

FROM SERVICE PROVIDER TO STRATEGIC PARTNER



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As drug development grows more complex and timelines compress, sponsors require CDMO relationships built on integration, flexibility, and shared accountability.

By Tom Sellig, CEO, Adare Pharma Solutions

The relationship between pharmaceutical sponsors and their CDMO partners has undergone a fundamental transformation. Not long ago, CDMOs were largely treated as capacity providers that executed a defined scope, then stepped aside. Today, the most successful partnerships look nothing like that. They are deeply embedded collaborations in which both parties are genuinely invested in outcomes, from early formulation through commercial launch and beyond.

Moving Beyond the Handoff Model

Several converging forces have made the traditional handoff-based outsourcing model increasingly obsolete. Supply chain volatility – driven by pandemic aftershocks, tariff pressures, inflation, and transportation bottlenecks – has exposed the fragility of fragmented provider networks. At the same time, therapies themselves have grown more complex, demanding tighter coordination between formulation science, process design, regulatory strategy, and commercial manufacturing. In a capital-constrained environment where timelines are compressing, sponsors cannot afford the delays, rework, and miscommunication that arise when multiple vendors operate in silos.

The CDMO landscape is responding accordingly. Consolidation is accelerating as organizations that lack the infrastructure, scalability, or operational discipline to keep pace fall behind. The partners that are emerging as leaders share a common profile: differentiated technology platforms, global manufacturing footprints, and integrated end-to-end service offerings.

The Case for End-to-End Integration

Working with a single, fully integrated CDMO from early development through commercial manufacturing and packaging delivers measurable advantages. Consistency across the program lifecycle reduces handoff risk. Teams that are involved from the outset understand scale-up considerations, process constraints, and quality requirements before they become problems. Technical leads and project managers who stay with a program from start to finish maintain institutional knowledge that simply cannot be replicated when work is parceled out among multiple providers.

At Adare Pharma Solutions, we have built our operating model around this philosophy. Our integrated capabilities span formulation development, clinical and commercial manufacturing, and packaging, with specialization in oral solid dosage forms like tablets, capsules, multiparticulates, orally disintegrating tablets, and sprinkle formulations. Our manufacturing network has facilities in both the United States and Europe to give sponsors regional access and supply chain resilience across the world's two largest pharmaceutical markets. We have successfully manufactured more than 65 products across this network, and that experience and that experience is reflected in every aspect of how we operate.

Culture as a Competitive Advantage

What ultimately distinguishes a true strategic partner is culture: the habits, behaviors, and values that determine how an organization responds when plans change, challenges arise, or timelines shift. And the most effective culture is one built around the customer, fostering open communication, faster problem-solving, and proactive risk management. A customer-focused culture means every customer is paired with a dedicated project manager, cross-functional teams stay aligned throughout each program, and potential issues are flagged before they become obstacles.

I challenge our teams every day to find creative ways to be faster, safer, and more cost-effective for our customers. This continuous-improvement mentality is what turns a contractual relationship into a genuine partnership.

Meeting Tomorrow's Challenges Today

The trajectory is clear. As programs move faster and grow more complex, sponsors will place even greater importance on CDMO partners that align formulation, manufacturing, and packaging from the outset. The CDMOs that thrive will be those that combine operational excellence, technological innovation, and an unwavering commitment to their customers' success. In the end, the principle is simple: when your CDMO cares about your success as much as you do, that is a true strategic partnership.



Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, customized release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare's facilities in the US and Europe have developed and manufactured more than 65 products sold by customers worldwide.

From Early Development to Commercial Launch: An End-to-End Partnership for a Critical Therapy

Bringing a life-changing therapy to patients facing a rare, aggressive disease requires a partner with deep technical expertise, regulatory foresight, and manufacturing excellence. For nearly eight years, Adare Pharma Solutions has stood alongside a global health sciences company, supporting the development of a breakthrough oncology therapy from its earliest days of clinical development through FDA fast-track review and commercial launch.

Early Development: Supporting a Promising Therapy From the Start

The customer first engaged Adare when the therapy was still emerging as a highly promising candidate and the company itself was a small, investment-backed organization with limited resources. Adare supported the treatment's earliest Phase 1 clinical supply needs, working closely with the customer's scientists to develop a viable solid oral dosage form and providing the speed, flexibility, and cost-conscious execution needed to generate proof-of-concept data and secure additional investment. As clinical activity accelerated, Adare supplied material in rapid, tightly coordinated production cycles, converting API into finished dosage almost immediately upon release. Over the course of development, Adare produced more than 35 clinical batches, functioning at near-commercial scale long before formal commercialization began.

Formulation & Manufacturing Challenges: Engineering Robustness in Real Time

The final dosage form contained approximately 65% API – an exceptionally high loading that exposed process risks due to batch-to-batch variability in the API's physical properties. Adare addressed these challenges through roller compaction, excipient blending strategies, chrome-plated encapsulation components, and environmental dehumidification systems, all implemented while maintaining uninterrupted clinical supply. When the API was found to exist in multiple polymorphic forms, Adare supported manufacture of material from both forms to confirm consistent performance and give regulators confidence in the product's robustness.

Analytical & Regulatory Support During Fast-Track Development

The FDA's decision to grant Orphan Drug and Fast Track designation accelerated timelines considerably. Adare's analytical, quality, and regulatory teams responded to FDA inquiries in real time, often within two-week windows, supporting dissolution method modifications, expanded characterization studies, and phase-appropriate analytical validation.

Transition to Commercialization & Commercial Launch

Nearly a year before the FDA goal date, a dedicated commercial launch team was formed spanning formulation, analytical chemistry, quality, validation, packaging, supply chain, and senior leadership. Registration batches were completed, packaging and serialization processes were qualified, and the FDA elected to waive the Pre-Approval Inspection for Adare's site. When approval arrived ahead of schedule, Adare was fully prepared – first commercial product shipped within 8 days, and patients received therapy within 10 days of NDA approval, with no deviations or disruptions.

Long-Term Value Through Deep Partnership

From early clinical supply to global commercialization, this collaboration has spanned nearly eight years, a truly distinctive partnership in the CDMO landscape. Throughout that time, Adare and the customer have worked side by side through every phase of development, navigating scientific complexity, regulatory acceleration, and evolving operational demands with agility and alignment.

The partnership continues today, built on shared trust and proven performance, focused on sustaining long-term product success and delivering continued value to patients.