Build on Your Quality Foundation – Accelerate your Results

The second stage of the Quality Journey is Accelerate. Organizations in this phase have made investments in a quality management system and are ready to leverage its power to drive enhanced quality processes.

Now that you've automated your core quality processes and decision-making, and you've made sure employees understand these processes through a broad training approach, a key next step is to integrate functions and systems to take advantage of the benefits.

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By integrating your QMS with other enterprise processes, you can optimize the visibility of critical quality information and improve the consistency of data across systems. In fact, in the Accelerate stage of the Quality Journey, many organizations find significant value integrating their QMS with their ERP. Bringing quality to the forefront also means getting your message in front of management. And this means getting data into the hands of leadership. Then when they talk about quality, arming them with this data will make quality more real for them.

Going beyond the core quality functions, such as employee training and corrective action, you should consider taking the next step in further automating quality functions. Corrective actions come from nonconformances, so consider a system that can tie these functions together, that can help you perform root cause analysis, and can help solve systemic issues.

Current state

You've defined basic processes; they are online, and you've made them available across the organization.

By providing organization-wide access, you are now able to leverage the sharing of best practices, while reducing the time and cost of decision-making, reporting, and acting. Addressing the need to find the right information improves resolution times which lessens the risk for organizations because they don't delay implementing critical quality improvements that could reduce the risk of defects, improve product quality and boost customer satisfaction. And you should be able to ensure quality for new product introduction as early as possible, starting in the product design phase.

As you are well aware, policies and processes are not static – they need to change as your business conditions change. And just automating core functions doesn't unlock the power of your quality programs or the QMS. Having a QMS that can grow as your needs grow is critical. You have automated the base functions and now it is time to take advantage of additional quality functions.

Without a flexible quality management system, it can be difficult to perform root cause analysis. You react to issues as they arise, but how easy is it for you to tie different issues to the same underlying cause?

Not having a system that can track all quality findings and then provide analytics against all that data means you are repeating the same root cause analysis and possibly missing underlying systemic issues.

Many companies at this stage are just starting to think about supplier quality. Since your suppliers are such a key part of the product lifecycle, not tracking supplier quality

can have significant impact, especially when it is late in the production process, leading to excess costs to remediate.

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Recommendations

You are ready to grow your quality management approach to go beyond the basic controls that you now have in place to deliver insights across the product lifecycle. Beyond core functions such as document control, corrective actions and employee training, there are some key capabilities you should consider.

Nonconformance handling is a great next step. When you are able to manage all of your nonconformances in a centralized system, you have a better way to track issues and perform root cause analyses. You can track customer feedback, so small problems don't become larger issues that have a serious impact on your organization.

Your organization has multiple enterprise systems that have information that would be useful for quality. While integrating multiple systems can seem like a large task, you can start with one system and add additional integrations in the future. One of the first systems where you can drive synergy with your QMS is your ERP. In fact, you can leverage nonconformances and corrective actions to drive change in your ERP. What if a nonconformance reported in the QMS could automatically put materials on hold in the ERP? You could limit your exposure to quality issues leading to large scrap and rework costs. And this is just one example of an integrated process that can make you and your team more efficient and significantly reduce your costs..

Nonconformances and corrective actions can occur well after you've designed your products and you are tracking quality during production. We know that the earlier you catch a problem in the product lifecycle, the less expensive it is to correct. So, designing quality in at the beginning is critical, which impacts the other end of the product lifecycle when you bring new products to market.

And, even with the best processes and quality programs, customers can still run into issues. Therefore, being able to manage customer feedback, and regulated customer complaints for life sciences organizations, can help identify and react to issues more rapidly, allowing you to better manage the risk associated with your products. And to track all customer feedback, another key integration point is with your CRM.

By capturing customer feedback, by integrating with other key enterprise systems, you can take audit readiness to the next level as well. "Always audit ready" is an important, if overstated, catchphrase in the quality space. For organizations that host multiple customer audits, regular internal audits, and at least one regulatory audit per year, being "always audit ready" is not just a matter of frequency, but also optimizes your resources.

By taking these steps, the QMS will also prepare you to provide secure policy access for your suppliers in the future. Now is the time to start thinking about how you get suppliers integrated into your quality processes. You should begin to understand how they measure quality and define acceptable quality levels. And as much as you get audited, consider auditing your key suppliers. It's time to hold your suppliers accountable.

Reporting and analytics become more and more important as you expand the QMS and the message of quality reaches throughout the organization. This is how you not only can be more effective in solving problems, you are also better able to communicate throughout the organization and with management. What's important to the quality team and leadership really are aligned; however, many times you and leadership speak different languages. By translating the language of quality into the language of business, you can drive the quality message more broadly and garner more support for your quality initiatives.

Sure, you have nonconformances and corrective actions, but what do these mean to the business? Framing the data for management in terms of financial impact can really drive home your message. Show how the cost of quality really has a positive impact not only on the bottom line, but also on the company's brand, leadership and reputation.

The earlier you build quality into the product, the lower the risk of issues during production and with customers. When you consider the critical to quality characteristics as part of new product introduction (NPI), quality gets baked in so you do things right the first time and you're in position to bring out innovative products, leading to market leadership. When your products look like your competitors, when you are dealing with the constraints of money, time and resources, quality becomes the primary differentiator.

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ETQ quality journey stages

Ignite
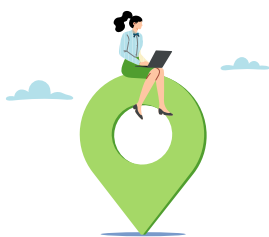
Build a strong quality foundation, streamline processes, and manage documents and training.
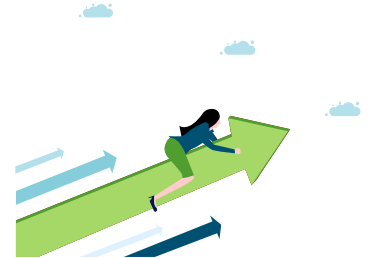
Accelerate

Enable process flows between functions and systems, capture data at its source, leverage everywhere, produce actionable information.

Expand

Integrate internal and external stakeholders in the quality process, extend to Health & Safety, and provide value-added analysis.

Transform

Provide competitive advantage by becoming proactive, making quality strategic, with a consistent global deployment.

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