

Building a Business Case for Quality Management Transformation

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Can the pharmaceutical industry embrace the goals of Quality 4.0?

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Transforming quality management is the underlying goal of Quality 4.0 (1), a global, cross-industry initiative that pursues quality excellence through digital transformation. Disruptive technologies that connect systems, processes, and people provide the foundation for quality transformation by enabling pharmaceutical companies to become more proactive in addressing quality issues throughout the product lifecycle.

Quality 4.0 offers significant potential for life-sciences companies, though many are still uncovering new ways to leverage the initiative across their organizations. Early requirements for electronic records and signatures set by FDA prompted a movement to digital technology in the early 1990s, but efforts to go digital in quality were limited to specific process areas. At the time, quality was not viewed as a strategic area in life sciences, so less emphasis was placed on making holistic, sweeping changes. Instead, companies implemented digital technology in piecemeal, plant by plant, or reactively, as a way to address specific issues. The result was system fragmentation.





Companies today use one or more discrete quality management systems (QMS) for change control, complaints management, audits, and other applications. These disparate systems cannot seamlessly support end-to-end processes and create inefficiency. Additionally, management cannot easily see how this patchwork of systems impacts the company's overall business, making it difficult to build a convincing case for transformative change.

The Quality 4.0 movement coupled with globalization, compliance changes, and pressures to operate more efficiently, are driving transformation, however. Already, 18 of the world's top 20 pharmaceutical companies are either transforming or planning to transform at least one area of quality management with modern cloud technology. A cloud-based quality management platform that connects all quality systems enables organizations to bring products to market faster while ensuring quality and compliance.

Quality 4.0 is now within reach, and the results will be transformative. However, quality managers must first build the right

Figure 1: Quality transformation is being driven by the systems below, and a focus on value rather than cost.

Modern Systems Driving Transformation and Value

Cloud	Standardization	Unification	External Engagement
 <ul style="list-style-type: none"> • Modern consumer inspired user experience • Always current with 3 releases per year • An appreciating asset over time 	 <ul style="list-style-type: none"> • Industry cloud applications are delivered with robust best practices • Massive requirements definition and configuration is no longer required 	 <ul style="list-style-type: none"> • Unification of multiple disparate quality applications onto a single platform • Large business process & efficiency improvements 	 <ul style="list-style-type: none"> • Seamless interconnection with contract services partners • Elimination of a risky disconnect point

business case to ensure that the entire organization is in sync. The key is to first map all of the benefits with the business goals, and measuring each quality outcome against business values.

Align benefits with corporate goals

Adopting new transformative technology is not easy, because it requires more than changing technologies. It requires changing minds. This effort is usually driven by a visionary leader or forced by management after a major regulatory action, such as a warning letter. Further, most quality teams have only implemented projects incrementally over the past 25 years, so a single transformation project designed to overhaul everything is going to require careful planning and a strategic case that aligns benefits with business goals. To succeed, the strategy (Figure 1) must shift from focusing predominantly on cost to added value. From a system perspective, four key areas are enabling change, driving transformation and value generation:

- True cloud platforms—A cloud platform provides a modern, consumer-inspired user experience that is always current with regular system updates. It becomes an appreciating asset over time because it works better with more use.
- System and process standardization—Process standards that align with best practices eliminate the need to go through massive requirement definitions and configuration exercises. As a result, they enable the standardization of metrics for better reporting, smoother new-hire transitions within the organization, and shorter overall development cycles.
- Unified models—With a unified systems model, companies bring together multiple, disparate applications onto a single global platform for greater visibility, collaboration, and efficiency. Companies no longer need a separate content management system, training system, and QMS.
- External engagement—Advanced application programming interface (API)-driven technology enables seamless external engagement with today’s growing pool of contractors to leverage their expertise. True cloud soft-

ware allows the seamless interconnection between these contractors, service partners, and the organizations that they’re doing business with, and eliminates potentially risky manual hand-offs.

Measure outcomes according to business values

To build a convincing case for quality transformation, the quality organization must show how it is an important partner to the business rather than just a cost center. This can be an uphill battle, because many quality organizations are viewed as compliance-centric business units (i.e., part of the cost of doing business).

To prove its value, the quality team must measure a quality transformation based on more than just compliance to also show how a transformation impacts patients and business operations (Figure 2). PwC has identified the following as outcomes that impact business value:

- Competitive compliance
- Speed to market
- Robust product and data
- Reliable supply
- Innovation.

The return on investment for each quality outcome is measured by the business according to its impact on revenue, cost, inventory, and regulatory risk. Creating a framework within which to measure quality outcomes against these four parameters demonstrates the business value of the quality management transformation initiative.

For example, “competitive compliance” is a quality outcome that reduces costs and regulatory risk. This is made evident according to specific, related metrics, including audit and inspection observations, recall and deviation rates, and supplier risk profiles.

