ENTERPRISE QUALITY IN LIFE SCIENCES

EMBED QUALITY BEST PRACTICES TO DRIVE PROFITABILITY

QAD

CONTENTS

SEEING THROUGH A NEW LENS

Manufacturers of medical devices, in-vitro diagnostics, surgical devices, orthopedics and others must consistently prove their conformance with strict global quality standards and requirements such as FDA CFR Part 820 and international ISO 13485. New entrants to the market and even incumbent leaders often recognize the burdens of the regulatory framework but overlook the value of quality. In many cases, the need to be first to market or market leader is the sole driver of an investment while quality best practices are an afterthought.

But can quality be a competitive advantage?

Can quality be a profit maker instead of a profit taker?

Yes to both.

Leading life sciences manufacturers must view quality through an enterprisewide, continuous improvement lens — with a focus on overall organizational goals rather than as a compliance exercise. By doing this, manufacturers can reduce total cost of quality and increase profits by embedding quality best practices throughout the value chain, from product design and manufacturing through post-market sales and service. This quality improvement approach, combined with an Enterprise Resource Planning (ERP) system that integrates these quality processes across the enterprise, pays dividends in customer satisfaction and provides significant competitive advantages while maintaining effective and efficient regulatory compliance. As a result, manufacturers can focus on innovation and delivering new and advanced medical devices to growing markets around the globe.

Medical device companies that focus on meeting regulatory requirements as an exercise in compliance rather than adopting the best quality practices often have poor business outcomes and do not necessarily experience high quality. For example, a McKinsey study found that the direct cost of poor quality, which includes labor cost of remediation, routine quality failures and non-routine external quality failures, ranges from 4.8% of revenue for best of class to 6.9% of revenue for the poorest performers. Applying an average percentage to the estimated $562 billion global medical device market (2022) shows $32.9 billion lost to poor quality. What is striking is that the organizational direct costs of ensuring good quality through prevention and appraisal differ by a mere 0.5% of revenue between best-of class and worst-of-class.

However, the cost of poor quality is also measured in terms of reputation and indirect costs. A major medical device quality failure can have a severe impact on a life sciences company's reputation and competitive position if customers perceive their products aren't safe for patients. A significant quality failure could even lead to a major regulatory compliance penalty like an FDA consent decree that requires a shutdown and recall until the issues are resolved to the regulator's satisfaction. The inability to manufacture new products or sell existing inventory would have a crippling cost on a company and a significant impact on future sales, reputation, as well as share price.

By embedding quality best practices through an enterprise-wide, continuous improvement environment, compliance becomes a natural outcome of the process, and medical device manufacturers can reduce costs and increase profits. McKinsey estimated that by applying leading quality practices, a medical device manufacturer can recover costs that range between 1.5% and 3.0% of sales. This quality improvement approach also pays dividends in customer satisfaction and provides significant competitive advantages. High performing organizations typically focus on the following elements that correlate with good quality.

- Quality system maturity and culture
- Product and process design
- People
- Supplier quality
- Process automation

Companies use a risk-based approach to determine how much money and effort they spend on quality activities. This balancing act can be best described by a curve (Figure 1) that shows how companies that spend little money and effort on quality face huge risks, while increasing cost and effort will decrease risks until an optimal point is reached: where increased costs yield a diminishing return on compliance or risk reduction. Each company will have a different approach to risk and how to mitigate it. This difference may depend upon factors such as risk tolerance, a life sciences company's regulatory compliance history or even process improvements that may yield additional quality benefits or offer competitive differentiation.

