



WHAT TO LOOK FOR WHEN CHOOSING THE RIGHT CDMO

Focusing on customer relationships and ensuring access, transparency, and alignment are essential to success as a CDMO. *Pharma's Almanac* Scientific Editor in Chief David Alvaro, Ph.D., recently sat down with TriRx Pharmaceutical Services' Chief Client Services Officer Michael Kays and Vice President, Sales Jeremy Tatum to discuss how nimble CDMOs keep their eyes on the customer experience in the face of ever-changing customer needs and how to avoid common pitfalls on both sides of the table.

David Alvaro (DA): When innovator companies are evaluating potential CDMO partners, some criteria are fundamental, like capabilities, capacity, and quality. But are there other critical qualities that may be overlooked or insufficiently emphasized early on but can have a significant impact on execution and the overall customer experience?

JEREMY TATUM (JT): When you talk about the typical priorities or criteria that innovator companies use to evaluate potential CDMOs, the most obvious are definitely the things you mentioned. In my opinion, one element that is incredibly important but often overlooked is access – and not just access broadly, but access to the right people. Who's going to put me in touch with the

right people? Who's going to let me talk to the plant general manager or to the head of regulatory? Unfortunately, too many companies rely overwhelmingly on junior project managers to manage these projects. As a result, clients are simply not getting access to the top-notch partners, even at the site. It may be the right company, but it's the wrong person managing the project. Even at the best CDMOs, that can have an enormous impact on the success of the project, how valued the customer feels, and, ultimately, how satisfied they will be and how inclined they will be to stick with the CDMO in the future.

MICHAEL KAYS (MK): Another error that many companies make is considering each service need in isolation, saying "Who can make this

liquid? Who can make this tablet?" You can find a good partner at a good price for each product-specific need, but that doesn't necessarily add up to a sensible outsourcing strategy. Innovator companies need to think more holistically to reduce their total number of suppliers by finding real partners who they can rely on for a broader range of needs and have the flexibility to adapt in sync with the customer as their needs change.

Of course, this is complicated by the reality that many drug companies grow by acquisition and add multiple products through each deal, and they can end up with multiple products with the same dosage form produced by multiple legacy CDMOs. Even if they do recognize the benefits of streamlining their outsourcing to fewer partners, they don't always have the time to run the analyses and determine how to move these acquired products to one strategic partner with one team that can manage all of their products.

To me, a much better strategy is to approach a CDMO like TriRx and ask: "What all can you do to support the full scope of my business? What is your strategic plan? Where can you invest to help me reduce the huge number of outsourcing relationships to a number that is a lot more manageable?"

DA: Clearly, there are a lot of less tangible but highly differentiating qualities that make the difference between a decent provider for a single transaction and a CDMO that is properly aligned in terms

of culture and philosophy to be an effective long-term partner. But when it comes down to acquiring business, how can a CDMO outwardly project those more subjective qualities to potential customers?

MK: The best way for a CDMO to put their best face forward is to involve the senior management team from the start. For the customer, being able to sit down at a table with senior executives to have a real strategic discussion is an invaluable opportunity that really gives them insight into the true nature of a CDMO.

Equally important is getting everybody around the table for an interactive discussion, so you have full access to the people with the appropriate expertise to understand your needs, whether it is quality, manufacturing, or site scheduling, and also your concerns, so that you can align at the top level from the very start.

JT: Other keys to success are projecting the same message throughout the organization and continually pushing the customer to talk a little more strategically. The best approach is to always bear in mind that every single person in the company that interacts with a customer is part of the sales process. Even at those initial technical calls, the director of technical operations can help present the CDMO's full picture to potential customers and acquire an upfront understanding of what is in the customer's pipeline and how the CDMO might be able to help with the customer's current and future needs.

DA: How challenging is it for a CDMO to establish a culture that enables it to be an ideal partner for potential customers with such a range of sizes, needs, and processes?

MK: Honestly, that's the fun part of this job, at least for us! First, you get to know people, develop a very personal relationship with them, and build that crucial trust factor. That requires the CDMO team to have the necessary depth of knowledge and the agility to forge those relationships, build that trust, and steward so many different types of projects for different companies.

At TriRx, we really do feel like we can be an ideal partner to so many different types of customers. It's all in how we approach them. We treat the smallest customers the exact same way we do the absolute largest cus-

tomers, because every customer and every project is important. And to them, of course, every single product is important, no matter who they are, and they really want that emphasis reflected back to them from their partners.

JT: We focus on relationships. Everything that we do is focused on the relationship with the customer and on building that trust, because with that comes more open and transparent communication and more opportunities to collaborate on new projects and anticipate what's on the horizon. Serving customers on these critical, life-changing and lifesaving products is ultimately about delivering on a very high level of expertise, communication, and transparency and taking care of the customer's products as if they were our own. It also makes a huge difference to keep sight even beyond the customer to their ultimate customers, the patients who depend on these products.

DA: What can you tell me about some of the common pitfalls that CDMOs can fall into or mistakes you've seen other CDMOs make?

MK: For tech transfer projects, often either milestones aren't accomplished on time or change orders have to occur because when the proposal was originally conceived, the CDMO didn't really think every element through to completion or put everything into the right context. The CDMO team either didn't ask the right questions or didn't fully understand what they were putting into the proposal, so the pricing or the timeline was wrong and simply not achievable.

For commercial projects, one of the worst things you can do is to launch a product and then have a stock-out. Often within the CDMO world, the person that's delivering the information to the customer on when products will ship really does not have full knowledge of what's happening inside the operation. These CDMOs typically don't have regular, integrated sales and operations planning meetings at the site and at the global levels. Nor do they have customer-facing processes and open lines of communication in place.

