SUCCESS STORY

Strategic 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 4 to 5 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.

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

- Despite facing unforeseen global supply chain disruptions beyond our control, Avid and our client demonstrated resilience and adaptability. Critical components, including WCB and essential media materials sourced from China, were impacted by evolving geopolitical conditions. Through proactive collaboration and exceptional teamwork, our team secured the neces sary resources to initiate development with only a 32-day delay

- Thanks to this collective effort, we remain firmly on track to achieve the original project timelines for GMP thaw and lot release, ensuring delivery excellence and client confidence, while continuing to look for opportunities to maintain these timelines efficiently

APPROACH

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

RESULTS

- **Successfully completed the first development run, demonstrating product quality is comparable to the originator process. This was achieved with minimal changes to the original process and design, ensuring compatibility with Avid's GMP standards and manufacturing capabilities**

EXPERT INSIGHTS

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

14191 Myford Road, Tustin, CA 92780 avidbio.com/contact 1+ 714.508.6100