

What Medical Device OEMs Should Look for in a CDMO's Quality Organization

Quality is more than meeting requirements. It's about understanding customer expectations early and turning them into manufacturing processes that hold up.

Every medical device OEM says quality matters. It shows up in nearly every RFP, every scorecard, every vendor review. But ask five OEMs to define it, and the answers rarely match. For some, quality means a clean audit history. For others, it means a low complaint rate, or a supplier that has never missed a launch date. All of these are reasonable measures. None of them tell the whole story.

That gap between what OEMs measure and what actually drives good outcomes is exactly where **Ron Koronkowski, Vice President of Quality Assurance and Regulatory Affairs**, and **Adin Potter, Executive Director of Quality Assurance and Regulatory Affairs**, start. Both make a case that runs counter to how quality often gets discussed in this industry: it is not a department, and it is not a phase of the project. It is a discipline that must be present from the very first requirements conversation through years of commercial production.

"Customer-centric quality is about more than compliance. It's about understanding our customers' expectations early, communicating openly, and translating those requirements into reliable manufacturing processes that help reduce risk and support a successful product launch."



Ron Koronkowski
 Vice President, Quality Assurance and Regulatory Affairs

So, what does that look like from the outside, as an OEM sitting across the table from a prospective CDMO? A few things stand out: how early quality shows up in the relationship, whether the organization behaves as one system or several, how well it translates requirements into a working manufacturing plan, and how it behaves when something inevitably goes wrong. Here is a closer look at each.

Quality should show up before production does

It is easy for quality to become an afterthought in a CDMO relationship. Development teams move fast, timelines are tight, and quality can start to feel like the function that shows up once a design is finalized and a manufacturing plan is already underway. By that point, though, any gap in understanding is expensive to close.

"The most successful projects are those where quality is engaged early, helping define requirements, align expectations, and support development from the start."



Ron Koronkowski
 Vice President, Quality Assurance and Regulatory Affairs

What that looks like in practice is a quality team involved in quoting and early development, not just final inspection. It sounds like a small shift, but the effects compound. Requirements get defined more accurately the first time. Expectations are aligned before tooling decisions get made. And when it comes time to transfer to production, there are far fewer surprises waiting on the other side.

One quality organization, not several

For an OEM working with a CDMO across multiple facilities, consistency can be surprisingly hard to come by. Different sites often mean different documentation habits, different interpretations of the same standard, and different levels of rigor, even within a single company. An OEM should not have to relearn how to work with quality every time a program moves to a new location.

Potter sees this as one of the clearest signals of a CDMO that has matured past a collection of individual plants. "Customers want a

seamless experience,” he said. “Whether they work with one site or multiple sites, they should experience one unified quality organization.”

That kind of consistency does not happen on its own. It requires quality teams across facilities to actively compare notes, sharing best practices, audit findings, and customer feedback so that lessons learned at one site do not stay siloed there. The result, when it works, is that a customer gets the same standard of execution regardless of which site is doing the work.

Look for a team that can translate requirements, not just record them

Every CDMO will tell an OEM it understands their requirements. Fewer can explain, in specific terms, how those requirements become a control plan, a set of measurement systems, and a validation strategy that holds up once production starts.

“A key role of quality is translating customer requirements into robust manufacturing processes, control plans, inspections, and validation strategies.”



Adin Potter

Executive Director, Quality Assurance and Regulatory Affairs

This is where quality engineering expertise separates itself from quality administration. It shows up in the willingness to ask pointed questions early, rather than making assumptions that surface later as rework. Done well, it means fewer iterations, faster implementation, and meaningfully less risk during scale-up, the stage where unresolved ambiguity tends to be most costly.

Watch how they respond when something goes wrong

No manufacturing relationship runs without a hiccup somewhere along the way. A material lot fails, a measurement trends out of spec, a customer raises a concern. What separates a strong quality organization from a mediocre one is not whether these things happen. It is how quickly, and how honestly, the organization responds when they do.

“When issues arise, customers need a manufacturing partner that responds quickly, communicates clearly, and works collaboratively toward a resolution.”



Ron Koronkowski

Vice President, Quality Assurance and Regulatory Affairs

In practice, that means immediate acknowledgment rather than silence, a rapid assessment rather than a delayed one, and early communication about findings and next steps rather than a polished summary weeks later. Much of that responsiveness traces back to a relationship OEMs should look for well before any issue arises: direct, ongoing collaboration between their quality team and the CDMO’s quality team, so both sides already understand how the other thinks by the time it matters.

Quality that follows the product, not just the project

The strongest argument for treating quality as a lifecycle discipline is what it prevents. A quality organization that is only involved at fixed milestones, an initial review here, a validation signoff there, tends to miss things that surface between those checkpoints. One that stays engaged through requirements gathering, process development, validation, release, and ongoing production monitoring is far more likely to catch a problem while it is still small and inexpensive.

That gap, between collecting data and actually using it, is one **Alejandro Miranda, Director of Quality Assurance and Regulatory Affairs**, has spent much of his career watching organizations fall into.

“One of the risks for any Quality organization is becoming DRIP: Data Rich, Information Poor. We can collect enormous amounts of inspection, process, complaint, and performance data, but data alone does not improve quality. Our responsibility as Quality leaders is to turn that data into meaningful information that identifies trends, highlights risk, and drives action.”



Alejandro Miranda

Director, Quality Assurance and Regulatory Affairs

That same lifecycle view is what makes prevention possible in the first place. Strong, proactive quality processes reduce the likelihood of complaints, escalations, regulatory inquiries, and recalls well before any of them happen, protecting a program’s timeline, budget, and reputation along the way.

The bottom line for OEMs

None of this is a knock on compliance. A robust, well-documented quality management system is still the baseline every CDMO should meet. But compliance is the floor, not the differentiator. The CDMOs worth partnering with are the ones that treat quality as a relationship discipline: engaged early,

consistent across sites, fluent in translating requirements into manufacturing reality, and honest when something needs attention.

“Customers should look for a CDMO that integrates quality into every stage of development and manufacturing, communicates openly, understands their requirements, and can consistently translate those requirements into robust manufacturing processes. At DuPont Healthcare Solutions, quality is embedded in everything we do because every decision matters.”



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