

INSIGHTS**Looking Ahead with Quality Systems**

The importance of knowing where you are—and where you need to go...

In April 2011, the Food and Drug Administration (FDA) released an update of its strategic priorities, outlining the goals and priority areas that will guide the agency through the next five years. If the FDA is successful in executing its plan, a more mature, better-run organization will no doubt evolve. Not surprisingly, the FDA document included a heavy focus on ensuring product quality.

Is your organization looking ahead as the FDA is taking proactive steps to ensure product quality through optimizing the performance of its quality systems?

Although several business functions within a regulated company are responsible for product quality, it is the Quality Assurance group that is ultimately accountable. As a Quality Assurance leader, do you have a good understanding of how effectively your quality systems perform? When was the last time you assessed your quality system processes to evaluate their compliance and business effectiveness?

Just as the FDA identified its strategic priorities in order to build a stronger, more effective agency, your company would benefit from an assessment to identify the strengths and weaknesses of its quality systems. The idea of undertaking a detailed analysis like this may seem daunting, but there is a straightforward, structured approach.

Assessing your organization's quality systems involves three straightforward steps:

1. Determine your organization's current quality management maturity.
2. Go through the assessment process itself 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.

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How mature are your quality systems?

In the classic and respected book *Quality is Free*, Phillip Crosby, who created the concept of ‘quality maturity,’ outlined the Quality Management Maturity Grid. This grid theorizes that quality management maturation occurs in five stages:

Stage 1: Uncertainty. At this stage, general management has no comprehension of quality as a management tool, and the Quality department is blamed for quality problems. Problems are addressed as they occur (fire fighting is common), and limited effort is made to improve quality. In quality cost terminology, all of the resources are spent addressing internal failure, external failure, and appraisal costs. There is little understanding of prevention costs, and no resources are invested in prevention.

Stage 2: Awakening. Organizations evolve to this stage when they begin to recognize that quality management may have value; however, they are still not willing to invest money or time in it. They create teams to address major problems, but don’t consider long-range solutions. In quality cost terminology, some in the organization begin to understand the concept of, and benefits derived from, investments in prevention.

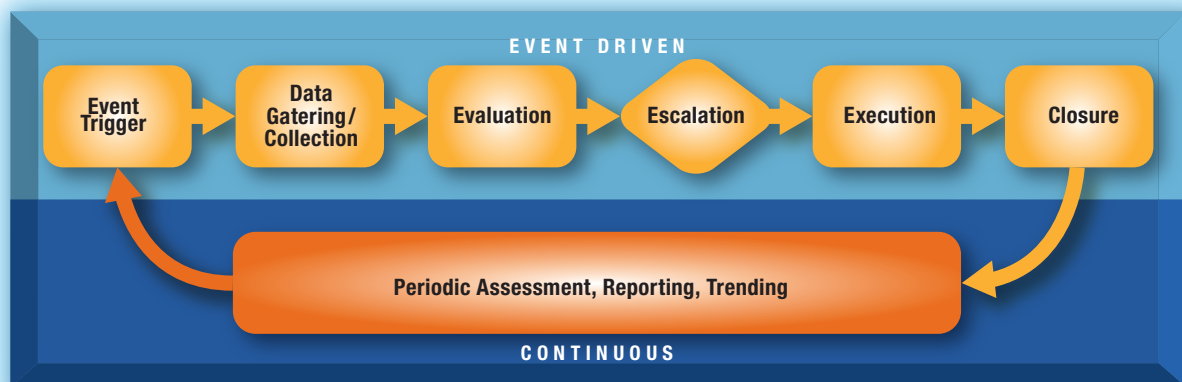
Stage 3: Enlightenment. At this stage, the Quality department is collaborating with the rest of the organization to identify and resolve quality-related problems. The organization is facing problems openly and resolving them in an orderly way, and it has established corrective action communication. In quality cost terminology, some resources are invested in prevention, and the organization begins to see reductions in internal and external failure costs.

Stage 4: Wisdom. An organization achieves wisdom when it integrates quality management into its processes and exposes all business functions to quality-related suggestions and improvements. The organization identifies problems in their early stages and then implements appropriate preventive action plans. In quality cost terminology, continued investment in prevention yields further reductions in internal and external failure costs, and the organization is now able to reduce appraisal costs.

Stage 5: Certainty. At this final stage of maturity, the organization considers quality management an essential part of its processes. The systems it has put in place prevent problems, and continuous quality improvement is a normal, routine focus. In quality cost terminology, the allocation of resources to appraisal, internal failure, external failure, and prevention areas is optimized, and overall quality costs are reduced significantly.

Most regulated companies can claim that they are well past the “Uncertainty” and “Awakening” stages, but within an overall quality system, individual processes can fall anywhere between the “Enlightenment” and “Certainty” stages. For example, some companies have strong, integrated change control processes, but these same companies run into problems when integrating their complaint handling process. Given that the compliance and effectiveness of separate processes within the overall quality system can vary, organizations would be wise to put a plan in place to evaluate the maturity of all of their quality systems.

