ARTICLE

The CDMO Sorting Hat: Selecting the Right CDMO in an Era of Complexity

Changes in the Industry are Impacting the Selection Criteria

LOTTE BIOLOGICS
Possibilities Beyond Limits

For biopharmaceutical companies, choosing a development and manufacturing partner is one of the most consequential decisions in a molecule's journey from development to commercialization. Every sponsor enters the selection process with a different set of priorities. An early-stage biotech racing toward IND may prioritize timelines. A company preparing for commercial launch may focus on manufacturing capacity and capabilities. Others may be looking for specialized technical expertise, global supply resilience, or cost efficiency.

For years, the core selection criteria have remained largely unchanged: timelines, capabilities, capacity, reputation, and cost. However, the environment in which these decisions are made is changing rapidly. Geopolitical uncertainty, economic pressures, supply chain disruption, technological advancements, and the rise of increasingly complex modalities are all influencing the standard selection criteria.

These shifts have not necessarily created entirely new selection criteria. Rather, they have changed how sponsors evaluate the traditional ones.

Industry Shift #1: Geopolitical and Economic Uncertainty

Geopolitical and economic factors have become increasingly intertwined, making it difficult to separate one from the other. Five years ago, sponsors primarily asked whether a CDMO could manufacture their molecule. The question is no longer,

“Can this CDMO manufacture my product?”

Today, the question is broader: can that molecule still be manufactured and supplied if trade policies shift, critical raw materials become constrained, or manufacturing operations in a particular region are disrupted?

Historically, risk assessments focused on quality and compliance. Today, sponsors evaluate operational resilience, supply chain robustness, manufacturing flexibility, and business continuity with equal rigor.

In other words, the conversation has shifted from capability to continuity.

Manufacturing success is no longer measured solely by whether a process works under ideal conditions, but whether it can continue operating when conditions become less predictable.

The best CDMOs are distinguished not by the absence of problems, but by how rapidly and transparently they solve them. Questions that once focused primarily on technical execution are now expanding into broader operational considerations. Sponsors are increasingly asking not only whether a CDMO can manufacture their molecule, but whether that manufacturing process can remain resilient in the face of supply chain disruptions, material shortages, geopolitical instability, or changing trade conditions.

This has also changed how companies evaluate manufacturing infrastructure. Supply chain challenges affecting single-use technologies, plastics, and critical raw materials have highlighted the importance of manufacturing resilience. In some cases, this has renewed interest in stainless steel manufacturing systems, where dependence on disposable components is reduced and exposure to certain supply chain constraints can be minimized.

Similarly, cost remains an important consideration, particularly for emerging biotechs. However, many sponsors are increasingly evaluating overall value rather than focusing exclusively on the lowest price. A lower initial manufacturing cost can quickly be offset by delays, supply interruptions, technology transfer challenges, or quality issues further downstream. Increasingly, sponsors are looking for the best balance of cost, reliability, expertise, and execution.

In an environment defined by economic uncertainty and supply chain volatility, the lowest-cost option is not always the lowest-risk option. As a result, these pressures are changing how sponsors define value. Cost is increasingly evaluated alongside supply chain resilience, manufacturing continuity, and risk mitigation. Sponsors are now regularly seeking partners that can provide both operational stability as well as long-term value.

Industry Shift #2: Technology is Raising Expectations

Technology is transforming every stage of biologics development and manufacturing. Technology is no longer a differentiator because it already exists. What differentiates a manufacturing partner today is how effectively technology is used to improve predictability, reduce risk, and accelerate decision-making.

Sponsors increasingly expect digital tools, advanced analytics, and AI-enabled insights to shorten development timelines, streamline technology transfer, and improve manufacturing outcomes—not simply because the technology exists, but because it delivers measurable value.

In early development, artificial intelligence and advanced computational tools are accelerating activities such as clone selection and process optimization. Further downstream, digital manufacturing systems, predictive modeling, and advanced analytics are helping reduce development timelines, improve technology transfer efficiency, and enhance manufacturing performance.

Real-time monitoring and advanced process analytical tools are also providing manufacturers with greater visibility into manufacturing operations, allowing faster responses to deviations and more accurate predictions during scale-up.

The impact extends beyond efficiency. Greater process visibility allows manufacturers to identify potential issues earlier, make informed adjustments faster, and generate stronger process understanding throughout development. As timelines continue to compress, predictability has become just as valuable as speed. Sponsors are increasingly looking for manufacturing partners that can provide both.

At the same time, scientific innovation continues to introduce increasingly sophisticated molecules into development pipelines. Bioconjugation (e.g., antibody-drug conjugates, antibody-oligonucleotide conjugates) multispecific antibodies, and other next-generation biologics are creating exciting opportunities for patients and developers alike.

