

# CONTRACT PHARMA

For Pharmaceutical & Biopharmaceutical Contract Services & Outsourcing

## Manufacturing where it **MATTERS**

Biologics capacity, tariffs, and the shift toward market-aligned supply

AI MOVES BEYOND THE  
BATCH RECORD

ADVANCED THERAPIES SUPPLY  
CHAIN: NO MARGIN FOR ERROR

ANNEX 1: FROM TALK  
TO EXECUTION

INHALATION'S NEXT WAVE

SHOW ISSUE

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SPONSORED BY



**STEPHEN LAM**  
Chief Executive Officer  
Bora Biologics

**MARC GOEMANS**  
Chief Commercial Officer  
Bora Biologics

**JOHN MOSACK**  
General Manager & VP - San Diego  
Bora Biologics



*Bora Biologics' FDA-registered San Diego facility expanded in January 2026 to support late-stage and commercial biologics manufacturing.*

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# Manufacturing in a Tariff-Driven World:

## Why Commercial Biologics Capacity Must Align with Market Demand

As trade policy, regulatory scrutiny, and capital discipline reshape biologics development, sponsors are rethinking where and how commercial manufacturing is secured. Bora Biologics' recent U.S. expansion and validated 2,000L scale-up reflect a broader shift toward demand-aligned, inspection-ready commercial capacity in the markets where products will ultimately be supplied.

### THE NEW DEFINITION OF CAPACITY

In biologics manufacturing, capacity used to mean stainless steel volume and available cleanroom space. Today, it means something more complex.

Sponsors evaluating CDMO partners are weighing geography alongside scale. They are assessing tariff exposure, regulatory familiarity, inspection history, and the probability of late-stage technology transfer disruption. As global trade policies evolve and geopolitical tensions influence supply chains, where a product is manufac-

tured has become a strategic decision—particularly for molecules targeting U.S. and European markets. At the same time, biologics pipelines are maturing. Phase III programs are larger, more capital intensive, and less tolerant of delay. Regulatory expectations continue to rise. In this environment, commercial manufacturing cannot be reactive. It must be engineered years before licensure.

The CDMO model is shifting accordingly—from offering capacity on demand to building validated, inspection-ready infrastructure ahead of sponsor inflection points.

## TRADE DYNAMICS AND THE RISE OF GEOGRAPHIC STRATEGY

Tariff volatility and geopolitical uncertainty have introduced a new risk variable into biologics supply planning. For programs intended for Western markets, sponsors are increasingly scrutinizing Asia-to-U.S. drug substance flows and the long-term predictability of cross-border manufacturing.

Late-stage manufacturing transfers driven by trade policy shifts can add six to twelve months to development timelines. They also introduce regulatory risk, validation complexity, and additional comparability work at precisely the stage when programs can least afford disruption.

As a result, commercial geography is being decided earlier. Sponsors are seeking:

- FDA-inspected commercial infrastructure in the U.S.
- Clear inspectional track records
- Reduced cross-border exposure at licensure
- End-to-end execution without forced site transitions

The question is no longer simply “Can you scale?” It is “Where will my product be manufactured at BLA—and will that location still make strategic sense five years from now?”

## BUILDING TO MEET COMMERCIAL MARKET DEMAND

In January 2026, Bora Biologics completed a \$30 million expansion of its FDA-approved San Diego biologics facility. The expansion significantly strengthened late-stage and commercial mammalian manufacturing capacity for North American and European markets (*Figure 1*).

The site now supports single-use bioreactor capacity spanning 500L through 2,000L, with facility infrastructure engineered to accommodate up to four 2,000L bioreactors or three 5,000L configurations.

The expansion was designed to address increasing sponsor demand for U.S.-based commercial-scale biologics manufacturing, including 2,000L and future 5,000L configurations. Importantly, this capacity is housed within an operational FDA-approved facility already producing commercial product for the U.S. market—reducing execution risk for sponsors transitioning to late-stage and commercial supply.

Within weeks of completion, Bora Biologics successfully executed its first 2,000L engineering run during the initial campaign. The run validated facility readiness, process integration, and cross-functional execution at commercial scale.

In today’s market, square footage announcements are no longer sufficient. Demonstrated performance at scale matters more.

