

pharma

TECH OUTLOOK



**BORA
BIOLOGICS**
**THE FULL-SPECTRUM
BIOLOGICS BUILDERS**

Stephen Lam,
CEO



Bora Biologics

*This award is in recognition of **Bora Biologics**’ stellar reputation and trust among customers and industry peers, evident in the numerous nominations we received from our subscribers. **Bora Biologics** emerged as the **Top Microbial Development and Manufacturer 2025** after an exhaustive evaluation by an expert panel of C-level executives, industry thought leaders, and our editorial board.*

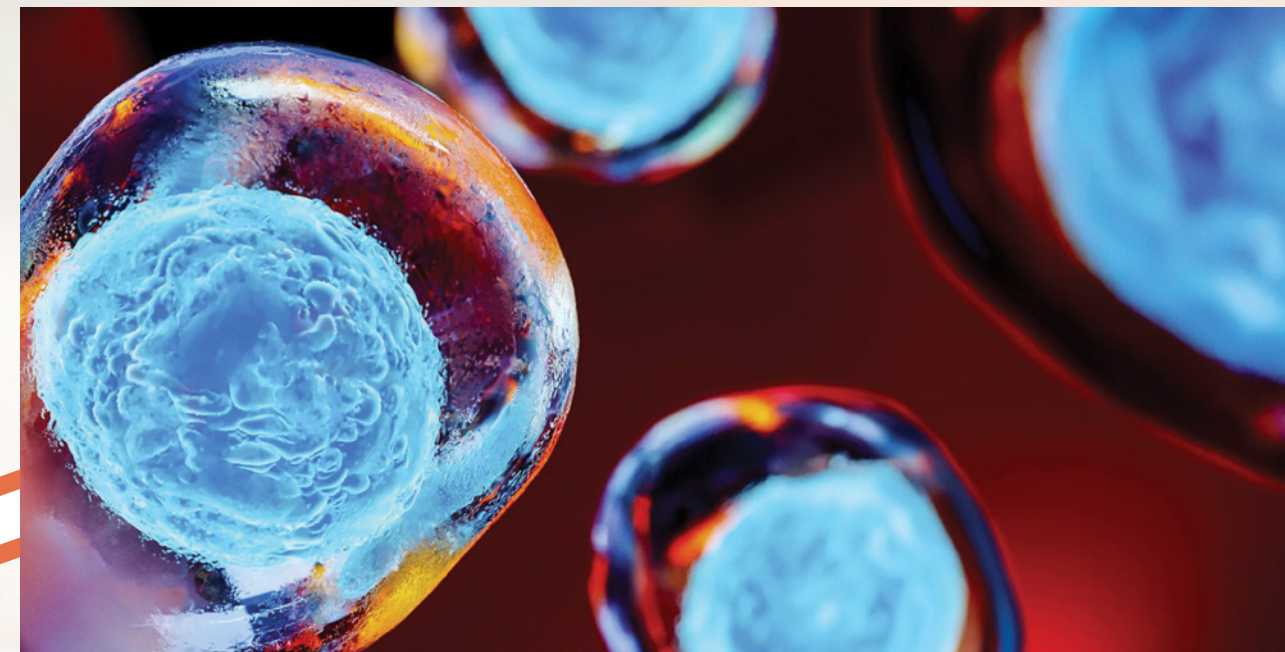
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COVER STORY

BORA BIOLOGICS

THE FULL-SPECTRUM BIOLOGICS BUILDERS



Biologics have become the crown jewels of modern medicine, yet for every molecule that successfully advances, dozens falter in the trenches. The path from discovery to production is fraught with hurdles: unpredictable scale-up, limited capital, lack of GMP infrastructure and the constant pressure to maintain speed to clinic while meeting regulatory expectations. In 2025, the greatest challenge lies in the leap from milliliters to manufacturing scale, where even minor deviations in process parameters can alter critical quality attributes and delay progress.