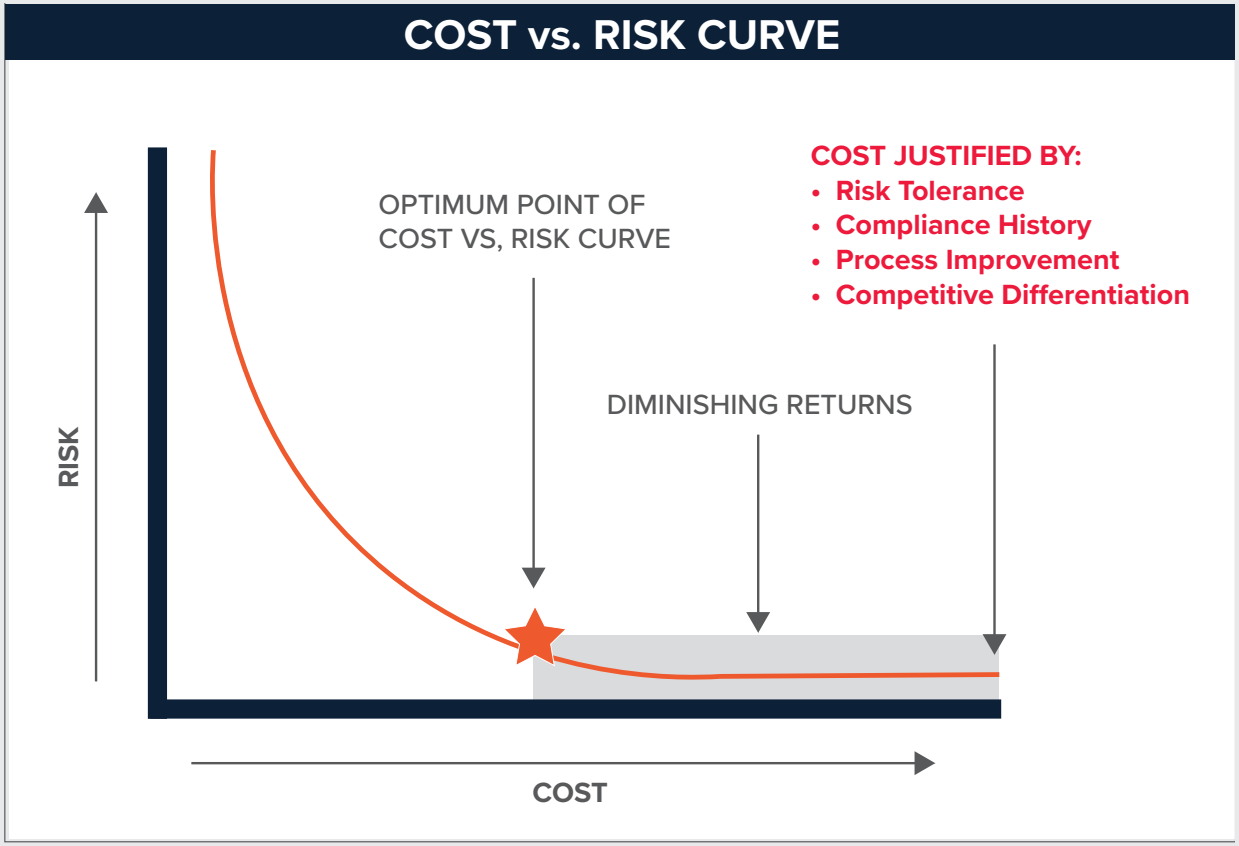

FIGURE 1: Cost vs. Risk curve

COST VERSUS RISK OF QUALITY

Cost and risk are two critical components that life sciences companies must keep in mind as they develop their business processes and procedures. Life sciences companies must balance the costs of conformance measures with the potential risks (or costs) of non-conformance. The costs of conformance include prevention costs, such as quality planning, training, statistical process control or system development and management; and appraisal costs, such as acceptance testing, inspections and audits. These costs also include process development and design, and investment in quality-related information technologies. These companies can reduce risk and the cost of poor quality by investing in preventive measures and in good, solid appraisal methods.

Not only do life sciences companies face critical challenges from increased regulatory scrutiny and focused quality initiatives, but they must also deal with downward margin pressure resulting from reduced market pricing and reimbursement requirements. As a result, companies must optimize the use of their resources to effectively achieve their quality goals and find their optimal balance between cost and risk.

A quality management system (QMS), which is the organization and collection of business processes used to achieve a company's quality policies and objectives, is a tool used by all life sciences organizations to achieve these goals.

A QMS is composed of organizational structure, plans, procedures, processes and resources (people, infrastructure, equipment, capital, etc.). It can be administered using either manual processes, an enterprise quality management software (EQMS) or a hybrid approach. The critical success factor is the degree to which companies can integrate these processes into their business practices, ultimately making them their own. One size doesn't fit all.

By placing quality at the core of process management, life sciences companies can shift the cost versus risk curve to reduce incremental costs for the same level of risks. Companies can increase efficiency and lower costs of conformance for the same risk by integrating ERP and EQMS functionality, to embed quality procedures into their business and manufacturing processes (Figure 2). Integrating and automating these processes help drive a quality culture throughout the organization.