## FROM ENGINEERING READINESS TO COMMERCIAL CONFIDENCE

High-titer biologics manufacturing presents challenges that

extend beyond upstream yield. As titers increase toward six grams per liter and beyond, downstream processing efficiency, impurity clearance, and critical quality attribute control become decisive factors in reproducibility.

The expanded San Diego facility was designed holistically aligning upstream, downstream, analytical, and quality operations to support robust scale-up without introducing variability.

Commercial success depends on more than volume. It depends on:

- Process robustness across campaigns
- Integrated analytics and comparability frameworks
- MSAT depth for late-stage troubleshooting
- Inspection-ready quality systems

Sponsors evaluating partners for Phase III, PPQ, and commercial supply are increasingly prioritizing reproducibility and resilience over raw reactor size. In this context, the ability to demonstrate a validated 2,000L engineering run within a newly expanded commercial facility sends a strategic signal: capacity is not theoretical.



*Figure 1. Newly installed 2,000L single-use bioreactors successfully completed initial engineering campaign following site expansion.*

## A DUAL-HUB MODEL DESIGNED FOR DE-RISKED PROGRESSION

While U.S.-based commercial capacity has become more strategically valuable, early-stage development economics still matter. Bora Biologics operates a dual-hub model designed to balance cost efficiency with long-term regulatory alignment.

Zhubei, Taiwan focuses on early-stage mammalian cell culture and first-in-human programs.

San Diego, California serves as the hub for microbial development and late-stage mammalian manufacturing, including commercial production under FDA approval.

## MANUFACTURING IN A TARIFF-DRIVEN WORLD

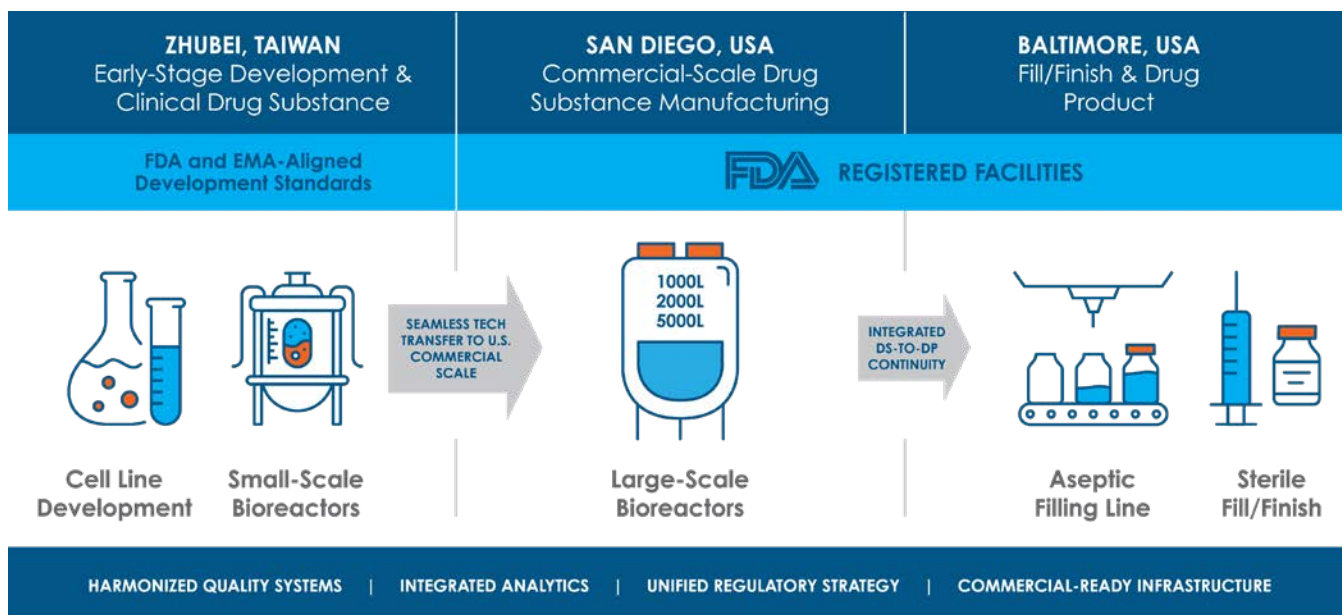


Figure 2. Bora Biologics' dual-hub development model connects early-stage activities in Zhubei, Taiwan with commercial-scale manufacturing in San Diego and integrated fill/finish in Baltimore, enabling seamless tech transfer, aligned quality systems, and a de-risked pathway to U.S. and EU market supply.

