FROST & SULLIVAN

Redefining Value in Biologics Outsourcing Partnerships

In collaboration with

Syngene

Putting Science to Work

FROST & SULLIVAN EXECUTIVE BRIEF

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The biologics manufacturing landscape has undergone a fundamental transformation over the past decade. What began as transactional outsourcing relationships have evolved into strategic partnerships characterized by innovation, specialized expertise, and shared success. This shift is driven by increasing biologic complexity, emerging modalities, geopolitical pressures, and supply chain challenges that demand more from manufacturing partners than ever before.

Contract development and manufacturing organizations (CDMOs) have responded by redefining their value proposition through integrated, digitally enabled, and flexible services. This report presents findings from proprietary research and industry surveys conducted by Syngene to explore how this reshaped outsourcing environment creates both opportunities and challenges. We examine the factors that distinguish meaningful partnerships from vendor relationships, and how organizations like Syngene are positioning themselves as partners of choice in this transformation.

1. The Market Imperative: Why Biologics Outsourcing Has Become Strategic

1.1. The Acceleration of Biologics Development

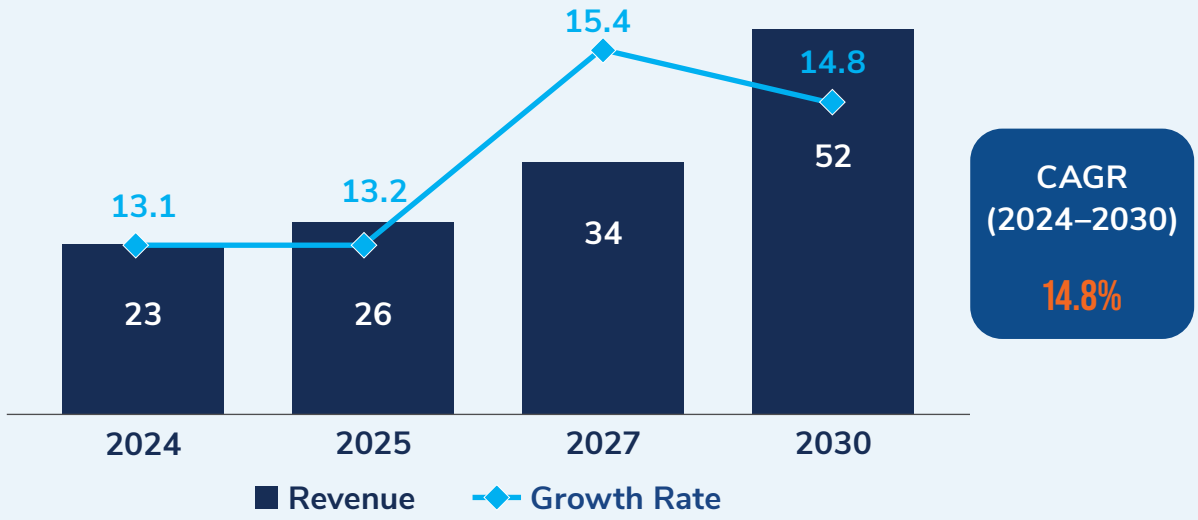
The biologics sector has decisively departed from conventional in-house manufacturing models. Biologics is expanding 1.45 times faster than small molecules, with global market share forecasted to reach approximately 40% by 2030. This acceleration stems from the therapeutic promise of increasingly complex modalities—monoclonal antibodies, gene and cell therapies (CGT), antibody-drug conjugates (ADCs), synthetic nucleic acids, and emerging next-generation platforms.

These advanced therapies require specialized capabilities and scale that most sponsors find difficult to cultivate internally. The rapid advancement of mRNA, AAV, and CRISPR innovations is driving development pipelines forward at an unprecedented pace, creating sustained demand for manufacturing expertise that extends far beyond production capacity. Emerging biotechs are externalizing 80–100% of manufacturing operations, while even larger pharmaceutical companies are adopting hybrid models that leverage external expertise for speed and specialization.