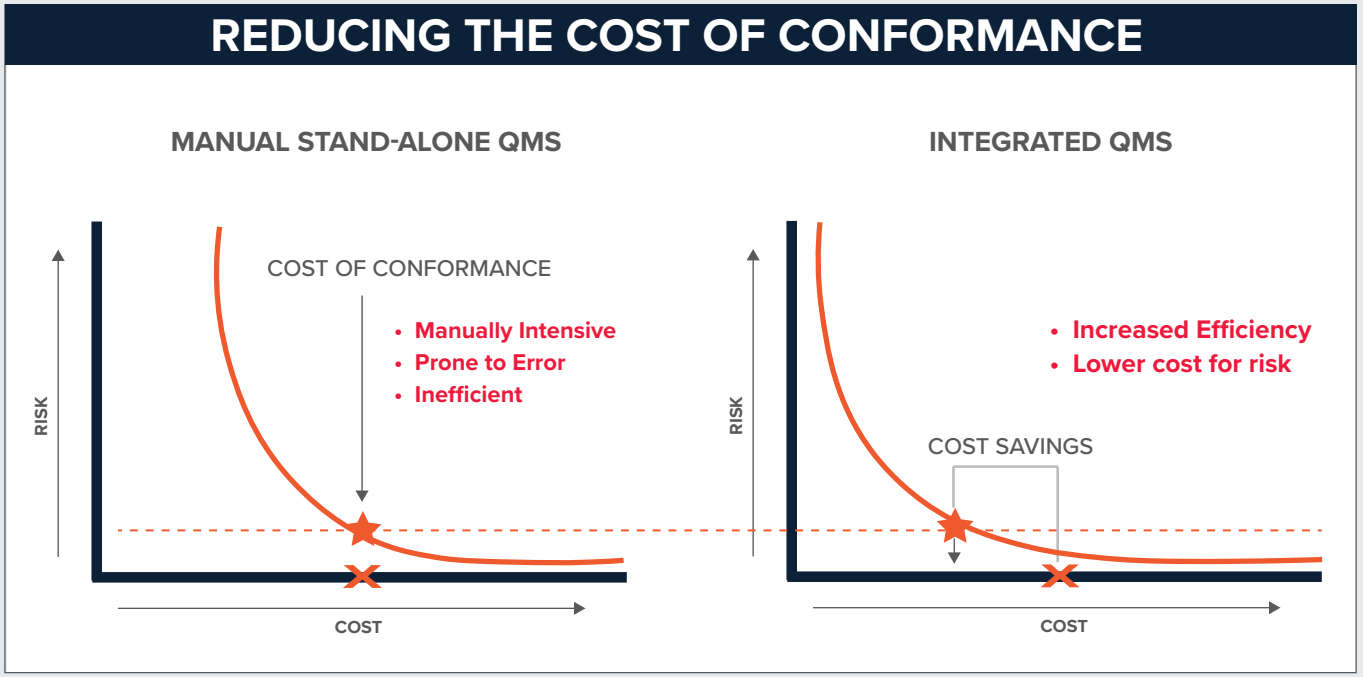

FIGURE 2: Reducing the Cost of Conformance

THE VALUE OF INTEGRATED QUALITY AND BUSINESS PROCESSES

Recent trends show that government regulators are viewing quality as more than a strict regulatory compliance issue by promoting the advantages of improved operational performance. For example, in developing its Case for Quality program, the FDA found that medical device manufacturers that managed quality risks by driving quality across the enterprise tended to be more productive, with fewer complaints and investigations per batch. Those companies also usually had smaller quantities with lower quality-related costs than their competitors. Thus, we see that quality can give life sciences companies a competitive advantage.

To drive enterprise-wide quality throughout a life sciences company requires the integration of quality and production processes. The ideal method to achieve this goal is by integrating ERP and EQMS. Integration of the quality processes of an EQMS with an ERP system can yield a number of benefits:

- **Ability to standardize processes and workflows** drives overall improvement in quality, compliance and cost. Integrating automated quality workflows into business processes will result in quality processes consistently applied across the enterprise.
- **Automatic collection of quality data** provides visibility across the quality process of an enterprise's value chain. Analysis of this information allows companies to gain insights into trends and risks as well as provide the ability to drive continuous improvements by modeling the impact on the enterprise.
- Product improvement is enabled by the ability to **quickly foster and implement best practices** through the automation of quality processes. Companies can easily build compliance into processes and then rapidly implement them across the enterprise.
- **Streamlining workflows and synchronizing** them between quality and manufacturing reduces cycle times and resource requirements.
- **Integration and automation** benefit supply chain quality and compliance governance by improving the monitoring of quality and compliance performance of partners.