Within this demanding ecosystem, Bora Biologics, a full-spectrum CDMO, emerges as a partner exceptionally equipped to bridge the widening gap between scientific innovation and manufacturable reality. The company stands out for its proven ability to provide end-to-end capability in microbial development, guiding molecules from early-stage research through to commercial launch. Its expertise spans cell line and strain development, upstream and downstream process optimization, analytical method development and formulation design. By managing the entire continuum under one roof, Bora Biologics ensures processes are robust, scalable, and aligned with regulatory expectations from the very beginning.

Stephen Lam,
CEO

This confidence
is grounded in
experience.

Bora Biologics has successfully launched its own microbial biosimilar product from its San Diego site, now partnered with a commercial organization. That achievement serves as clear validation that the company can take a molecule from concept to market readiness.

“Over the years, we have contributed to the development of more than thirty-seven molecules across microbial and mammalian cell culture systems, including five to six microbial programs,” says Stephen Lam, CEO.

This breadth of experience has sharpened the company’s understanding of what it takes to advance a molecule from the lab bench to large-scale production, balancing scientific precision with commercial foresight at every stage.

Turning Early-Stage Ideas into a Scalable Reality

Bora Biologics translates scientific innovation into manufacturable processes with tangible impact. Many early-stage clients arrive with limited funding and small-scale processes, often generated in shake flasks or micro-scale systems, needing rapid progression to first-in-human studies. The company can rapidly scale these processes to 150-liter microbial fermenters, optimizing critical parameters such as feed strategy and induction timing to enhance productivity. Mammalian processes benefit from larger bioreactors, enabling seamless progression into late-stage development while maintaining consistency and regulatory compliance.

“Our know-how in strain selection and process refinement delivers measurable improvements, frequently boosting cell-line productivity two- to fourfold,” says Lam.

By locking critical parameters, including the cell line, master cell bank and upstream/downstream process conditions, early in development, Bora Biologics ensures downstream scalability and reduces risk when transitioning to clinical and commercial stages. These enhancements accelerate timelines and reduce the cost of goods, allowing early- and mid-stage biotechs to conserve capital without compromising quality. By combining technical precision with practical scaling experience, Bora Biologics guarantees that early-stage programs can advance efficiently into first-in-human studies and beyond, minimizing risk at every step.



OVER THE YEARS, WE HAVE CONTRIBUTED TO THE DEVELOPMENT OF MORE THAN THIRTY-SEVEN MOLECULES ACROSS MICROBIAL AND MAMMALIAN CELL CULTURE SYSTEMS, INCLUDING FIVE TO SIX MICROBIAL PROGRAMS.



Scaling Success Across Every Stage of Development

Bora Biologics’ integrated model is designed to meet the distinct needs of clients at every stage of development. Early-stage biotechs, often navigating tight budgets and first-round funding, benefit from Bora’s ability to turn small-scale lab experiments into clinic-ready processes. By optimizing strain selection, feeding strategies and key process parameters, Bora

helps startups advance confidently toward first-in-human studies without overextending resources or risking quality.

For mid-size and later-stage developers, the focus shifts to process optimization and commercial readiness. Bora Biologics uses its full suite of expertise, from analytical development to formulation and large-scale strain engineering, to improve yields, reduce cost of goods and ensure regulatory compliance. This integrated approach removes the inefficiencies and risks associated with fragmented partnerships, helping companies maintain speed while safeguarding product quality.

Bora Biologics’ Dual-Hub Advantage

The company’s global setup improves this adaptability. Bora Biologics was formed by merging two experienced biosimilar developers, each bringing complementary strengths. The Zhubei site originated from Eden, a biosimilar company, whose manufacturing, process development, and quality infrastructure became part of Bora Biologics. The San Diego site comes from Tanvex, another biosimilar company, where Bora Biologics developed and successfully launched its own commercial biosimilars.

This dual-hub setup retains the full technical capabilities of a biosimilar innovator. Both sites possess end-to-end process development, from upstream and downstream optimization to formulation design, covering both liquid and lyophilized formats. They also maintain comprehensive analytical capabilities, including cell-based bioassays and complete characterization, as required for comparability studies. These capabilities differentiate Bora Biologics from typical CDMOs, many of which lack portions of this technical depth because they never started as full-fledged drug developers.

