Strength

- Our International Senior Leadership Team brings decades of experience to ensure technological and manufacturing superiority;
- Fully integrated CMC services provide cost savings by optimizing customer processes, increasing protein expression, and reducing production scale all of which increase affordability of biopharmaceuticals;
- Focus on CDMO capabilities and customized cell culture media business means we have no conflict of interest with customers as we don’ t develop our own biologic products;
- Flexibility is our advantage as we offer each partner a customized production process strategy where we employ a modular approach with various volume disposable bioreactors and processing equipment to allow for simultaneous projects to ensure continuous and efficient production;
- Leading digital PBR data platform, ensuring complete information traceability and security. Includes cell strains, product sample, processing and analytical data security systems, setting the customer regulatory authorities’ minds at rest;
- Customized Project Management provides multi-disciplinary approach, to accelerate speed up the clinic.

Quality System

TOBIO’s Quality systems are designed to comply with international cGMP standards and meet global regulatory requirments.

- Highly qualified and experienced analytical team
- Well documented quality control strategy
- Regular cGMP training
- Centralized CMC document management and strategy
- Meets NMPA / FDA / EMA filling requirements
- Robust quality assurance system

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THOUSAND OAKS
澳斯康生物制药

More Accessible, Affordable

Biologics for Humanity!

Integrated CMC Organization

About Us

Thousand Oaks Biopharmaceuticals (TOBio) is an integrated CMC Solution Provider dedicated to large-scale GMP production of biologics with CDO and CMO capabilities. The TOBio Senior Leadership Team brings decades of experience and robust track records with expertise in cell culture media technologies, process development, and full CDMO services to build its high-quality platform for biologics development and manufacturing. TOBio made a revolutionary breakthrough regarding its operational footprint and decided to integrate its core cell culture medium business which was founded in 2011 as JSBio (the first to develop serum-free medium options in China), Itessentially providing a one-stop solution from raw materials to complete CMC service. As a trusted partner of the global biological industry, TOBio supplies innovative solutions and partners with biopharmaceutical facilities all over the world to meet tight timelines, drive down cost and provide top-level compliance.

Objectives

we are dedicated to revolutionizing industry standards. Providing superior quality, customization, service with dedication to our partners, as they develop new drugs and technologies advancing the industry. We are fully equipped to support our partners outsourcing needs at all stages of the drug development process. We provide expertise in both small-scale and large-scale production as project demands change and mature.

Core Services

Cell Line Development, Media Formulation Development, Media Manufacturing,

Process development and Scale-up, Biopharmaceuticals Formulation Development, Analytical Method Development, Stability Study,

DS and DP Manufacturing, Commercial Manufacturing, Global Registration Filing, Regulations and Technical Support

Development and Manufacturing

TOBio has multiple sites throughout the world offering product development, manufacturing and laboratory services from bench-top to pilot to industrial GMP production. We specialize in cell line optimization, cell culture medium development, upstream and downstream process development, and establishment of analytical methods. Our laboratories are designed in a modular fashion to support short-term or longer-term contract manufacturing services and include multiple disposal bioreactors ranging in size from 50L-3000L, a complete suite of agnostic downstream pharmaceutical equipment, as well as various packaging options including lyophilization vials and prefilled syringes for drug substance and/or drug product. Our facilities meet FDA, EMA and domestic GMP standards.

- Factory: 10,000m²cGMP production facilities
- DS workshop Capacity: 20,000L
- USP/DSP PD lab: 1,500m²
- Lyophilization: 40,000 Vials/Batch (Tofflon), 0.5-20ml Fill & Finish (Bosch)
- Cultural process: Fed-batch Or Perfusion
- Equipment: GE，Thermo-Fisher，Millipore, JYSS