THE QUALITY INTEGRATION MATURITY MODEL

Improving business processes can be best achieved through an EQMS fully integrated with other critical business systems such as ERP, MES, PLM, etc. However, not all companies have achieved the same level of quality integration. As a guide for life sciences companies, a Quality Integration Maturity Model (Figure 3) helps identify the level at which companies are using information technology to synchronize automated enterprise quality functions. This quick assessment also helps identify how advanced, integrated business systems can bring step-change improvements across the value chain compared to disjointed, manual processes and systems.

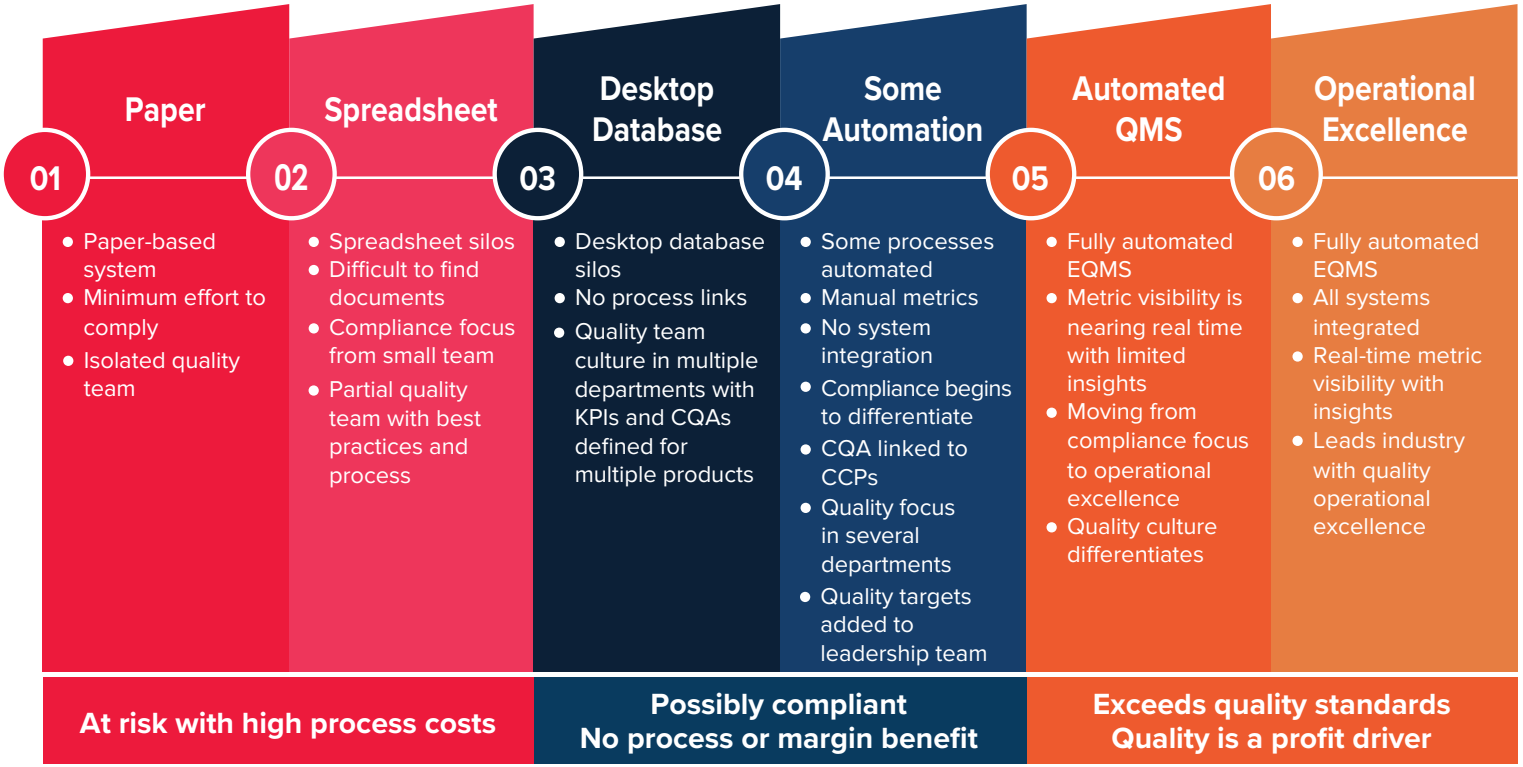

FIGURE 3: Quality Integration Maturity Model

BEST PRACTICE QUALITY MANAGEMENT

Life sciences manufacturers should integrate quality control and quality management system processes into their routine business processes and operations. These companies can then reduce costs and increase their profits by focusing on best practice quality measures. High performing organizations typically focus on the following elements that correlate with good quality.

