

Ending the Tug-of-War:

How to bring quality and efficiency into alignment...and drive peak performance



As Vice President of Quality of a life sciences company, your primary concern is ensuring that your products consistently meet the highest standards of safety and reliability. Meanwhile, your counterpart in Operations is focused on reducing cycle times, lowering costs and meeting ever-increasing production goals.

While both you and the Vice President of Manufacturing are on the same “team,” your organizations haven’t necessarily always worked well together. You’ve seen firsthand that quality is often perceived as a roadblock. A brick wall. An obstacle in the path of efficiency.

However, as a forward-looking leader, you know that the opportunity exists for quality to support operations in a way that is a win-win for both organizations and, more importantly, for the company as a whole. In fact, over the past several years, you’ve noticed a growing movement to increase efficiency and lower costs across the board. And you’ve taken note of the latest industry guidance from the U.S. Food and Drug Administration (FDA), the International Conference on Harmonization (ICH), and other regulatory bodies, which shows a strong commitment not only to achieving high product quality, but also to adopting better ways of doing business.

So what does this all mean? And how should you respond? What if you could reduce SOPs by 86%? What if you could achieve \$735 million in cost avoidance? How about a quality systems operation that returns \$1 million to \$5 million annually?

To find out more, we interviewed Michael Prucha, Director of Clarkston Consulting’s Quality Systems Solution. Michael has been working with life sciences executives, like you, for more than 10 years, helping them solve their strategic business problems by developing and implementing both process and technology solutions.

Most recently, he’s been helping them align both their operational efficiency and quality assurance goals with their company’s long-term business strategies to drive peak performance.

In today’s market, where both patient safety and shareholder value are critically important, are you still seeing situations where efficiency is winning out over quality or vice versa?

That’s the constant tug-of-war so to speak. Some companies are dependent on their ability to get product out the door in the most time-efficient manner. These companies usually have highly automated processes and focus on reducing cycle times associated with their quality operations. The end result is that they meet their efficiency and volume targets, but weaken their quality position — accepting the associated risks, such as increased regulatory scrutiny, potentially steep penalties, product recalls and so on.

On the other side of the spectrum are companies that require such a high degree of quality that they’re heavily reliant on manual, labor-intensive activities. In these companies, the quality organization often plays a go/no-go role. If the product doesn’t meet the standards they’ve established, they’ll release it at risk for recall, or they won’t release it at all. And in an industry where every day matters, that delay in getting the product into the patient’s hands also translates into a direct hit to the bottom line.

So yes, many companies often sacrifice one for the other. However, you can have a high degree of quality and efficiency. In fact, to truly mitigate risk and drive real business results, you have to establish the right balance, and you do that by aligning those functions with your overall business strategy.

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Michael Prucha

Director of Quality Systems Solution, Clarkston Consulting

Taking that a step further, what are you seeing in terms of how companies are approaching their quality assurance activities?

Unfortunately, too many companies are still reactive, addressing issues as they arise, which results in piecemeal solutions that address the symptoms, but rarely resolve the overarching problems. I heard it stated once that “many companies are operating with the compliance gun to their head.” I can’t think of a better way to summarize these approaches. But there is a better way and that’s a proactive approach to quality. A proactive approach means incorporating compliance into the core of your operations. Aligned with ICH Q8, Q9, Q10 and Quality by Design initiatives, it involves looking across your manufacturing and quality operations to determine what is your strategic direction? Do you want to operate in an optimized manner across both of these areas? And if you do, do you know where you are on the scale of efficiency and quality? Do you know how well your operations and quality assurance organization—and the metrics you use to evaluate those functions—align to your strategic goals? If the answer to any of these questions is no, there’s undoubtedly an opportunity for you to achieve a higher degree of success.

How important is it to break down the silos that exist before you adopt a proactive approach?

Operational silos (pockets of people performing critical business functions in non-standardized manners) are common in all industries. However, in pharmaceutical, biotech, and medical device companies, a lack of standardization poses tremendous risk. In developing a proactive approach to quality, you need to look critically at standardization within each of your quality systems. More and more companies are beginning to examine the long-term value of data management and if your data capture processes are not standardized, you’re already falling behind the curve.

