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Our Commitment to Sustainability

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Commercialization as the New Competitive Filter

How regulatory evolution and pipeline expansion are redefining biologics manufacturing

The biologics CDMO market is entering a structurally different phase. Sustained growth in mammalian cell line development and an expanding biosimilar pipeline are accelerating the number of programs advancing toward late-stage development. At the same time, evolving regulatory policy — including recent FDA draft guidance emphasizing analytical comparability and manufacturing control — is shifting approval frameworks toward operational discipline rather than duplicative clinical evidence.

As a result, the transition from clinical development to commercial manufacturing has become the defining inflection point in biologics execution. Capacity alone is no longer sufficient; regulatory durability, inspection readiness, and long-term supply reliability now determine competitive differentiation.

Bora Biologics has aligned its U.S. strategy around this commercialization stage, investing in purpose-built commercial infrastructure, late-stage transfer governance, and quality systems designed to support durable supply across North American and European markets.

IDEA IN BRIEF

CONTEXT

The biologics CDMO market is evolving into a new phase, driven by geopolitical changes, the rise of biosimilars while regulatory requirements tighten.

KEY FACTORS

The transition from clinical development to commercial production is becoming critical: capacity alone is no longer sufficient; regulatory robustness, quality, and supply reliability make all the difference.

STRATEGY

Bora Biologics focuses its U.S. strategy on commercialization, investing in dedicated infrastructure, late-stage transfer governance, and robust quality systems for reliable.

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BORA BIOLOGICS GMP MANUFACTURING BUILDING IN SAN DIEGO, CA

Part I – Strategy and Market Positioning

A Market Shaped by Transition Risk

The global biologics CDMO market has expanded significantly over the past decade. Early stage development capacity is widely available, and technological platforms have reduced barriers to clinical progression. First-in-Human project timelines continue to get shorter and more aggressive across the industry.

Yet as more programs approach commercialization, a structural imbalance is emerging.

Upstream trends reinforce this trajectory. The global cell line development (CLD) market is estimated at approximately USD 6-7 billion in 2024 and projected to grow at a CAGR of roughly 10-13% through the end of the decade.[1-3] Mammalian expression systems – predominantly CHO-based platforms – account for an estimated 60-70% of market activity, driven by monoclonal antibodies and increasingly by biosimilars.[1-3] Microbial systems represent approximately 20-25%.[1-3]

The implication is structural: the predominance of mammalian platforms in development today directly translates into future demand for commercial-scale biologics capacity. As more CHO-derived assets advance into Phase III and registration, downstream manufacturing readiness becomes the constraining variable. In this sense, growth in CLD is not only a development indicator – it is a forward signal of commercial manufacturing pressure.

The real pressure is no longer just at discovery or first in human. It sits at the transition into commercial manufacturing – where regulatory scrutiny intensifies, inspection readiness, and manufacturing control becomes decisive. Gains achieved during early clinical acceleration can erode at the point of commercial approval if manufacturing transition is not tightly governed.

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BORA BIOLOGICS 2000L PRODUCTION BIOREACTOR HALL IN SAN DIEGO, CA

In our view, this commercialization inflection point is where commercial discipline is most visibly tested. It is also where differentiation among CDMOs becomes most visible.

Sponsors entering Phase III are not simply seeking capacity. They are seeking operational maturity, regulatory durability, and infrastructure capable of sustaining long term supply across major markets.

Our Positioning: Focused, Not Broad

At Bora Biologics, we have intentionally positioned ourselves around this transition stage by organizing the company around two centers of excellence. One focused on early-stage development, and one purpose-built and staffed for commercial supply in San Diego. We believe depth at the commercialization stage creates greater long-term value than broad but undifferentiated phase coverage.

Our positioning is built on three pillars:

- Commercial grade infrastructure engineered for inspection readiness
- Disciplined late stage tech transfer governance
- Quality systems aligned with global regulatory expectations

This model allows us to support programs developed within our network as well as assets originating externally that require migration into a commercial platform.

Importantly, we do not view late stage transfer as a transactional event. It is a strategic milestone that demands operational maturity and disciplined governance.

North American and European Market Alignment

The United States remains the central hub for biologics innovation and commercial demand. Sponsors increasingly prioritize proximity to regulatory authorities and primary patient markets when selecting commercial manufacturing partners.

At the same time, European regulators continue to elevate expectations around inspection readiness and supply continuity. Dual region supply strategies are becoming more common as companies seek geographic resilience.

Our strategy reflects these dynamics. We are strengthening U.S. based commercial biologics manufacturing while ensuring our quality and regulatory frameworks align with global submission standards.

We believe the future market will favor partners capable of supporting multi jurisdictional filings with consistency and transparency.

Regulatory policy is also reshaping the commercial landscape. On October 29, 2025, the U.S. FDA issued draft guidance proposing to simplify biosimilarity assessments by reducing reliance on comparative clinical efficacy trials where analytical and functional comparability are robust.[4] Concurrently, the agency outlined initiatives to streamline pathways for interchangeability designation.[4]

This evolution signals a broader policy shift: regulatory confidence is increasingly anchored in analytical depth and manufacturing control rather than duplicative clinical studies. If finalized, these measures could accelerate biosimilar progression into Phase III and registration, intensifying downstream commercial manufacturing demand.

