

# The Science Is Complex. Your Manufacturing Shouldn't Be.

**U.S.-Based. Data-Driven.  
Centered on Your Molecule.**



## Your Trusted Partner for Commercial Manufacturing

Scalable, inspection-ready, global manufacturing with proven execution and a partnership-first approach that accelerates your path to patients.



**Minimize tech transfer risks** with structured protocols and demo runs that validate your process before full-scale production



**Accelerate your timeline with proven expertise** across 15+ Product Characterization projects completed and 3 products supported through commercial manufacturing



**Meet regulatory deadlines** through regulatory-grade Process Performance Qualification (PPQ) execution with flexible timelines (6–8 months typical) that adapt to your approval strategy



**Leverage our inspection-ready facilities** with our established track record across FDA, EMA, MHRA, PMDA, and Swissmedic inspections



**Patients shouldn't wait because of manufacturing bottlenecks.**

# Commercial Supply That Scales with You: From PPQ to Manufacturing

Scalable, inspection-ready manufacturing built for complex biologics with proven execution from tech transfer to commercial supply.

## Scale Confidently with Flexible Manufacturing Capacity



**Optimize development approaches** with flexible 500L to 2000L capacity that adapts to program requirements



**Access immediate scalability** with 10 x 2000L single-use bioreactor capacity for seamless volume expansion



**Reduce geographic supply chain risks** through strategic manufacturing capabilities throughout the world



**Support long-term program continuity** with dedicated expansion infrastructure for commercial manufacturing designed for sustained partnership

## Launch with Proven Operational Rigor



**Reduce manufacturing surprises** through comprehensive process fit assessment, gap closure, and risk-based alignment prior to cGMP initiation



**Accelerate informed decision-making** with integrated upstream and downstream process data that strengthens manufacturing confidence

## Deliver Consistently with Market-Proven Execution



**Build on demonstrated commercial expertise** from 3 successfully manufactured and approved products



**Minimize cross-functional delays** through integrated coordination between Manufacturing Science and Technology, Process Development, Quality Assurance, Quality Control, and Manufacturing teams



**Stay ahead of supply chain challenges** with structured weekly Sales and Operations Planning meetings that optimize material flow and capacity alignment

## Ready to Accelerate Manufacturing Timelines?

Contact us to explore available cGMP slots and discuss how we can accelerate your program timelines.

**Connect with our team and explore seamless manufacturing.**



**Scan to get in touch with our team today!**