Fragmented systems and manual workarounds can significantly compound risk and compliance risks in the long run – while restricting the capacity for growth.

Can you elaborate on ICH’s latest guidance?

First, let’s clarify the focus of the guidance: ICH Q8 is focused on Pharmaceutical Product Development, Q9 on Risk Management and Q10 on Quality Systems. Based on ISO and GMP requirements, ICH Q10 is focused on establishing a model for what an effective quality system is. Essentially what they’ve said is that, as an industry, we need to achieve the highest level of quality associated with a product, and we also need to be flexible in how we adopt and adapt to newer technologies that will help enable this. And Q10 politely nudges companies to apply quality systems throughout the entire product lifecycle, from product development and technology transfer to commercial manufacturing and product discontinuation.

Just imagine if your quality system could significantly reduce batch record errors and variability and provide hands-on data that facilitates FDA submissions. What if it could be specifically mined to aid in R&D and product innovation? Q10 advocates this type of approach and the capability is available. While many companies struggle with how to integrate these concepts into their operations, adopting a proactive approach to quality is the simply the best answer.

Q10 also underscores the fact that quality requires significant management responsibility. It requires a top-down commitment from the senior-most levels to provide the directional, as well as the financial, support necessary. It advocates that leaders should support efforts over the long-term that help drive higher levels of both quality and efficiency. Naturally, there are challenges associated with resources, time and budget. However, when you take a proactive approach to quality – you can identify the

smaller initiatives that bring about great gain, while providing time to plan out the longer, strategic initiatives that help you achieve your vision – a roadmap to peak levels of optimized efficiency and quality.

ICH Q10 also talks about continuous improvement. How does that play into this discussion?

That’s an important point. Q10 fosters the right type of messaging because it focuses on continuous improvement for product quality, process performance and the overall pharmaceutical quality system. To do that, you need to establish key performance indicators (KPIs).

When operating with the ‘compliance gun to the head,’ the justification for action is easy – do it or risk the wrath of the FDA or other regulatory body, negative publicity, significant fines, plant closures, etc. However, establishing a sustainable quality operation requires carefully selecting initiatives that not only align to strategic company goals, but also provide a return on the investment (ROI). Many companies struggle with identifying and quantifying these returns– often opting for the ‘cost avoidance’ tag. At Clarkston, we help companies forecast their ROI and then encourage companies to measure these benefits after they successfully implement their solutions. This is where KPIs come into play.

As you establish KPIs, you need to think about how well-aligned your quality organization is to your company’s immediate and long-term goals. Diagnostic efforts often reveal surprising insights. Often, companies find that they are measuring their people on the wrong metrics. The KPIs should be focused on what you strategically want to achieve with your quality initiatives.

With all of today's competing priorities, what's the value in companies looking at these issues now?

Well, frankly, if a company is looking to maintain the status quo, then it can afford to keep its head down and hope the wagon moves forward and the wheels don't fall off. But it has to be willing to accept that it's choosing to operate in a completely reactive manner – not as a market leader. Conversely a company that says, "We want to reduce compliance risk. We want to reduce variation and cost of operations. We want to get ahead of the maturation curve. We want to define the path, not walk down it years after" will not just survive, they'll excel – both in the short-term and long-term.

There's still reluctance on the part of some executives to move in this direction. Why?

There's one fundamental challenge for quality, when it comes to aligning to a company's strategic metrics – getting quality product out the door...FASTER.

Reluctance, or perhaps more accurately resistance to change, is usually due to fear. In this case, fear that they don't have enough resources. Fear of having their staff cut. Fear of new technology. Fear of replacing a process or system that is compliant and is proven to work, albeit inefficiently, with one they're not so sure about. CHANGE is challenging, but it's also the defining quality attribute and those willing to seize the moment are the first to gain the advantage. But it's important to understand your options as you approach any type of organizational change. Companies like Clarkston Consulting, for example, who have expertise working in regulated industries, can add experienced members to your quality team while you embark on longer-term solutions. Your proactive approach to quality should take this into account.

So where does technology fit?

Technology is an enabler; it's not a solution unto itself. And it has to be integrated into a broader, more strategic approach.