1.2. Market Growth and Platform Diversification

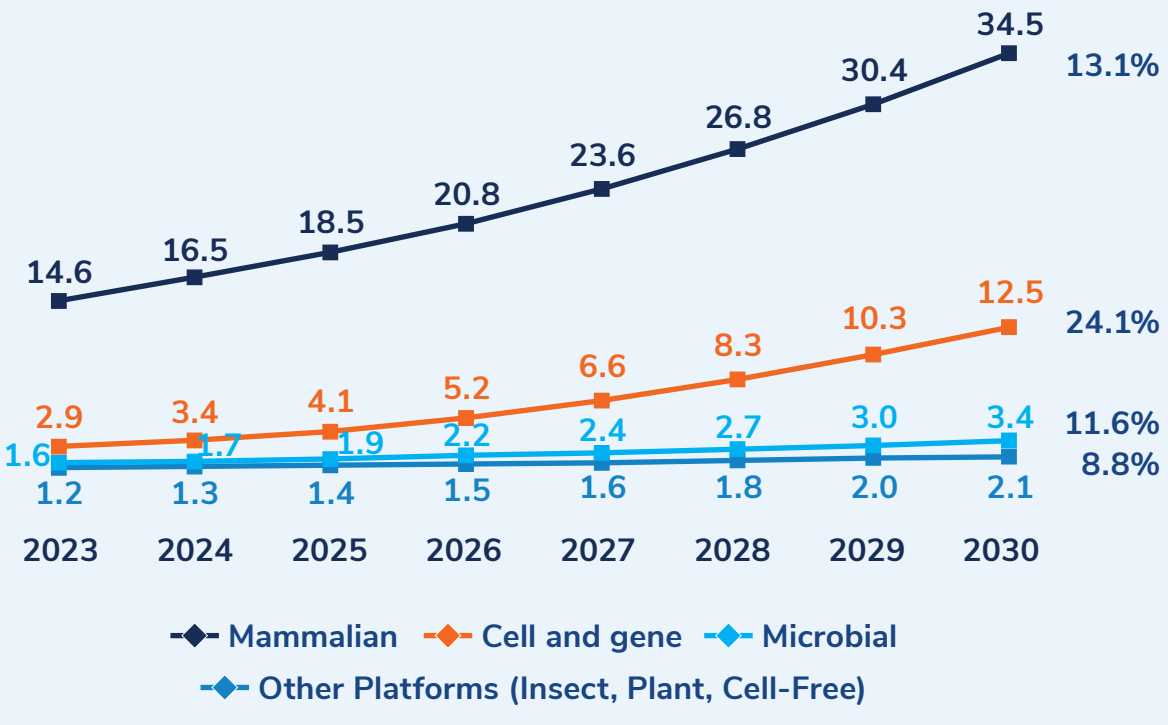
The biologics CDMO market reflects this urgency. Growing at a CAGR of around 15%, the market is expected to exceed USD 50 billion by 2030. This growth is not uniform across platforms, however, and understanding these distinctions reveals important strategic implications.

Chart 1: Global Bio-CDMO Market Revenue, 2024-2030 ($ Billion)



Mammalian biomanufacturing leads with robust year-over-year growth of 13%, driven primarily by demand for monoclonal antibodies, ADCs, and biosimilars. Mammalian cell culture capacity is projected to exceed 8,000 kL by 2027, representing 70% of total marketed biological production. Importantly, CDMOs and hybrid entities maintain approximately 50% control of this capacity, underscoring their central role in the supply ecosystem rather than as supplementary providers.

Chart 2: Global Bio-CDMO Market Revenue by Cell-Culture Type, 2024–2030 ($ Billion)



Microbial manufacturing is experiencing its own growth trajectory, driven by applications in CGT—particularly plasmid manufacturing—as well as enzyme therapeutics and synthetic biology. What makes this segment particularly noteworthy is the emergence of specialized platforms including insect-based, plant-based, and cell-free systems gaining traction for mRNA and viral vector manufacturing. These platforms enable decentralized, rapid-response biologics production, a capability that has moved from theoretical advantage to strategic necessity considering recent global health challenges and supply chain vulnerabilities.

The diversification of manufacturing platforms reflects a broader industry reality: therapeutic innovation is outpacing traditional infrastructure. This creates both a capacity challenge and capabilities gap that CDMOs are uniquely positioned to address.

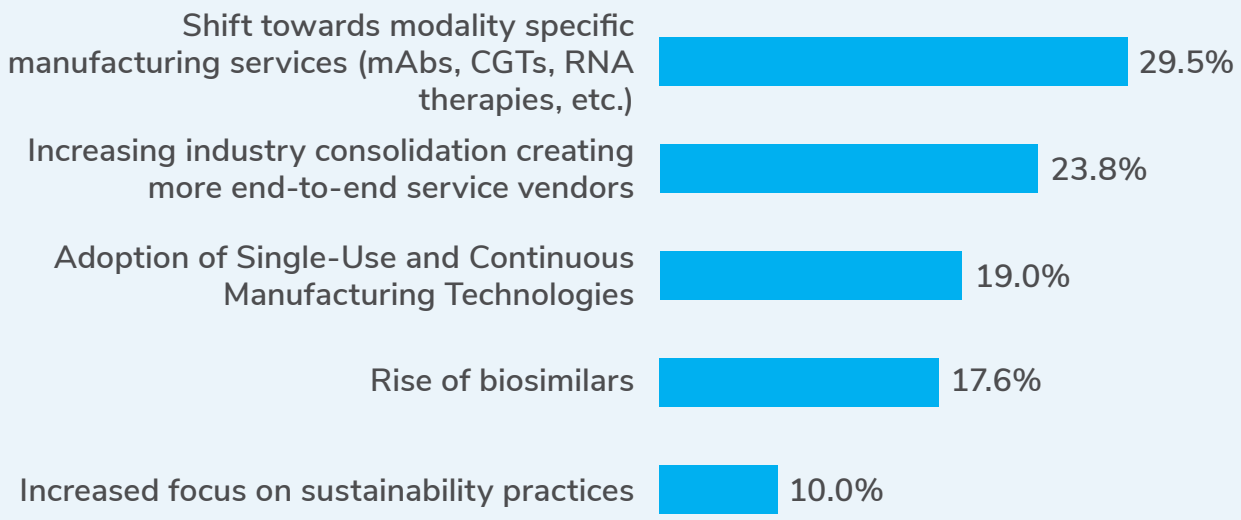
2. Sponsor Priorities: What the Data Reveals About Partnership Expectations

