SUCCESS STORY

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 supply to support clinical trials as sponsor enroll more patients.

CHALLENGES

Needed to transfer process and methods from China-based CDMO to a U.S. facility without disrupting development timelines

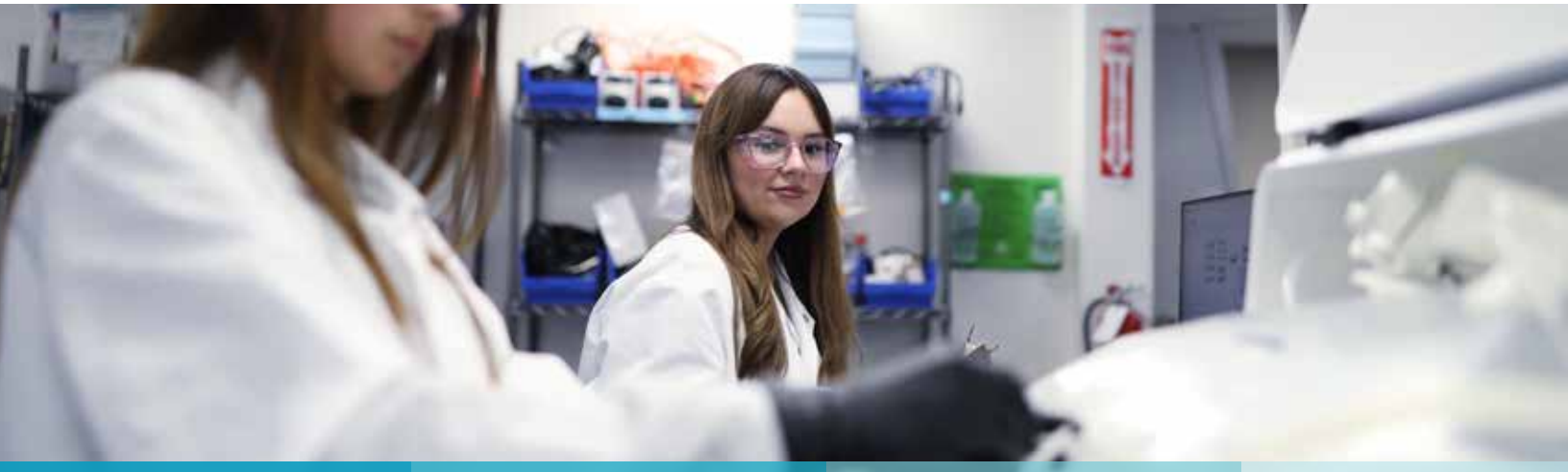
- No PD activities were performed, meaning Avid would leverage the China-based CDMO process and directly transfer the process to the Avid facility

Geopolitical concerns and exposure created business risk and investor pressure to onshore

- Client intent to utilize used resin from China and shipped to US
- Chromatography columns were re-packed and scaled up

Maintaining process performance and product quality attributes

Need for rapid bulk drug substance production to maintain ongoing Phase 1 study supply and continuity



APPROACH

1. Conducted gap assessment that outline the major difference between donor and Avid site. Gap assessment includes raw material, analytical, equipment, and process assessment.

2. Gap assessment outcome:

    a. Analytical: Avid would be able to leverage platform analytical test method and verified through analytical feasibility and qualification
    b. Raw Materials: Avid library of raw materials met quality standards needed by the sponsor, thus minimizing the requirement to qualify new raw material vendors
    c. Equipment: Avid platform equipment has the ability to perform manufacturing process that meet operational range requirement. Major equipment difference on centrifuge (donor utilized stainless vs Avid utilizes single use)
    d. Process: Avid platform process aligned with process requirement (major changes to align seed train expansion model with Avid platform)

RESULTS

- **Successful transfer from donor to Avid with comparable process performance and product quality**
- **GMP Bulk Drug Substance (BDS) produced within 8 months of initial tech transfer (initial document tech transfer occurred in February 2025, GMP batch completed by Oct 2025, batch release scheduled in December 2025)**
- **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

1. A structured cross-functional transfer model enables seamless handoffs even with limited originating documentation

2. Onshoring provides not only regulatory and geopolitical security but also speed, transparency, and quality control advantages

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