Sometimes quality organizations, are so focused on replacing a system or process they have now—which is compliant—with something else that's compliant. But having the right software, hardware, equipment is not the answer. You need to step back, take a holistic view of your operations and identify how technology can support your broader goals. And that requires leadership support from the highest levels of the organization. Keep in mind that you might need to streamline your processes and, you may need technology you haven't needed before to drive efficiencies...you may need either or both. You need to find out what makes the most sense for you.

You've stressed the need for alignment between a company's strategic vision and its quality and operations activities. How do you achieve this?

It's a three-step process. First, diagnose where you are now compared to where you want to be and benchmark the findings. Then assess the gaps and draft your plan. Prioritize those initiatives accordingly and establish a business case that outlines the tangible benefits. And, the last step of course, is to implement the initiatives you've defined.

Clarkston offers a tool to help companies through this process. How does it work?

Clarkston Consulting has developed a quality systems diagnostic tool. It goes one step beyond a traditional gap analysis to help you gain a clearer understanding of two important elements: where you want to be versus where you are now in both assurance of quality AND efficiency of operations. As part of that process, we examine a company's operations across the six components of quality systems as we've categorized them using the FDA's guidance (Figure 1). The tool lets us look across these areas very quickly and assess the "as is" versus the "to be" states. Presumably, most companies want to be operating at peak efficiency and peak assurance of quality, but for your particular industry, at a given point in time, you may desire peak efficiency while positioning yourself for pending legislation or regulation. In those scenarios, the diagnostic tool helps define that picture.

Once we understand what the gaps are, we assess considering industry best practices, provide a roadmap regarding how to achieve your strategic vision, and



FIGURE 1: Quality Systems

develop a business case justification with forecasted ROI. The roadmap includes everything from business processes and technology, if needed; to policies and procedures, to training and change management activities. We help you prioritize your efforts based on what will bring about the greatest return on investment in the shortest amount of time.

What type of timeframe does this require?

The diagnostic effort requires approximately two to three weeks, maybe slightly longer depending on the scope. It's a highly focused effort and while it doesn't require a huge investment, the results will help you clearly prioritize your quality initiatives and your fiscal year budgeting efforts. The subsequent roadmap and business case justification can require anywhere from 6-12 weeks depending on the agreed-upon scope. It's time well spent and moreover, it's a very revealing process. You might find that you have priorities lined up in a sub-optimized manner or that you might even be embarking on initiatives that mask a symptom, but aren't going to solve the root cause of a bigger issue.

What would you say to a VP of Quality who agrees with taking a proactive approach, but says, "Our CEO will never go for it?"

The challenge is always going to be around securing the upfront investment. No executive will green light an initiative if they're not convinced it will produce a meaningful return. Nor should they. That's why it's so important to build a detailed business case that defines strategic goals and identifies hard, tangible, and certainly measurable benefits. We can help our clients project the ROI but I can't overemphasize the fact that it's essential to determine how you'll measure those benefits. The opportunity is there for the taking. A VP of Quality can gain the kudos they deserve by demonstrating that they can not only lead an initiative based on projected ROI, but they can also prove it on the tail end.

What are some of the other benefits associated with a proactive approach to quality?

Perhaps a surprising benefit is the data opportunity that comes with taking a proactive approach to quality. If you look at the long-term vision of where companies

are going, knowledge or data management is critical. ICH Q10 talks about the need for companies to assess quality knowledge management from an enabler perspective. The data that's produced during your product development activities can be leveraged during technology transfer, manufacturing, and even your discontinuation activities. If you have a strategy in place, there are ways to manage that data so that it can be leveraged downstream in the product lifecycle. It's all part of the maturation process toward maximum optimization across efficiencies and quality.

What's your final piece of advice to Vice Presidents of Quality?

This isn't something that requires a VP of Quality to put his or her neck on the line for. In fact, there's very little risk in or cost in gaining this perspective. Taking a proactive approach is a very purposeful, step-by-step process that will help you get ahead of the curve. It's simply establishing a very clear path to achieve strategic goals. It's where we specialize. We can partner with you to build the supporting business case, communicate the value and, ultimately, help you achieve sustainable success.



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