To understand what sponsors truly value in outsourcing partnerships, Syngene conducted a comprehensive industry survey examining priorities, challenges, and unmet needs. The findings reveal a clear hierarchy of concerns that extends well beyond cost considerations.

2.1. Capabilities Trump Cost

Modality-specific manufacturing capabilities lead sponsor priorities at 30% of responses, with particular emphasis on monoclonal antibodies, cell and gene therapies, and RNA platforms. This top ranking reveals sponsors are not simply seeking manufacturing capacity—they are seeking expertise in specific, often nascent, therapeutic modalities where mistakes are costly and timelines are compressed.

Chart 3: Industry trends currently shaping the biologics CDMO market



The second-highest priority—industry consolidation at 24%—initially appears disconnected from the first. However, it reflects a complementary concern: sponsors are seeking to simplify their vendor ecosystems. Rather than managing multiple specialized providers, they prefer partners capable of supporting diverse modalities and development stages under one roof. This preference for integration reduces coordination friction, accelerates timelines, and minimizes the risk of knowledge loss across vendor handoffs.

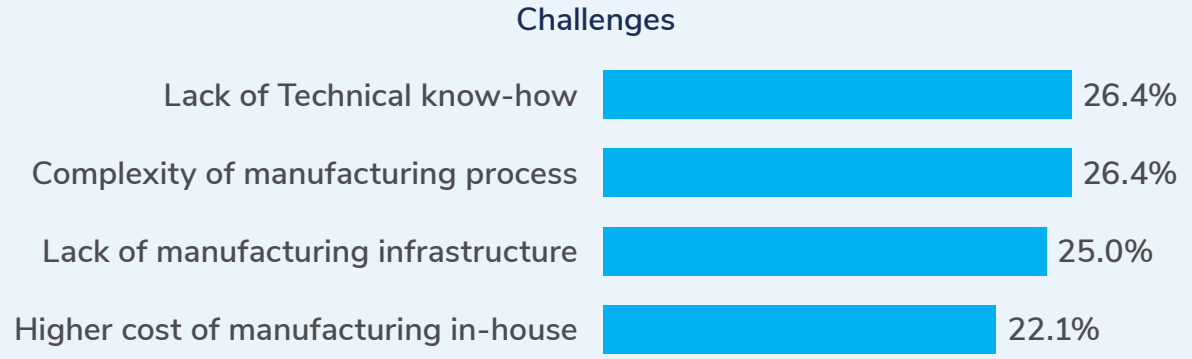
Advanced manufacturing technologies, particularly single-use and continuous manufacturing systems, rank at 19% of responses. The significance here lies in what these technologies enable: flexibility, reduced capital requirements, and faster campaign turnarounds. Over 85% of pre-commercial manufacturing now utilizes single-use technology, transforming what was once a premium offering into a baseline expectation. CDMOs must not only adopt these technologies but integrate them seamlessly with upstream development and downstream validation processes.

Biosimilars remain a focal point at 18%, driven by payer's pressure and evolving regulatory pathways that make these products increasingly viable across global markets.

2.2. The Challenge Landscape: Where Sponsors Struggle

Understanding sponsor priorities is incomplete without examining their challenges. Survey respondents identified lack of technical know-how at 26% and manufacturing complexity at an equal 26% as the most critical hurdles facing the industry. These dual challenges illuminate why modality-specific expertise ranks so highly in partner selection: sponsors recognize gaps in their own capabilities and are actively seeking partners who can bridge them.

Chart 4: Leading Challenges faced by Pharma companies relating to Biologics manufacturing



Infrastructure limitations follow at 25%, while higher in-house costs are cited by 22% of respondents. Together, these findings suggest that the decision to outsource is increasingly driven by capability gaps rather than simple cost arbitrage. Sponsors need partners who possess specialized infrastructure, experienced talent, and proven processes that would be prohibitively expensive and time-consuming to develop internally.

