

## THE COMMERCIAL STANDARD

Insights from Bora Biologics

MARCH 2026

### Commercial Readiness Is an Operating Model

Advancing a molecule through development is a scientific milestone. Sustaining commercial supply is an operational commitment. Commercial biologics manufacturing demands infrastructure, regulatory discipline, and execution systems designed for long-term performance — not development flexibility.

In 2026, sponsors approaching late-stage development face increased scrutiny around supply reliability, data integrity, and inspection readiness. Commercial success depends on decisions made well before launch.

### 2000L U.S. Capacity Now Live

Bora Biologics' 2000L single-use bioreactor capacity is now operational in the United States, strengthening our commercial-scale platform.



Commercial capacity is not defined by vessel size alone. It requires:

- Integrated upstream and downstream execution
- Quality systems built for commercial inspection cadence
- Structured governance and change control
- Supply chain alignment for sustained demand

Infrastructure must support repeatability, predictability, and regulatory confidence.

Our U.S.-based platform is structured accordingly.

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### Regulatory Discipline is Structural

Inspection readiness cannot be activated late. It must be embedded.

Commercial manufacturing environments require:

- Mature quality management systems
- Data integrity embedded in daily operations
- Governance frameworks aligned with regulatory expectations
- Cross-functional accountability

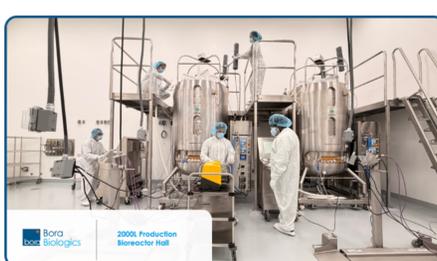
Sponsors evaluating commercial partners should assess structural discipline as rigorously as technical capability.

### The Transition to Commercial Supply

The move from Phase III to commercial production is not incremental — it is foundational.

Key considerations include:

- Process robustness at scale
- Long-term throughput planning
- Commercial change control governance
- Risk mitigation across supply chain



Commercial manufacturing is a distinct operational state.

It demands a platform built for it.

### 2026 Industry Priorities

Recent industry engagement continues to highlight:

- Heightened focus on U.S.-based supply resilience
- Increased regulatory expectations
- Scrutiny of late-stage tech transfer execution
- Infrastructure alignment with long-term demand

Sponsors are prioritizing partners who combine scale with regulatory maturity and operational governance.

### A Deliberate Approach to Commercial Manufacturing

At Bora Biologics, our focus is clear:

- U.S.-based commercial infrastructure
- Regulatory and quality discipline
- Operational systems engineered for sustained supply



Commercial readiness is not declared.

It is demonstrated.

### Connect with Our Team

For sponsors preparing for late-stage scale-up or commercial transition, early alignment on infrastructure and execution strategy is critical.

We welcome discussions with teams evaluating commercial biologics manufacturing partnerships in 2026 and beyond.

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