinations and formulation of preventive actions.
- Establish a strong management team that can determine causal relationships with speed, implement necessary changes to prevent recurrence of quality incidents, and drive information back to R&D and the supplier to improve their processes.
- Evaluate your root cause investigations, which will identify quality system gaps and contribute to a roadmap for improvements.

Is your supply chain aligned with your quality system standards?

- Compare your vendor selection process against peer companies and industry best practices.
- Increase the frequency or intensity of supplier audits when supplier issues are determined to be the root cause.
- Have a strategy for disqualifying an approved supplier that is tied to severity of risk and frequency of quality incidents.
- Establish a supplier requalification process that includes assessing risk of recurrence of similar quality incidents.

Do you have computer systems in place that can customize your technical and regulatory information for each nation's format?

- Audit your computer systems to ensure compliance with current regulatory standards.
- Hire the necessary expertise to address any gaps discovered during the audit.

Can your quality system withstand resource, organizational and economic changes without becoming fragmented and ineffective?

- Make sure that your quality system is an interactive process between management, quality, and production, and that it allows employees to navigate and respond to change appropriately.
- Measure and track your company's organizational effectiveness.

If your quality system confidently ensures your product is safe, effective, and fulfills its intended use, then global harmonization has become an administrative issue for your company, not a quality system issue. Global harmonization as an administrative issue can be addressed by dedicating resources to creating adaptable, flexible computer software systems that can accommodate each nation's regulatory format. The key is that safety, technical, and quality information will be accurately captured, electronically stored and accessed across nations. Once these elements are established, your company can report globally – achieving quality maturity in a global marketplace.

About the Author

Melanie Drayton is a Senior Consultant with Clarkston Consulting. She has 20 years of Life Sciences industry and lab experience. As an investigator for the FDA, she led investigations and audits across the pharmaceutical, biotech, medical device, and food manufacturing verticals.

For more information on how your company can evaluate and improve your quality systems, or establish adaptable quality systems that adhere to global standards, please contact **Melanie Drayton / mdrayton@clarkstonconsulting.com.**

CLARKSTON CONSULTING

Headquarters
2655 Meridian Parkway
Durham, NC 27713
Phone: 800.652.4274
Fax: 919.484.4450

www.clarkstonconsulting.com

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 10-year average client satisfaction rating of 97%.