However, these molecules often bring manufacturing challenges that are fundamentally different from those associated with more traditional biologics. Greater molecular complexity frequently translates into greater process complexity, more demanding analytical requirements, and more challenging scale-up considerations.

As a result, sponsors are increasingly looking beyond whether a CDMO can manufacture a molecule today. They are evaluating whether that CDMO understands the long-term implications of the molecule's complexity and can develop a manufacturing strategy that will remain robust as the program advances.

> “...these pressures are changing how sponsors define value.”

What This Means for CDMO Selection

The industry shifts above are influencing how sponsors evaluate the three criteria that continue to matter most: timelines, capacity, and capabilities.

Timelines: Speed is No Longer a Competitive Advantage — It's an Expectation

The influx of innovative molecules from emerging biotechs around the world, combined with increasing competition across therapeutic areas, has intensified the pressure to move programs forward quickly.

For many companies, being first to IND or first to market can significantly impact valuation, funding opportunities, partnership discussions, and ultimately commercial success. As a result, timeline discussions have evolved beyond simple project scheduling.

Sponsors are increasingly evaluating how a CDMO can actively accelerate development.

Can development activities run in parallel rather than sequentially? Can platform approaches reduce development time? Does the CDMO have established analytical methods, proven technology transfer frameworks, and streamlined processes that eliminate unnecessary delays?
Speed today is not simply about moving faster.
It is about removing friction from the development journey while maintaining quality and regulatory rigor.

Capacity: Availability Matters More Than Scale

Capacity is often one of the first topics discussed during CDMO selection, but sponsors are becoming increasingly sophisticated in how they evaluate it.

Large installed capacity does not automatically translate into available capacity for their program. For sponsors operating against critical clinical, regulatory, or commercial milestones, the relevant metric is no longer reactor volume—it is access.
The ability to secure the right capacity at the right time has become more valuable than the size of the facility itself.

Large bioreactor capacity may look impressive on paper, but available capacity and installed capacity are not always the same thing.

This distinction is becoming increasingly important as development timelines continue to accelerate. A facility may possess significant manufacturing scale, but if scheduling constraints delay a program by several months, that capacity provides limited value to the sponsor. In many cases, manufacturing access—not manufacturing size—is the factor that ultimately determines whether critical milestones can be achieved on schedule.

Manufacturing schedules, existing customer commitments, turnaround times, and site utilization can all influence whether a project can begin when a sponsor actually needs it to begin. For a biotech operating against investor milestones or clinical timelines, a six-month scheduling delay can be just as impactful as a technical failure.

The question therefore becomes less about whether a CDMO has capacity and more about whether that capacity aligns with the sponsor's timeline requirements.

As a result, capacity discussions are evolving from infrastructure conversations to planning conversations. Sponsors are looking beyond facility specifications and asking deeper questions around scheduling flexibility, project prioritization, campaign planning, and long-term manufacturing availability.

They increasingly want transparency around scheduling realities and confidence that their program will receive the attention and urgency it deserves. In some cases, this has led sponsors to secure manufacturing slots well in advance, even financially committing to reserve capacity before signing manufacturing agreements.

The ability to secure the right capacity at the right time has become increasingly valuable in a competitive development environment. At the same time, sponsors are beginning to think beyond the manufacturing needs of a single molecule. There is a growing trend toward identifying strategic manufacturing partners that can support future pipeline assets as well, effectively treating CDMOs as an extension of their own internal manufacturing network. Capacity therefore becomes more than an operational consideration, instead becoming part of a broader long-term manufacturing strategy.

Capabilities: Expertise is Becoming More Specialized

As molecules become more complex, the definition of capability is changing.

Capability is no longer simply a checklist of equipment, technologies, or manufacturing scales. It increasingly reflects a CDMO's ability to understand a molecule's unique challenges and anticipate future manufacturing requirements before they become obstacles. As sponsors conduct CDMO evaluations and facility visits, they are increasingly looking beyond the physical manufacturing facility itself. While infrastructure remains important, sponsors also want access to the technical experts responsible for development and manufacturing. They want to understand the expertise of the scientists, engineers, and manufacturing teams who will ultimately be supporting their molecule, especially for advanced modalities and bioconjugates. They want to leave the visit with the sense of connection and confidence in the CDMO and the trust that their program is being handled by a team that places as much importance on the program as they do.

For advanced biologics, decisions made during early process development can have significant consequences during scale-up and commercial manufacturing. Selecting a CDMO that understands those downstream implications can reduce risk, prevent costly redevelopment work, and improve long-term manufacturing success.

This is particularly important as developers evaluate novel modalities that may require specialized bioconjugation containment strategies, unique process designs, advanced analytical approaches, or dedicated manufacturing expertise. The most valuable manufacturing partners are often those that can identify complexity early, develop solutions proactively, and build processes that support not only today's milestones but tomorrow's commercial objectives.