This represents a fundamental shift in the value equation. Ten years ago, outsourcing was primarily a make-versus-buy calculation. Today, it is a question of accessing capabilities that may not exist within the sponsor's organization or broader network.

2.3. Geopolitical Realities Reshape Outsourcing Strategy

External pressures add another dimension to outsourcing decisions. Supply chain disruptions affect strategic planning for 24% of respondents, while trade tariffs and regulatory barriers impact 20%. The need for near-shoring and friend-shoring is cited by 18% of sponsors, reflecting how geopolitical realities are driving organizations to prioritize partners with global reach, regional flexibility, and robust supply chain resilience.

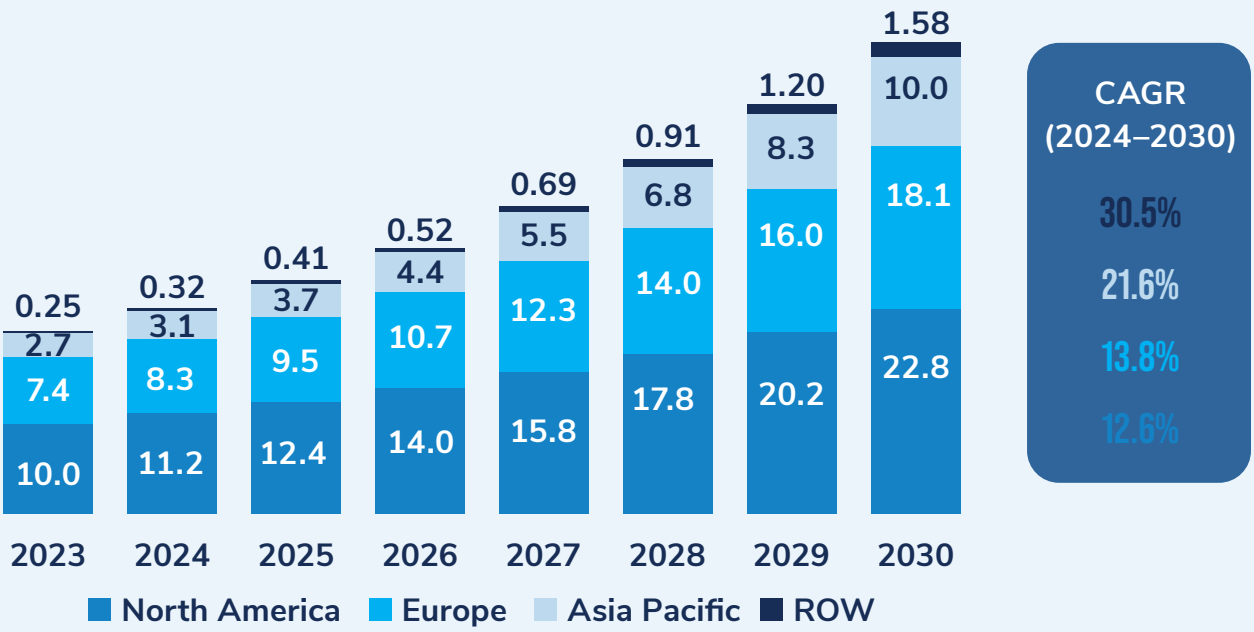
Chart 5: Geopolitical changes impacting outsourcing to Bio CDMOs

These findings confirm that outsourcing decisions have become inextricably linked with broader strategic considerations around risk mitigation, regulatory navigation, and long-term supply security. Geographic diversification is no longer a premium feature—it is essential for risk management. Sponsors want the ability to shift production between regions in response to regulatory requirements, supply chain disruptions, or changing trade policies without compromising timelines or product quality.

3. Regional Dynamics: The New Geography of Biologics Manufacturing

The interplay between global demand and regional capabilities is reshaping where and how biologics are manufactured. Different regions offer distinct advantages, and leading CDMOs are positioning themselves to leverage these dynamics strategically.

Chart 6: Global Bio-CDMO Market Revenue By Region, 2024–2030 ($ Billion)



3.1 North America: Innovation and Speed

North America leads in early-phase development and complex programs, supported by governmental initiatives, robust intellectual property protections, and a dense biotech ecosystem. Proximity to innovation hubs, clinical sites, and regulatory agencies makes this region ideal for programs where speed and regulatory interaction are critical. However, capacity constraints and higher operating costs drive many commercial-stage products toward alternative regions.