Another outcome, “improving speed to market”, increases revenue by reducing protocol amendment rates and serious breach and critical data error rates and increasing on-time post-approval changes. Yet another, “robust product and data,” can be measured by brand image, product release cycle time and variability, yield, and complaint rate.

Figure 2: The effects of a transformative QMS are shown below on key performance areas.

Quality Outcomes	Business Value - Return on Investment (ROI)			
	↑ Revenue	↓ Costs	↓ Inventory	↓ Reg. Risk
Competitive Compliance		✓✓		✓✓✓
Innovation		✓✓		✓✓
Speed to Market	✓✓✓			
Robust Products & Data	✓	✓✓✓	✓✓✓	✓
Reliable Supply	✓		✓✓✓	

Finally, “reliable supply,” which impacts both revenue and inventory, can be demonstrated with metrics. Examples would include service levels, shipping complaints, and adherence to manufacturing schedules.

Demonstrate the impact of innovation

One quality outcome has far-reaching implications: innovation. Quality organizations often overlook a number of ways that innovation can be improved. Each company will have a different set of metrics, depending on its level of technology maturity. The following are five areas where new technology can have a significant impact on life sciences innovation:

- **Modernize manufacturing.** The quality organization can play a major role in automating manufacturing processes. Quality organizations define how to provide feedback loops from laboratories back into the process. They look at how to leverage rapid micro techniques and electronic batch records. These are innovations that can be measured.
- **Leverage emerging technologies.** Emerging technologies (e.g., artificial intelligence and natural language processing or analytics) can be used to detect problems proactively. Quality teams can adopt these solutions to predict and prevent batch failures or to predict where the inspectors might find issues and resolve those issues beforehand.
- **Unify quality operations.** Unifying systems into one, integrated quality platform drives speed, agility, and visibility across the enterprise, creating measurable business value. This integrated system should also extend across the product lifecycle from research to distribution through commercial. It should also connect with clinical trial management and regulatory information management systems.
- **Improve clinical trial design.** Innovative quality solutions support, improve, and speed up clinical trials. Quality can play a significant role in developing more robust protocols which help reduce data error rates and even serious breaches, all of which accelerate reporting and the submission process.
- **Apply quality by design/quality risk management.** Incorporating proactive approaches (e.g., quality by design [QbD], quality risk management [QRM], and continuous process verification [CPV]) help organizations speed up innovation. These techniques allow companies to focus their limited resources on the most critical items and that will make a positive impact on product quality and on patient wellbeing.

Translate value into bottom-line results

While qualitative metrics can be used to assess value, executives also want to know the bottom-line impact of quality transformation on revenue, costs, inventory, and regulatory risks. **Figure 2** shows the effects of a transformative QMS implementation on each of the main assessment areas.

The implementation of a cloud-based QMS can significantly impact revenues and costs by reducing the number of devia-

tions, corrective action and preventive action (CAPAs), and recalls. With fewer investigations, companies can also reduce the resource burden in operations and quality assurance. The use of an innovative system with an automatic feedback loop also reduces the number of hours necessary for training, as well as the number of serious breaches, or protocol amendments that are required to improve yields.

New technology also impacts inventory and regulatory risks. Modern quality systems can reduce regulatory risk by identifying quality issues faster while at the same time reducing costs and total inventory. For example, by reducing the capital tied into the business and improving innovation around inline testing, or using more modern testing techniques, organizations can shorten cycle times across end-to-end product manufacturing to speed production and reduce inventory.

For a multi-billion dollar company, just a 1% increase in revenue through improved quality can translate into millions of dollars in savings. For example, improving inventory turnover by 10% can free millions of dollars. Preparing an organization for quality transformation by looking at revenue, cost reduction, inventory reduction, and regulatory risk profile is critical to the business case.

Talk the language of executives to make a business case

Most executives do not speak the language of quality. For instance, they may not understand the impact of a deviation or a complaint, nor will they speak in those terms. Therefore, to demonstrate the value, quality teams need to talk the language of business.

Every executive has slightly different priorities in addition to improving bottom-line revenue. Because each business area is different, it is important for quality professionals to consider how to speak with each member of the executive team, not only to get their buy-in to make the investment but to orchestrate and support the organizational change required for a quality transformation.

When talking to the chief operations officer, for instance, focus on the robustness of processes and products and improved cycle times. The chief financial officer (CFO) wants to know about the overall cost of quality, and the chief quality officer focuses on traditional compliance, so, when speaking to the them, change the conversation from dollars (which would be used with the CFO), to the impact of quality on business.

Think in terms of value, not just cost, about how a unified QMS can help improve revenue, reduce costs, lower inventory, and reduce regulatory risk. Moving to a unified solution is transformative and possible today. As more companies in the pharmaceutical industries do this successfully, Quality 4.0 may finally take hold in the life-sciences industry.

Reference

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