Beyond Timelines, Capacity and Capabilities

While sponsors may begin the CDMO selection process with scorecards, comparison matrices, and technical evaluations, the final decision often comes down to something much less tangible.

Partnership.

The best CDMO relationships are not transactional. They are collaborative.

Timelines, capacity and capabilities may determine which CDMOs make the shortlist. Partnership is what determines which one remains the partner throughout the molecule's journey. That partnership extends beyond the manufacturing of a single product and grows across multiple products over time. Rather than selecting a CDMO solely for an immediate manufacturing need, sponsors are increasingly looking for strategic partners that can support future pipeline assets as well.

At every stage of development and manufacturing, challenges will emerge. Timelines will shift. Technical hurdles will appear. Supply chains will face disruption, deviations and other unplanned events. When those moments occur, sponsors need more than a vendor executing a contract. They need a partner invested in the success of the molecule.

The right CDMO is not simply the one with the largest facility, the newest technology, or the lowest price. It is the one that approaches the molecule with the same sense of ownership, urgency, and commitment as the sponsor itself.

Putting Partnership into Practice

At LOTTE Biologics, we recognize that the industry's evolving expectations require more than manufacturing excellence alone. While sponsors continue to evaluate timelines, capacity, and capabilities, our focus is on delivering these through a true partnership approach.

Accelerating timelines requires more than simply moving faster. Through integrated development approaches, established analytical platforms, and close technical collaboration, we work with sponsors to reduce development timelines while maintaining quality and scientific rigor. Our integrated approach allows us to go from DNA to DS fill in 8.5 months which we have demonstrated in real-world scenarios including for a high titer, dual target, complex antibody.

Capacity is equally about access as it is about scale. By combining flexible manufacturing with long-term expansion plans and transparent project planning, we strive to provide sponsors with the flexibility and confidence needed to support both immediate programs and future pipeline growth.

As molecules become increasingly complex, technical expertise becomes an equally important differentiator. Backed by specialists with over 20 years in biologics, our scientific and manufacturing teams work closely with customers to understand each molecule's unique challenges, applying specialized expertise to develop robust, scalable manufacturing processes designed for long-term success.

Ultimately, we believe that timelines, capacity, and capabilities deliver the greatest value when they are supported by partnership. By combining technical expertise, operational excellence, and transparent collaboration, we aim to become an extension of our customers' teams, helping them navigate complexity from development through commercial manufacturing.

Conclusion:

While the environment surrounding biologics development and manufacturing continues to evolve, the factors that matter most in CDMO selection remain largely unchanged. Sponsors still prioritize timelines, capacity, and capabilities. What has changed is how those factors are evaluated. Speed is no longer simply about project schedules, capacity is no longer simply about reactor volume, and capabilities are no longer defined solely by facility infrastructure.

Taken together, these shifts point to a broader trend within CDMO selection: the growing importance of partnership. Sponsors are increasingly seeking manufacturing partners that can navigate challenges alongside them, adapt to changing circumstances, and support programs throughout their lifecycle. In an increasingly complex industry, partnership has become the lens through which timelines, capacity, and capabilities are ultimately evaluated.

About the Author

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Brian Greven brings more than 25 years of leadership experience across global CDMO organizations in the United States, Europe, and South Korea. His professional background spans operational management, manufacturing, quality, and business development, with senior roles at Matica Biotechnology, Merani Biotech, Samsung Biologics, Boehringer Ingelheim, and Amgen. With a proven track record of leading large-scale manufacturing operations and building cross-cultural teams, he has developed a deep understanding of both the global CDMO landscape and Korean business culture.

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Dr. Brett Budis is a seasoned professional with over 29 years of experience in the biopharmaceutical industry. He has cultivated extensive expertise in regulatory operations, CDMO oversight, technology transfer and Process Performance Qualification (PPQ), quality compliance, inspection readiness, and quality validation.

About LOTTE Biologics

LOTTE Biologics is a global contract development and manufacturing organization delivering integrated biologics and bioconjugate services across the full product lifecycle.

With a unified Dual Hub Service model spanning the United States and South Korea, we strengthen supply chain security, enable scalable manufacturing pathways, and uphold consistent quality across regions.

Our capabilities encompass phase-appropriate drug substance manufacturing for mammalian-cell-based biologics, including monoclonal antibodies, fusion proteins, and multispecific modalities, as well as fully integrated bioconjugate manufacturing supported by strategic investment in onsite conjugation facilities.

LOTTE Biologics is committed to serving as a long-term, trusted leading global CDMO partner, supporting efficient scale-up, dependable manufacturing execution, and the continuous advancement of clients' therapeutic programs.