The sites also have strategically specialized roles. Zhubei focuses on early-stage mammalian cell culture, supporting first-in-human programs and scaling processes up to 500-liter bioreactors. San Diego handles microbial programs and late-stage mammalian development, including commercial production. This separation allows each site to operate as a center of excellence, concentrating expertise and resources where they matter most and responding precisely to the unique needs of each client segment.



Real Results in Action

A striking case brings Bora Biologics’ full potential into focus. One early-stage microbial client arrived with a process producing barely a tenth of a gram per liter in shake flasks, far below what was needed for clinical studies. Bora Biologics stepped in and scaled the process to 150-liter fermenters while fine-tuning critical parameters like induction timing and feed strategy. As a result, productivity soared to one and half gram per liter, and manufacturing costs dropped by 35 percent, allowing the client to advance to first-in-human trials faster and more efficiently than planned.

Another example highlights Bora Biologics’ ability to optimize processes for longer-term growth. By carefully refining strain selection and process conditions, the team delivered two- to fourfold improvements in cell-line productivity, reducing both risk and cost of goods.

Across microbial and mammalian programs, Bora Biologics’ consultative approach makes sure clients understand the rationale behind every process decision, creating confidence that molecules can progress from early-stage promise to reliable, scalable results.

Brains Behind the Success

The team steering Bora Biologics have lived the full biotech journey, from innovator breakthroughs to CDMO-scale execution. They bring a developer’s mindset, understanding the challenges and priorities of clients at every stage.

The CEO himself spent over three decades in the biotech industry, including leadership roles at multiple CDMOs over the past ten years. Every other leader at Bora Biologics brings at least 25 years of industry expertise, combining deep technical knowledge with strategic insight.



OUR KNOW-HOW IN STRAIN SELECTION AND PROCESS REFINEMENT DELIVERS MEASURABLE IMPROVEMENTS, FREQUENTLY BOOSTING CELL-LINE PRODUCTIVITY TWO- TO FOURFOLD.



This rare mix of backgrounds gives Bora Biologics an edge. They understand what matters most to clients, anticipate potential bottlenecks and decode these insights into actionable solutions. Close, consultative conversations with clients allow the team to translate these insights into real-world process decisions that save time and resources.

A Global Setup for Focused Excellence

Bora Biologics’ global structure is designed to match the pace and complexity of modern biologics development. Early-stage mammalian cell culture work is concentrated at the Zhubei, Taiwan site, creating a dedicated hub for first-in-human programs. That focus allows teams to specialize, refine processes and move swiftly while maintaining tight control over quality and regulatory compliance.

In contrast, San Diego serves as the center for microbial and late-stage mammalian production. By separating early-stage and late-stage operations, Bora ensures that each site can operate as a center of excellence, fully optimized for the specific needs of its client segment. This approach minimizes distractions, speeds decision-making and reduces the risks associated with trying to manage multiple development stages under one roof.

Scaling for the Future

Bora Biologics is not standing still. In 2025, the company is investing to expand its capabilities, guaranteeing that it can support an increasing number of clients and more complex programs. In San Diego, multiple 2,000-liter single-use bioreactors are being added for mammalian cell culture, enabling late-stage and commercial production to meet growing demand. These upgrades will also allow the purification of higher-titer processes, supporting productivity goals of six grams per liter and beyond.

At the Zhubei site, development labs have been doubled in size, expanding process development capacity for early-stage clients. This enables Bora Biologics to take on more first-in-human programs from both local and international biotech partners, accelerating timelines without sacrificing quality.



Technology investments are running in parallel with physical expansions. Bora Biologics is upgrading information systems, electronic quality management, ERP and laboratory information management systems, giving clients real-time visibility into their programs. This access to data enhances collaboration, increases transparency and makes sure decisions are informed by the latest insights.

With these expansions and technological enhancements, Bora Biologics is positioning itself to meet the demands of 2025 and beyond, providing clients with scalable, reliable, and fully integrated biologics development without compromising speed, quality, or regulatory compliance. 