3.2 Europe: Regulatory Harmonization and Advanced Manufacturing

Europe's bio-manufacturing sector is advancing through regulatory harmonization across EU member states and targeted investments in advanced manufacturing capabilities. The region offers a balance of technical sophistication, regulatory predictability, and cost competitiveness relative to North America, making it attractive for both clinical and commercial manufacturing.

3.3. APAC: Scale and Cost-Effectiveness

APAC is emerging as a major biologics hub due to cost advantages, biosimilar expansion, and significant infrastructure investments. The region's appeal extends beyond cost, however. Substantial capacity expansion, growing regulatory sophistication, and increasing acceptance of APAC manufacturing sites by Western regulatory agencies are transforming the region from a low-cost alternative to a strategic manufacturing location capable of supporting global supply chains.

3.4. Middle East and Latin America: Building Regional Capacity

The Middle East and Latin America are emphasizing regional supply chain independence, with significant capacity expansions underway to reduce import dependency and enhance healthcare access. While these regions currently represent smaller market segments, their growth trajectories signal increasing global distribution of manufacturing capabilities.

3.5. Strategic Implications for Sponsor-CDMO Partnerships

This regional diversification creates both opportunities and complexity. Sponsors increasingly seek partners with multi-regional presence capable of supporting different stages of development across different geographies. The ability to conduct early-stage development in innovation-rich North America, scale up in cost-effective Asia-Pacific, and ensure commercial supply through strategically distributed facilities represents a competitive advantage that single-site providers cannot match.

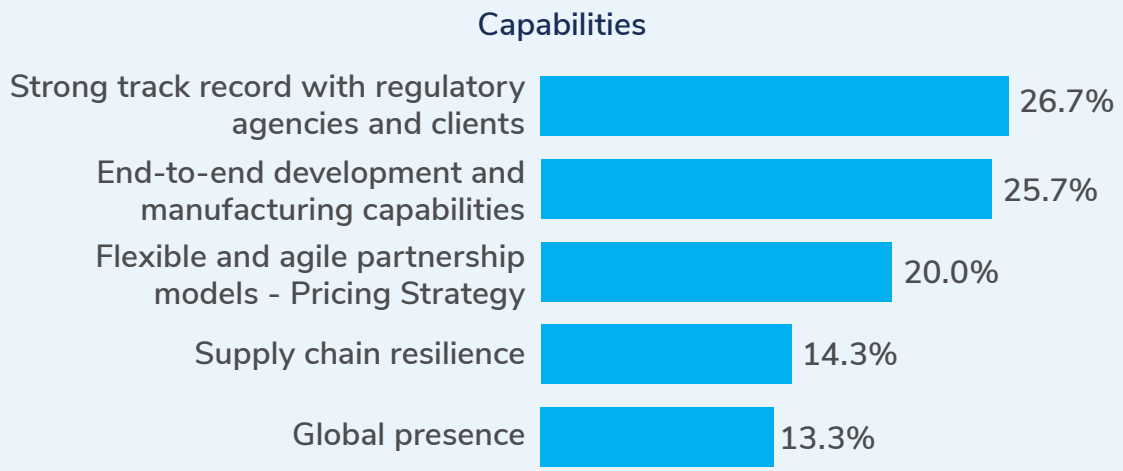
4. Partner Selection: What Distinguishes Strategic Partners from Vendors

The criteria by which sponsors select CDMO partners reveal what truly matters when the stakes are high and the technical challenges are formidable. Survey data provides clear insight into these priorities.

4.1. Regulatory Excellence: The Foundation of Trust

Regulatory excellence ranks highest at 27%, demonstrating that a track record with global regulatory agencies remains paramount. This makes intuitive sense: manufacturing failures resulting in regulatory delays or rejections can cost sponsors years and hundreds of millions of dollars. Sponsors need partners with proven systems, experienced regulatory affairs teams, and a history of successful inspections across multiple jurisdictions.

Chart 7: Capabilities considerations when selecting a biologics CDMO



The emphasis on regulatory excellence also reflects increasing global complexity. A product designed for multiple markets must meet divergent regulatory standards, and sponsors value partners who can navigate these requirements without compromising timelines.

4.2. End-to-End Capabilities: Reducing Friction and Accelerating Timelines

End-to-end development and manufacturing capabilities follow closely at 26%. This preference reflects hard-won lessons about the costs of fragmentation. Every handoff between providers introduces risk: knowledge loss, timeline delays, quality inconsistencies, and coordination overhead. Sponsors increasingly prefer partners capable of supporting programs from concept through commercialization, eliminating these friction points.

This preference also enables better process economics. When a single partner oversees cell line development, process optimization, analytical method development, clinical manufacturing, and commercial production, economies of scale and process knowledge create efficiencies impossible to achieve across multiple vendors.

