JHL Biotech CDMO Services

Quality and Efficiency to Drive Satisfactory Result for Clients
FACILITY

- JHL Biotech established R&D and manufacturing facility at Taiwan with over 130 staffs, majority include scientists and engineers. The facility holds 48,438 sq. ft with two 500L bioreactor trains with capacity be expand to two 1000L trains.
- The facility is GMP compliance and built in accordance with ICH, FDA, EMA, NMPA and TFDA standards and GMP certified (by TFDA) and had been audited by European Union (EU) Qualified Person (QP).
- JHL has additional clinical and commercial site with over 140 staffs locate at Wuhan, Hubei with the first in the world GE KUBio modular construction technology. The facility holds 150,695 sq. ft. with four 2,000L and one 200L bioreactor trains.
- Wuhan can provide vial fill finish service by Q3 2019.

PROVEN CAPABILITIES

- An established platform for antibody and enzyme process development and manufacture.
- Robust and proprietary CLD technologies to generate high-performance CHO cell lines in 5 months.
- Successful technology transferred process from client's CMO facilities to JHL and manufactured clinical materials for global trials in EU, US, CN, and AU.
- Develop several biologics cell lines, analytical methods, processes and manufacture drug substance/ drug products at production scale for global clients.
- Improve/ fine-tune on charge variants, purity, glycosylation and potency to achieve clients' desired product quality.
- Optimize target cell depletion method by novel mechanism with commercialized immune cells. Characterize size variant and charge variant of product related impurities.
- Deliver stable and high-concentration antibody formulations over 100 mg/mL.
- Fully CMC regulatory support to clients with success IND filing in EU, US, CN, AU, and SG.

REGULATORY CMC SUPPORT

JHL provide a well-versed regulatory submission service for our clients, including consulting/strategic services, initiating Scientific Advisory Meetings, preparing dossiers on all CMC topics and support in agency communication/responses. We established a close working relationship with agencies in US, EU, Australia, India, China and other Asian countries, with proven success in leading and providing PK/ PD clinical trial applications and safety and efficacy clinical trial applications.

PROJECT MANAGEMENT

JHL Project Management Organization's (PMO) service is responsible to completely deliver our client's goals & expectation, including tailored project planning, project execution, and timely monitoring & reporting. Our experienced PM's will be your one-stop contact to firmly grasp all aspects of your project with focus on milestones, deliverables, and issue escalation/resolution while managing risks and controlling the budget.
OUR VISION

To improve global healthcare by increasing the availability of biotechnology medicines

PROCESS DEVELOPMENT

JHL have scalable platform technologies for cell culture and purification to provide optimal protein product qualities and yield. We develop processes in 3L and 50L, and then scale it up to 200L, 500L or 2,000L for use in non-clinical, clinical trials and commercial production.

TECHNOLOGY TRANSFER

JHL facilitate seamless technology transfer to and from our facilities at any stage in the product development lifecycle. We use industrialized scale-up and scale-down technology to transit biologics process technical transfer in between laboratory and cGMP manufacturing scales, as well as providing systemized process gap analysis for site and equipment changes in between clients and JHL.

CELL LINE DEVELOPMENT

Our strength is to generate high-performance production cell lines under a target product profile by our proprietary CHO expression technologies. We are implementing state-of-the-art single cell printer and high-resolution imager to ensure monoclonality and to reduce the time of single cell cloning.

ANALYTICAL SERVICE

JHL fully support method development & qualification, tech transfer & optimization, and method validation. The broad analytical, portfolio enables JHL to provide testing of the structural and physicochemical drug attributes, and also to assess binding and functional activities with regards to the mode-of-action.

cGMP MANUFACTURING

JHL has world-class manufacturing capabilities using single-use bioprocessing equipment with QC laboratories to provide robust drug substance production service. We can run multi-products manufacturing with range of production scales flexible for clients in clinical and/or commercial cGMP batches, with cGMP cell banking facility for Cell Bank manufacturing and secured storage.
Strongly positioned partner for asset intensive and rigorously scrutinized development stage

Discovery & Development

Cell Line Generation
Analytics
Process Development
Quality & Manufacturing
Regulatory
Project Management

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