This separation is intentional.

Early-stage programs often prioritize speed and capital efficiency. However, as programs advance, alignment with Western regulatory frameworks and commercial geography becomes increasingly important.

By maintaining harmonized quality systems, analytical platforms, and technical oversight across both sites, programs can transition from Zhubei to San Diego without the disruptive redevelopment often associated with late-stage tech transfers.

In a tariff-sensitive environment, this model allows sponsors to optimize early development economics while preserving a de-risked pathway to U.S. commercial supply (Figure 2).

### THE SPECIALIST'S MARKET

Market dynamics in 2026 suggest that biologics outsourcing is evolving into a specialist's market. Scale alone no longer differentiates CDMO partners. Competitive advantage increasingly comes from:

- Mammalian process depth
- Demonstrated commercial track record
- Inspection history
- Regulatory fluency
- Commercial infrastructure aligned to market demand

Sponsors are consolidating vendor relationships, favoring partners they will not outgrow as programs mature. The cost of switching CDMOs between Phase II and commercial launch—financially and operationally—has become prohibitive.

The result is a premium on continuity.

CDMOs capable of supporting development through licensure and commercial supply within an integrated network are positioned to reduce risk at the most capital-intensive stages of drug development.

### EXECUTION BEYOND DRUG SUBSTANCE

Commercial readiness extends beyond bulk manufacturing. Increasingly, sponsors seek integrated drug substance and drug product solutions to minimize handoffs and accelerate time to market.

Through its partnership with Bora Pharmaceuticals' FDA-approved Baltimore facility, Bora Biologics provides fill-finish capabilities within a coordinated quality and governance framework. This alignment supports streamlined progression from drug substance to drug product without introducing additional vendor complexity at PPQ or launch.

As regulatory scrutiny intensifies, reducing the number of independent operational interfaces has become a strategic advantage.

### TAIWAN EXPANSION AND OPERATIONAL MOMENTUM

In parallel with the San Diego investment, Bora Biologics continues to strengthen capabilities in Zhubei, Taiwan, supporting early-stage mammalian development and clinical manufacturing.

Recent engineering and process scale-up successes at the Taiwan site reinforce the strength of the company's integrated model. Programs initiated in Zhubei benefit from structured scale-up planning that anticipates eventual commercial transfer



Figure 3. Bora Biologics' Zhubei facility supports early-stage mammalian development and first-in-human manufacturing within harmonized global quality systems.

to San Diego when appropriate (Figure 3).

Rather than operating as independent facilities, the two hubs function within a coordinated development-to-commercial framework—aligning technical documentation, quality systems, and regulatory strategy from the outset.

This alignment reduces comparability risk and supports smoother progression into pivotal manufacturing.

**REDEFINING LONG-TERM PARTNERSHIP**

The CDMO relationship has evolved. Sponsors are no longer selecting partners solely for a phase of development. They are evaluating whether a CDMO can remain aligned through market launch and lifecycle management.

Key questions now include:

- Will this partner still be strategically aligned at BLA?
- Can they absorb increased demand without site change?
- Are they insulated from trade volatility affecting my target markets?
- Can they support inspection readiness without rebuilding infrastructure midstream?

Investing in capacity aligned with market demand and commercial geography shifts the conversation from contingency planning to execution confidence.

**OUTLOOK: COMMERCIAL READINESS AS PREREQUISITE**

Biologics pipelines are advancing into increasingly complex therapeutic categories, including high-concentration antibodies, engineered proteins, and combination modalities. Regulatory expectations are unlikely to relax. Global trade dynamics remain fluid.

In this environment, commercial readiness cannot be a future milestone. It must be a present capability.

The CDMOs that will define the next phase of outsourcing are those that anticipate inflection points and build validated, inspection-ready infrastructure aligned with commercial market demand in the markets where products will ultimately be sold.

Manufacturing geography now influences valuation, launch timing, and long-term supply resilience.

In a tariff-driven, inspection-focused world, the question is no longer whether a CDMO can scale. It is whether that scale is positioned where it matters most. **CP**