4.3. Flexibility and Supply Chain Resilience

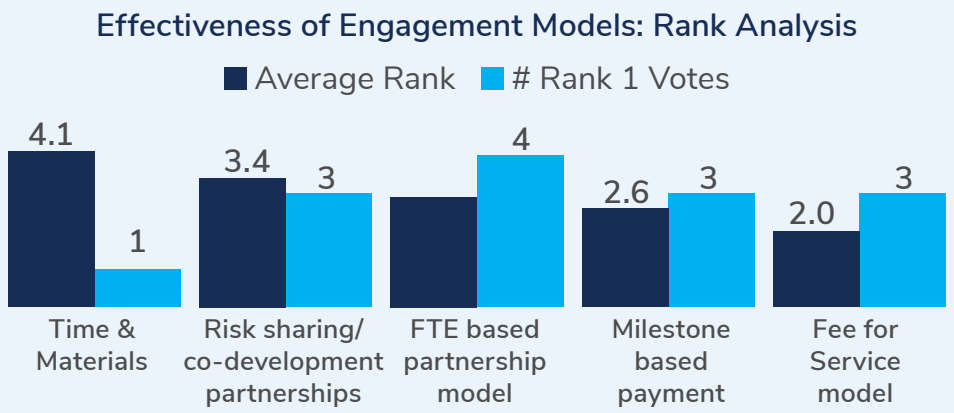
Flexible, agile engagement models are valued by 20% of respondents, highlighting the importance of adaptability to changing timelines, priorities, and technical challenges. Supply chain resilience is noted by 14% of sponsors, while global presence is important to 13%. Together, these factors underscore that sponsors are evaluating partners on their ability to respond to the unexpected—whether that means accelerating a promising program, navigating a supply disruption, or pivoting in response to clinical findings.

4.4. Evolving Partnership Structures

Survey data reflects a marked evolution from transactional to more strategic engagement models. The “Fee for Service” model remains foundational and is most prioritized on average by respondents (mean rank 2.0), securing three first-choice votes—most often seen in well-defined projects with clear specifications. “Milestone-based payments” is another leading model (average rank 2.6), also garnering three Rank 1 votes, indicating strong alignment with performance-based objectives.

The “FTE-based partnership model” stands out for its number of respondents (four) ranking it as their top choice, with an average rank of 2.9. This model ensures dedicated resource allocation for longer-term initiatives.

Chart 8: Effective engagement models



Risk sharing and co-development contracts, though rated lower on average (mean rank 3.4), are valued in a subset of partnerships for their innovation and speed potential. These models illustrate a fundamental shift where sponsors seek not just service providers, but genuine partners ready to share risks and rewards. This alignment fosters transparency, joint problem-solving, and deeper collaboration—key hallmarks of the most successful partnerships today.

The “Time & Materials” model was deprioritized (average rank 4.1), with only one respondent ranking it as their top choice, underscoring an industry preference for more outcome-driven structures.

5. The Capacity Challenge: Navigating Overcapacity and Strategic Investment

The biologics manufacturing landscape is marked by a paradox: overall market growth coexists with significant overcapacity in certain segments, particularly monoclonal antibodies. Understanding this dynamic is essential for both sponsors and CDMOs making strategic decisions about capacity investment and utilization.

Monoclonal antibody manufacturing overcapacity, cost inflation, and ongoing geopolitical shifts are prompting strategic responses across the sector. CDMOs are implementing cost optimization measures while restructuring regional supply chains to enhance resilience. However, capacity constraints persist in high-growth areas such as CGT, mRNA therapeutics, and viral vector production.

This creates a bifurcated market: mature platforms like monoclonal antibodies face pricing pressure and capacity selection, while emerging modalities command premium pricing due to limited specialized capacity. For sponsors, this means careful alignment of programs with partner capabilities. For CDMOs, it necessitates strategic CAPEX allocation toward high-value, capacity-constrained modalities rather than adding to already-saturated segments.

Leading CDMOs are addressing these dynamics through targeted capability upgrades rather than broad capacity expansion. Investments focus on integrated technology platforms, process analytical technology (PAT), artificial intelligence and advanced analytics, continuous manufacturing systems, and increasingly modular, single-use facilities that enhance manufacturing agility without long-term capital lock-in.

