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Article

Show, Don't Tell: How CDMO Quality Systems Affect Your Product

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Kindeva's quality philosophy embraces customer audits and regulatory inspections as opportunities for continuous improvement in both our operations and the products we manufacture.

A CDMO's approach to deploying its quality management system (QMS) directly impacts its ability to deliver a high-quality product. As a secondary benefit, an effective QMS also facilitates positive customer audits and agency inspections.

This article explores how a CDMO's capability ties into its QMS. It also examines Kindeva's philosophy on audits and inspections: Rather than events to be dreaded, they are opportunities to continuously improve our operations, as well as show customers and regulators how we pace the industry in complex drug delivery.

Does Your CDMO Welcome Risk-Sharing?

It should be inherently understood that — in an OEM/CDMO partnership — the CDMO shoulders a significant portion of the risk mitigation burden. Some CDMOs don't outwardly consider their risk mitigation responsibility. A "widget" mentality may be prevalent, where the CDMO views a customer product as a common item, versus a critical medicine.

Of course, the customer considers the CDMO's risk burden, because the customer's product and reputation are on the line. Kindeva approaches its own risk-mitigation responsibilities with equal seriousness, making them a principal part of initial customer discussions. Not only is this necessary to serve our customers' interests, it is an acknowledgment of the value we place on our own reputation and the pride we take in producing these critical medicines.

Risk mitigation, in the context described here, can be broadly placed into three categories:

- ***Compliance Risk*** — The customer needs to know the CDMO can consistently meet all relevant standards and regulations.
- ***Business Continuity Risk*** — The customer needs to know that, when something does go wrong, the CDMO is able to quickly identify, investigate, and resolve the issue to mitigate any impact to supply. A reputable CDMO will not hide from tough questions: How did this happen? What are you doing to fix it? How will you prevent it from happening again?
- ***Reputational/Brand Risk*** — The CDMO's approach to quality will either promote or diminish the customer's brand.

How a CDMO handles compliance risk is indicative of, and directly affects, its efforts on all three fronts. Consider that customers evaluate a CDMO's compliance effort thoroughly. This is particularly true for larger customers, who are likely to have an in-house group dedicated to understanding changing regulations. Thus, the CDMO is expected to know at least as much as, and probably more than, the customer in terms of up-to-date regulatory practices.

Customers will visit and audit a CDMO's facility before penning any agreement, likely using their own quality systems (and regulatory expertise) as a basis by which to judge the CDMO. This comparison is sure to reveal subtle differences in organizational quality philosophy. If a CDMO is not agile, it will be unable to adequately adapt to customer expectations.

If a CDMO has regulatory inspections that touch customer products, the customer must be notified or asked to be present at the inspection. Thus, in addition to agency review, the CDMO will experience a customer review assessing the CDMO on the same agency findings. The more customers a CDMO has, the more opportunities for productive interactions the CDMO will have. Further, customers can access each CDMO's inspection history via the FDA website.

Ultimately, a CDMO's quality system will dictate its ability to mitigate development and manufacturing risks, allowing the organization not only to withstand customer audits and agency inspections, but to apply the findings to improving all its operations. Most important, an effective quality system ensures consistent, on-time delivery of high-quality customer products.

Quality Management Is a Ceaseless Process

While a robust QMS is intended to ensure exceptional products, and not simply to clear audits and inspections, the latter is a vital secondary benefit. If a QMS prevents issues as intended, that effectiveness will be revealed during audits and inspections.

Effective CDMOs apply audit and inspection learnings as part of their continuous improvement process, making improvements to build upon strengths and buttress weaknesses across all their facilities — not just the one where issues were identified. This approach leads to an operation that experiences fewer issues during both agency inspections and customer audits.

A typical agency inspection focuses on exposing issues, not what the CDMO does well. Inspectors may request a list of all production batches that were scrapped, or a list of all product complaints. No CDMO will be able to show perfection; the top CDMOs are those who best exhibit an effective pursuit of excellence in their operations — resulting in fewer issues overall.

Indeed, research relevant to customer complaints finds companies that have received some complaints and demonstrably addressed the underlying issues maintain a higher customer advocacy score than companies that have never had a complaint (i.e., companies whose quality

system is unproven "under fire"). As the adage states, be wary of a painter with no paint on their shoes.

Kindeva's Pursuit of Excellence

From a regulatory standpoint, every CDMO must follow the same rules. However, the reality is that the bigger and more mature a CDMO becomes, the higher customer expectations become. Addressing feedback from 25 customers is much more complicated than addressing feedback from just a few customers. The CDMO receives so much feedback that, if something is out of control, the CDMO will not be able to catch up.

Kindeva's quality system — hence, its global operation — is structured specifically to address that complexity, ensuring customer confidence in our ability to successfully produce their product, as well as quickly catch and correct any issues.

We start by building our operation on a thorough base understanding of the technologies with which we work (and their inherent risks), from both a design and a manufacturing standpoint. Since most CDMOs are essentially product agnostic, their expertise will be limited to their core delivery forms. Kindeva handles numerous complex drug products, including inhalation and transdermal products.

Additionally, each customer audits our production site(s) regularly, so Kindeva exists in a constant state of inspection. Rather than just claiming we execute our quality system well, we apply regular customer feedback to fuel improvement based on how customers interact with regulations around the globe.

For example, we've studied the most effective approaches our customers have taken to ensure data integrity in their processes and applied them to deployment of our own quality systems. Attentiveness to our customers' needs, therefore, is critical to Kindeva's continuous improvement of our own operational strengths.

Kindeva's quality system is grounded in this commitment to continuous improvement.

We excel because we choose to. Even when a CDMO constantly undergoes audits and inspections, continuous improvement is a choice, rather than a necessity, because a CDMO can choose to just focus on completing audit checklists, doing the minimum necessary to satisfy the customer and move forward with a project. Kindeva welcomes audits and inspections as vehicles driving continuous improvement.

If a CDMO does not maintain this always-learning mindset, it may be fixing problem symptoms versus root causes. Kindeva asks, where else could this problem occur in our organization (e.g., other operational areas, other sites)?

Finally, continuous improvement empowers Kindeva to tackle projects other CDMOs might mishandle or balk at. A reactive CDMO (versus a proactive one) may not accept riskier products/projects, depending on its specialty, because it does not want to jeopardize the rest of its business.

Conclusions

A CDMO can outwardly exhibit good regulatory compliance and still manufacture a poor-quality product. However, rarely does a CDMO produce a high-quality product and fall short in compliance.

Kindeva strives toward continuous improvement built on a stable QMS methodology and deep understanding of the technologies we produce. This approach allows us to successfully manufacture high-quality products delivered on-time, while inviting customer audit and agency inspection feedback, rather than dreading it. In this industry, you're always one incident away from not having a good day. Choose a CDMO partner with proven capability to turn that day around.

About the Author

William Donovan is VP of Quality for Kindeva Drug Delivery. Kindeva delivers innovative drug delivery technology and has partnered with major pharmaceutical companies in both contract development and product manufacturing. Will has been with Kindeva since its inception and brings to the company more than 25 years of experience in quality and regulatory leadership roles across the healthcare industry. Will holds a bachelor's degree in chemical engineering and an MBA.