For the CDMO sector, the consequence is clear. As barriers to clinical redundancy decline, manufacturing discipline and validated process control assume greater regulatory weight. Analytical characterization, comparability protocols, and inspection readiness become central determinants of approval success. Our investment strategy reflects this shift, emphasizing infrastructure and quality systems designed to support analytically driven regulatory review frameworks.

Growth Strategy: Depth Over Diversification

The CDMO sector continues to consolidate, and scale has become a dominant theme. However, indiscriminate expansion does not necessarily translate into strategic strength.

Our growth strategy is disciplined.

We are building depth in commercial biologics manufacturing rather than broadening across unrelated modalities. This includes:

- Expanding validated commercial capacity in the United States
- Strengthening late stage transition expertise
- Enhancing regulatory and quality infrastructure
- Prioritizing long term partnerships over short term manufacturing contracts

We anticipate that the next phase of biologics manufacturing growth will reward regulatory durability and sustained manufacturing control over acceleration alone.

In a market where early-stage capacity has proliferated, not all platforms are structurally designed for inspection-grade commercialization. The transition from clinical agility to regulatory permanence requires different infrastructure, governance, and capital discipline.

Part II – Investments and Outlook

Investing for Reliable Commercial Supply

Our recent investments reflect a clear objective: to consolidate our position as a specialized commercial biologics CDMO.

In January 2026, Bora Biologics completed a $30 million expansion of its San Diego biologics manufacturing facility. The expansion increased commercial-scale single-use bioreactor capacity, strengthened analytical and process characterization laboratories, and enhanced redundancy across critical utilities. The site was designed specifically to support late-stage and commercial supply programs under multi-market regulatory oversight.

This investment reflects a broader strategic thesis: commercial biologics manufacturing requires resilient infrastructure capable of sustaining inspection scrutiny and long-term market supply, not simply incremental capacity. By expanding U.S.-based commercial operations, we are reinforcing geographic proximity to primary regulatory authorities and major pharmaceutical markets while creating a scalable platform for Phase III through post-approval growth.

We are deploying capital in areas that directly reinforce commercial readiness:

- Expansion of validated biologics manufacturing capacity
- Upgrades to analytical and process characterization platforms
- Increased redundancy in critical utilities and infrastructure

San Diego Manufacturing Site Expansion Walk-Through Video

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Scan to view video

- Strengthening inspection ready quality systems

These investments are designed to institutionalize regulatory durability and sustained manufacturing control. They are intended to strengthen regulatory durability and sustained manufacturing control.

Commercial manufacturing requires infrastructure that can withstand regulatory scrutiny and sustain market demand over many years. Additionally, customers today want partners that can provide a path for increased supply as their product demand grows.

Building Organizational Capability

Equipment alone does not define commercial maturity. Governance, technical depth, and leadership capability are equally critical.

We are therefore investing in:

- Dedicated late stage tech transfer teams
- Expanded regulatory affairs support for global submissions
- Advanced quality oversight systems
- Cross functional integration between process development and commercial operations

As more programs enter pivotal stages, disciplined commercialization management will become increasingly important. Our objective is to make that transition predictable and controlled.

PDF **Building Organizational Capability**

Outlook: Commercial Discipline as the Next Competitive Filter

Looking ahead, biologics demand across North America and Europe is expected to continue expanding, supported by sustained growth in mammalian cell line development[1-3] and an accelerating biosimilar pipeline.[5] Upstream innovation remains strong. However, recent regulatory developments – including the FDA's October 2025 draft guidance emphasizing analytical comparability over duplicative clinical trials – suggest that the center of gravity in biologics development is shifting.

As regulatory frameworks increasingly prioritize analytical rigor and manufacturing control, commercial execution

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becomes more than an operational milestone. It becomes a regulatory gatekeeper.

This evolution reinforces a structural reality: while development platforms are becoming more efficient and accessible, the transition to commercial supply remains capital intensive, inspection driven, and unforgiving of variability. We believe the commercialization phase will consolidate share toward CDMOs purpose-built for inspection-grade manufacturing rather than retrofitted clinical platforms. Demonstrated manufacturing control, validated infrastructure, and operational maturity will.

We anticipate a market in which sponsors evaluate manufacturing partners not only on technical capability, but on regulatory durability, supply chain resilience, and the ability to sustain multi market supply without disruption.

Our objective is not simply to scale alongside market growth. It is to define and serve a distinct segment within it – commercialization stage biologics requiring operational maturity and long term supply reliability.

The industry has successfully accelerated innovation at the front end of development. The next competitive advantage will belong to organizations that ensure those innovations reach patients without interruption at the final stage.

In that respect, commercialization is not the conclusion of development.

It is the proving ground. ■

Bora Biologics Website

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