JT: Everyone always wants to be the customer's best friend, but you can't give them everything all the time, at least not on a timeline that wasn't comprehensively considered. Far too often, we have seen that CDMOs de-

lay the inevitable. They wait until the very last minute to deliver bad news, which invariably puts the customer in an uncomfortable position.

DA: How is digitalization changing the relationship between CDMOs and their customers?

JT: The ability to have virtual customer visits – not pre-recorded tours, but truly interactive virtual tours – is having a real impact. Customers can traverse the entire facility and stop anywhere to ask for a close-up look at any piece of equipment or process that is underway. This technology helps facilitate quality audits and site visits and even makes it possible to exhibit batch manufacturing processes. In our experience at TriRx, this capability has helped us to win multiple projects.

Obviously, this technology helps to make this huge world a little smaller and more manageable, enabling CDMOs to meet and speak with both new and existing customers around the world and allows them to really investigate their facilities and processes. Being able to unite large groups of people from around the world to hold strategic discussions facilitates building strong relationships and more effective alignment.

MK: For CDMOs that are invested in peer-to-peer access and discussion across disciplines, virtual meeting platforms like Zoom and GoToMeeting enable spontaneous discussions with people from all over the world. This doesn't mean that travel as it was conducted before the pandemic is a thing of the past; we will still all visit customers and have

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them visit us. But, if a customer is remotely located, we can very easily have conference calls with our site and our executive team, reducing the total number of excursions without impacting that critical, high-level access and transparent communication.

DA: An overall trend that has been widely discussed is an increased interest on the part of innovator companies in onshoring and working with domestic suppliers. What have you heard from customers about how much of a priority that is to them?

MK: Lately, what I often hear is a greater demand for regional manufacturing. I'm hearing it in Europe, and I'm hearing it in North America, and, in both cases, customers are definitely looking to simplify supply chains so that as much manufacturing as possible is done in that region. However, the problem is that not many CDMOs are offering those alternatives. I think we're going to see more of that, and, for our part, it's definitely something that we are trying to honor and accomplish.

JT: For CDMOs, building capabilities that mirror each other in different countries or regions is important, such as offering sterile and oral liquids capabilities in both Europe and the United States. We are fortunate to have both sides covered, should the customer have a very specific need or desire for a product to come from a certain region, and

I think you will see more acquisition activity on the part of major CDMOs to do the same.

DA: As a relatively young company, how did you build TriRx from the start to emphasize customer service and differentiate yourselves from your peers and competitors?

MK: Our leadership team brought decades of experience – not only from top CDMOs but from commercial innovator companies as well – and those experiences led us to design TriRx from day one to provide a different experience for customers. Our focus has always been on making customers feel that our sites are their sites and that our people are their people. They're in charge, and they don't have to worry about the execution of the product. We provide world-class performance, and providing exceptional customer service is always top of mind when we evaluate acquisitions and new hires.

Every aspect of our operations network is ultimately designed around the customer relationship team. When a customer receives a proposal from TriRx, the technical team that prepared the proposal is already in place and ready to execute. They know where the supplies are coming from, what the costs are going to be, and how long it will take to make things happen. That full knowledge enables us to be fully transparent with the customer and set realistic expectations that we can guarantee we can fulfill.

At TriRx, customers know they can speak to the top-level team members about any issues they have. That level of communication takes a real commitment from the top down. That part of our strategy and the manner in which we go to market was designed into the company from the beginning.

JT: Once a project is signed, it is handed over to the site, which is responsible for managing the project and adhering as closely as possible to the timeline. The senior director of technical operations, the head of the labs, and the site GM are all heavily involved. If there are any disruptions or anything arises that could delay or impact a milestone, it gets escalated pretty quickly through all relevant stakeholders so that we can rapidly determine the best way to get the project back on track.

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JT: As importantly, the customer relationship has helped to guide our acquisition strategy. On both the human and animal health sides, we have learned what our customers need and made acquisitions that will help us address those needs. The same is true for investments in facilities. Our customers help to guide our growth and how we reposition ourselves. In fact, we are in a tremendous growth curve at the moment, and it is a perfect time for companies that aren't dealing with TriRx right now to call us, because they can help shape our acquisition strategy and grow with us as their needs grow or as they look to transfer projects and simplify their outsourcing activities. ■

ABOUT THE AUTHORS



Michael Kays
Executive Vice President, Chief Client Services Officer

Michael Kays has extensive leadership experience in operations, supply chain, Lean Six Sigma, and cultural change, demonstrated across multiple industries. His successive positions included Operations Director, Vice President of Manufacturing, and CEO of a leading high containment/isolation provider across the Americas, Europe, and Asia. Michael later joined Valeant Pharmaceuticals as SVP of Global Supply, Aptuit, as EVP of Global Operations Planning, and Avara as EVP of Client Services. Michael is a past board member ISPE International Leadership Forum.



Jeremy Tatum
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Jeremy Tatum has more than 18 years of commercial experience in the pharmaceutical industry. Prior to TriRx, Mr. Tatum served as VP, Commercial and Portfolio for SunGen Pharma, where he managed multiple licensing deals in the United States and abroad. Before SunGen, he ran the global serialization project for Par Pharmaceutical, a project that spanned five manufacturing locations, two distribution centers, and over 30 CMOs. Mr. Tatum grew up working in his family's independent pharmacies and holds a B.S. degree in marketing from Tennessee Technological University.