QUALITY SYSTEM MATURITY AND CULTURE

Companies that execute core quality processes well — such as fast but thorough corrective and preventive action (CAPA) investigations that effectively act upon all enterprise data leveraged through easy integrations — drive better quality performance and lower quality costs. The ability to effectively execute quality processes, analyze results and implement continuous improvement from the results, all while involving individuals and organizations across the enterprise, is a hallmark of a strong quality culture.

Properly architected EQMS provides not only the infrastructure to increase the speed of maturity and quality culture, but also delivers it in a streamlined manner using well-characterized processes to facilitate GMP.

PRODUCT AND PROCESS DESIGN

Quality performance is directly affected by specific practices in product and process design. Companies that show good practice in design for manufacturability and quality often identify a set of critical quality attributes (CQAs) and link them with critical control points (CCPs) in production, with relevant in-process testing steps established at the outset of manufacturing. Companies that have a high share of products with defined CQAs — and CCPs tied to those CQAs — have a significantly lower share of low-quality products, as measured by complaints and recalls, in the market.

An EQMS Design Control application is critical to move your organization from a reactive organization of fire fighters to a cross-functional team of SMEs proactively planning quality into the product design and manufacturing processes, greatly reducing the cost of poor quality.

PEOPLE

Organizations with well-trained employees with a continuous improvement mindset and actively involved in quality activities experience higher quality performance and lower staff turnover. The ability to disseminate and track training progress across an enterprise requires automation.

EQMS Document Control and Training Management applications work together to help make sure personnel are properly trained. Each position/title can have required skills and ratings for that position/title and then knowing the current skills an employee has, the system can help define the training each employee requires. Skills can also be associated with documents and when the document undergoes a change, impacted employees can be identified and targeted retraining can be conducted.

SUPPLIER QUALITY

High performing companies don't rely on simple inspections to manage supplier quality. They actively share their internal quality processes and metrics with suppliers, actively collaborating with them toward a goal of continuous improvement. A quality management system that provides supplier performance metrics and reports can enable manufactures to identify top performing and underachieving suppliers based on an effective supplier scorecard or rating program. EQMS should be open to suppliers to increase their involvement, cooperation, and coordination, incorporating them into your ecosystem and supplying them with the information they need to support your objectives.

PROCESS AUTOMATION

The ability to promulgate standard processes, based on best practices, as well as rapidly disseminate changes due to continuous improvement, across an enterprise with multi-national locations requires automation and cloud technology to be effective.

Top EQMS systems will be based on industry-leading best practices for quality processes, including robust change management with approvals in appropriate phases of workflow.

When looking at the combination of these integrated controls and processes, EQMS can have a big impact on operations and the business (Figure 4). When added together the cost of delay can be in the hundreds of thousands of dollars per month.

EQMS CAN HAVE A BIG IMPACT ON OPERATIONS AND THE BUSINESS

AREA	IMPACT	COST OF DELAY
On Time Delivery	2-4%	Can be in the hundreds of thousands
New Product / New Program Introduction Rates	5-6%	
Inventory Availability / Lead Time Reduction	3-4%	
Supplier Performance	5-10%	
Supplier Chargebacks	10-15%	
Audit / Inspection Costs	12-20%	
Non-Conformance Occurrence	10-25%	
Rework Costs	7-10%	
Cost of Quality (CoQ) (Good and Poor)	8-12%	
Manufacturing Operating Margin	5-7%	

FIGURE 4

GET ALIGNED, ADAPTIVE

Manufacturers in the highly regulated life sciences industry face a number of challenges from current and emerging regulations that directly impact their operations. A life sciences company can become a more effective enterprise by ensuring that its processes are well thought through, operating at peak efficiency and perfectly aligned with the strategic goals of the company. Putting quality management at the core of business processes can greatly reduce the burden of compliance while enhancing the effectiveness of standard business processes.

Adaptive business systems and advanced technologies are crucial to the ability to stay ahead of competitors and ensure healthy profits -- by not only meeting today's regulations and integrating enterprise quality but ensuring survival and success as the industry continues to shift over the coming years.

We call manufacturers that are able to innovate and change business models at unprecedented speed Adaptive Enterprises. Traditional tactics, processes and systems often hinder a company's ability to rapidly respond to change and keep or gain competitive advantage. How do you stack up against the ideal Adaptive Enterprise? To see how prepared you are to survive today's disruptions and provide the flexibility needed to address tomorrow's challenges, take the Diagnostic.

For more information on how QAD can help your company integrate quality and business processes to increase your efficiency as well as regulatory compliance contact your QAD sales representative, or visit

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