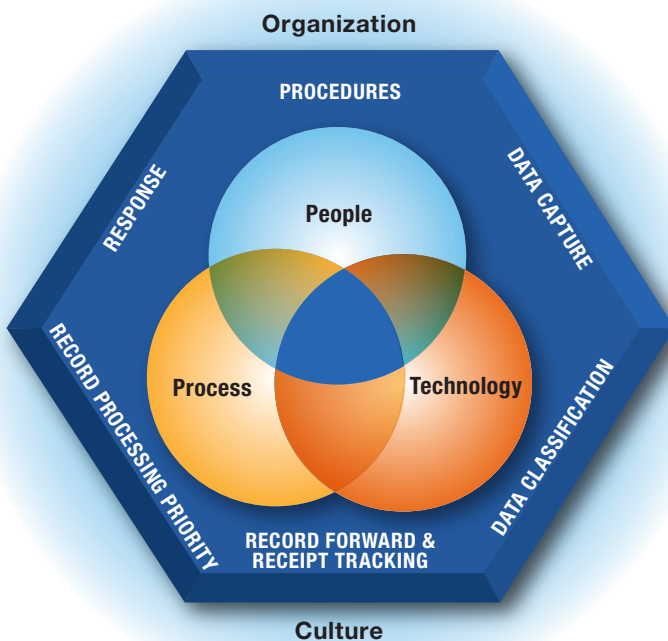
Quality Systems Assessment Framework



Setting strategic priorities through a quality systems assessment

An assessment may seem overwhelming, but it can easily be broken down into component parts, as illustrated in this graphic:

Quality System Assessment Elements



Within each step (component), you can evaluate the procedure, technology, and people involved during that stage of the quality process. Also for each step (Event Trigger, Data Gathering / Collecting, Evaluation, etc.) you should evaluate the Procedures, Data Capture, Data Classification, Record Processing and Priority, Record Forward and Receipt Tracking, and Response in place for that step. The graphic above depicts the elements that should be assessed for each step. Note that the all-encompassing element is the organization's culture – specifically, its readiness to embrace the importance of a strong, integrated quality system.

When evaluating each stage, organizations need to focus on potential compliance concerns as well as process efficiency improvements. For each stage and across each element, the assessment report should identify the findings (observations) and the opportunities for improvement as well as specific recommendations on how and when to address the findings. The time frame should be determined based on risk, ease of implementation, and the business return.

Another element to consider during a quality systems evaluation is how well a company's quality systems are integrated with one another. Fortunately, there are many technology applications that make it easy to integrate disparate quality systems.

For example, an observation about the audit management quality system can trigger a related investigation in the investigation management quality system. Effective quality system integration can help reduce human error and optimize work effort and flow. Addressing the opportunities for improvement identified in the assessment not only improves the individual quality processes but also helps the business to evolve its overall quality management system.

Creating a roadmap for change

Assessments are valuable, but all of those insights gained are rendered useless unless the organization creates a plan for translating observations into concrete changes. Organizations should start by prioritizing the needs identified in the evaluation and creating a resource and project plan for addressing each of them. An assessment should not be seen as yet another "audit activity" – i.e., a passing, "check-off-the-box" exercise – but should instead be used to shift the organization to a mindset of continuous improvement and awareness.

To plot out an effective roadmap, take the assessment findings and organize them into these priority buckets:

- **High priority activities** – Changes that need immediate action.
- **Medium priority activities** – Changes to address after high-priority steps have been completed or when resources become available.
- **'For Consideration' activities** – Significant, helpful input, though less important than other industry-leading practices that should be considered first.

Once your steps have been prioritized, build a project plan and timeline that addresses the resources needed to complete each step. The roadmap should include key milestones, target dates to meet these milestones, then recognize and celebrate their completion.

A well-defined, realistic roadmap with detailed tasks, milestones, and resources moves a quality system process forward on the maturity scale and promotes a culture of sustainable quality and continuous improvement.

From Assessment to Roadmap – an example

Understanding the importance of a thorough quality systems assessment and well-developed road map for results, Clarkston assisted a \$2B over-the-counter pharmaceutical and store-brand supplement manufacturer. The company wanted to ensure that best practices and the right technology initiatives were in place to support their operations in a regulated pharmaceutical environment. They further understood that they needed an information services/quality systems strategy that was both aligned with their corporate strategy and leveraged pharmaceutical best practices. In just a two-month period, a solution was delivered with the following components:

- A disciplined and structured assessment of the company's quality systems strategy and IS roadmap;
- Gap identification and assessment based on business need and industry benchmarks;
- Clarkston's point of view on approach to achieve immediate and future business needs;
- A quality systems road map with prioritized initiatives;
- Estimated costs and time line for quality systems initiatives; and
- Assessment of targeted funding levels and support organization needs related to quality systems.

Most importantly, the company had a quality systems strategy and road map with the following key components:

- **Insight** – industry benchmark analysis providing key insights into opportunities for improvement;

- **Perspective** – start /stop analysis providing recommendations on which projects should continue, and which should be placed on hold based on alignment to corporate business strategy;
- **Direction** – five-year quality systems strategy and to-be landscape providing current systems overview and recommendations on systems that should be implemented;
- **Describable Targets** – prioritized initiatives to maximize ROI and mitigate rework risks; and
- **Sense of Achievability** – detailed proposed support organization recommendations including resources and procedures to enable the manufacturer to meet its goals.

Getting started

The example cited above can be used as a general outline. The first step is recognition that existing quality systems are likely not at an optimal state and a commitment by management to identify and act upon opportunities. A baseline assessment of all areas of the quality organization should then be performed against industry benchmark standards. The outcome of the assessment is the identification of gaps between existing states and desired states. Remediation project plans can then be developed. Prioritization of efforts based on the outcome of the assessment and the nature of the remediation projects is the next step, followed by execution of the improvement projects. Seize this opportunity and determine how your quality systems measure up.

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