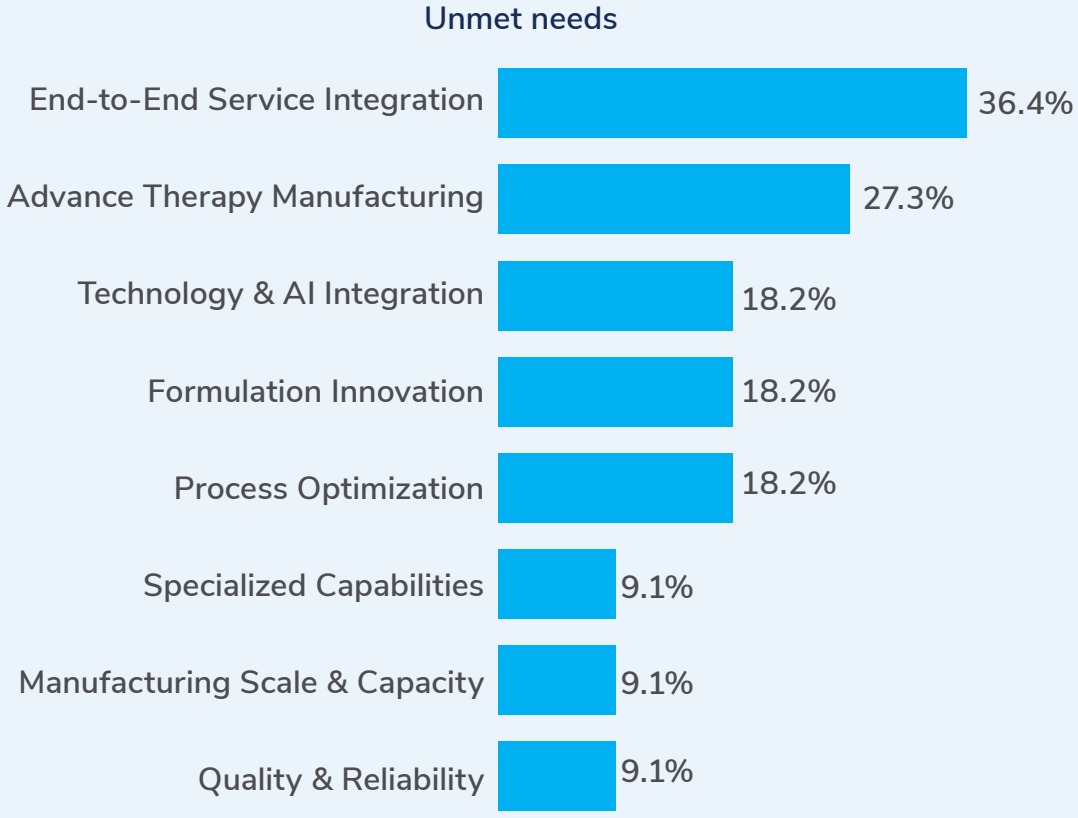
6. Looking Forward: Future Needs and Strategic Positioning

Understanding current priorities and challenges is essential but sponsors also identified critical unmet needs that will shape the competitive landscape over the coming years.

6.1. Service Integration Leads Future Demands

Service integration leads future needs at 36% of responses, with sponsors emphasizing seamless end-to-end solutions that eliminate friction points and accelerate timelines. This top ranking reinforces earlier findings: sponsors want fewer, more capable partners rather than managing multiple specialized providers. The emphasis on integration extends beyond manufacturing to encompass regulatory strategy, analytical development, formulation optimization, and supply chain management.

Chart 9: Unmet needs or white spaces in the biologics CDMO market today



6.2. Advanced Therapy Manufacturing Expertise

Advanced therapy manufacturing expertise, particularly for CGT modalities, is prioritized by 27% of respondents, acknowledging the specialized requirements of these complex therapeutic platforms. This represents a clear market signal: CDMOs that develop deep expertise in gene therapy delivery systems, cell therapy manufacturing, and associated analytical methods will capture disproportionate value as these modalities move from early development to commercial scale.

6.3. Process Optimization and Technology Integration

Process optimization and formulation innovation are valued by 18% of sponsors, while AI and technology integration are sought by 18%. These preferences reflect growing recognition that data-driven approaches can enhance outcomes across the development and manufacturing lifecycle. Sponsors are seeking partners who view manufacturing not as static execution, but as continuous improvement supported by advanced analytics, predictive modeling, and process understanding.

Looking beyond 2025, the outlook is defined by digital biomanufacturing maturity, CGT scaling capabilities, and strategic realignment of global supply hubs across North America, Europe, and Asia. CDMOs that anticipate these trends and invest accordingly will be positioned as partners of choice, while those that rely on legacy capabilities and traditional engagement models will face increasing commoditization.

7. Syngene as Partner of Choice: Translating Market Insights into Capabilities

The market dynamics, sponsor priorities, and future needs described throughout this report represent concrete requirements that sponsors use to evaluate potential partners. Syngene's strategic positioning directly addresses these demands through differentiated capabilities, global presence, and engagement models aligned with the evolving partnership paradigm.

7.1. Integrated Scientific Depth Across the Development Continuum

Syngene's integrated service portfolio covers discovery, toxicity profiling, process development, clinical manufacturing, and commercial supply of Drug Substance and Drug Product, supporting the seamless end-to-end transitions that sponsors identified as a top priority. Early decisions about cell line selection, expression systems, and purification strategies have profound implications for clinical and commercial manufacturing success.

