Success Story

AVID BIOSERVICES®

Seamless Onshoring from China-based CDMO to Avid Bioservices

Background

A U.S.-based biotechnology company sought to relocate its manufacturing program from a China-based CDMO to a trusted U.S. Partner. Amid evolving geopolitical tensions, rising tariffs, and growing implications of the BIOSECURE Act, the biotech sponsor wanted to ensure its critical clinical stage biologic program was protected, compliant, and future-ready for commercial success.

The molecule, a monoclonal antibody in phase 1 clinical trials had been produced at a 2,000L scale in China achieving a titer of 5.2 g/L.

> **The sponsor partnered with Avid Bioservices to execute a complete process transfer, analytical transfer (partial method) and CGMP manufacturing, ensuring continuity of product quality and accelerated timelines while mitigating risk.**

Challenges

- Needed to transfer process and methods from China-based CDMO to a U.S. facility without disrupting development timelines
  - No PD activities performed – meaning Avid would leverage China-based CDMO process and directly technology transfer process to Avid facility.
- Geopolitical concerns and exposure created business risk and investor pressure to onshore
  - Client transfer used resin from China to US
  - Chromatography was re-packed
- Requirement to transfer 2,000L to 2,000L while maintaining process performance and product quality attributes
- Need for rapid regulatory alignment to maintain ongoing Phase 1 study supply and continuity

Approach

1. Conducted comprehensive information transfer, including process data, analytical methods, and product quality profile.
2. Performed method feasibility assessments and experiments to identify and close data or procedural gaps prior to method qualification
3. Executed full method qualification and pre-production activities to ensure readiness for CGMP manufacture
4. Produced CGMP batch using a 2,000L single-use bioreactor system operated in fed-batch mode to mirror process origin
5. Implemented Avid's cross-functional technology transfer framework aligning process development, manufacturing, quality, and project management teams for rapid onboarding
6. Delivered full documentation package enabling regulatory confidence and streamlined future submissions

Results

- Successful transfer and scale-up from 2,000L to 2,000L with comparable process performance and product quality
- CGMP material produced within 8 months of initial tech transfer
- Achieved on-time batch release, supporting uninterrupted clinical trial supply
- Met all critical quality attributes with strong comparability data to originating site batches
- De-risked program from geopolitical and BIOSECURE Act exposure, ensuring U.S.-based security and supply continuity
- Strengthened sponsor confidence through Avid's proven tech transfer discipline and white-glove project management

Expert Insights

- Early engagement of analytical and process development teams is critical to de-risking overseas transfers
- A structured cross-functional transfer model enables seamless handoffs even with limited originating documentation
- Onshoring provides not only regulatory and geopolitical security but also speed, transparency, and quality control advantages