Cutting-edge biologics manufacturing capabilities enable high-yield bioprocesses across monoclonal antibodies, ADCs, and recombinant proteins. Transposon-based cell line development accelerates timelines for stable, high-producing cell lines critical for rapid concept-to-clinic progression. Comprehensive viral clearance and validation programs assure product safety aligned with regulatory expectations.

7.2. Advanced Manufacturing Infrastructure Designed for Flexibility

Manufacturing infrastructure includes multiple 2KL and 4KL single-use bioreactors, high-speed vial filling lines capable of producing up to one million vials per day, and robust upstream and downstream process development platforms optimized via design of experiments (DoE). This addresses the flexibility and reduced capital requirements that 85% of pre-commercial programs now expect, while enabling the optimization and formulation innovation that sponsors identified as critical unmet needs.

7.3. Global Footprint Addressing Geopolitical and Supply Chain Imperatives

The acquisition of a state-of-the-art biologics manufacturing site in Baltimore, Maryland—Syngene's first U.S. facility—significantly enhances capacity bringing single-use bioreactor capability up to 50,000 liters.

> The Bayview facility was built with a vision to impact Maryland's biopharma sector, and I find it fitting that Syngene—an organization with a strong legacy of ESG and community impact—is now carrying that vision forward. As a Maryland native, I couldn't think of a better company to continue this legacy.
> – **Founder, biotech, life sciences, and workforce engagement platform**

This strategic location provides access to Northeast U.S. biotech clusters, enables onshore supply continuity for innovators navigating near-shoring pressures, and strengthens offerings for animal health clients requiring USDA approvals.

Complementing established Indian facilities, this dual-location strategy balances cost competitiveness with the regulatory and supply chain considerations that 24% of sponsors identified as affecting strategic planning. Sponsors gain flexibility to shift production between regions in response to regulatory requirements, supply disruptions, or changing trade policies.

7.4. Flexible Engagement Models Aligned with Partnership Philosophy

The "Chemists-on-Demand" approach dynamically scales scientific expertise, adapting to fluctuating client requirements while fostering close collaboration. Diverse contract structures include milestone-based payments, FTEs, and risk-sharing partnerships, the latter reflecting the modern ethos of strategic collaboration that 18% of sponsors now prefer for its innovation and acceleration advantages. Different programs require different partnership structures, and Syngene structures arrangements around client needs rather than rigid commercial templates.

7.5. Proven Track Record Across Diverse Client Base

> Syngene's new US GMP facility reflects the team's passion and commitment. The site is well positioned to support new clients and drive meaningful collaborations.
> – **Senior Manager, Emerging Technologies & Digital Transformation, biotechnology and pharmaceutical services**

Serving over 400 global clients, including 11 of the world's top 15 pharma companies, Syngene's track record in delivering on complex development, regulatory, and commercial mandates substantiates client trust. This client diversity enables Syngene to bring best practices from multiple therapeutic areas and development stages to each partnership. Regulatory excellence—sponsors' highest priority at 27%—is evidenced through successful navigation of global regulatory pathways, positive inspection outcomes, and proven ability to support products through approval and commercial launch.

8. Conclusion: Partnership as Competitive Advantage

The biologics outsourcing landscape has matured from transactional relationships toward strategic collaborations built on trust, innovation, and shared success. This transformation reflects the reality that therapeutic complexity, regulatory demands, and market pressures have made partnership quality a competitive differentiator rather than a cost variable.

Sponsors are clear about what they value: modality-specific expertise, end-to-end capabilities, regulatory excellence, flexibility, and geographic diversification. They seek partners who can address not only current programs but future needs, particularly in service integration, advanced therapy manufacturing, and technology-enabled process optimization.

Achieving sustainable value in this environment requires providers who combine broad scientific and technological capabilities, operational agility, regulatory excellence, and customer-centric engagement models. The most successful partnerships will be characterized by transparent communication, agile response to technological advances, regulatory harmonization across global markets, and genuine co-creation rather than transactional execution.

Organizations that recognize this evolution and invest accordingly—in specialized capabilities, flexible infrastructure, global presence, and collaborative engagement models—will capture disproportionate value as biologics continue their rapid expansion. Those that treat outsourcing as a purchasing decision rather than a strategic partnership will find themselves increasingly marginalized in a market that rewards depth over breadth, expertise over capacity, and collaboration over transaction.

The future of biologics manufacturing is not about finding the lowest-cost provider—it is about identifying partners capable of translating scientific breakthroughs into accessible and effective therapies while navigating unprecedented complexity. This is the essence of redefined value in biologics outsourcing partnerships.

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