聯亞生技開發股份有限公司

UBI-Asia's cGMP Manufacturing Facilities for Clinical Grade Biopharmaceuticals

Your Asia-Pacific Regional Partner in Biologics cGMP Production and Development

United Biomedical, Inc. Asia (UBI Asia) is a bio/pharmaceutical firm dedicated to the discovery and development of a new class of immunotherapeutics and vaccines for chronic and infectious diseases. Our manufacturing facilities located at Industrial Park in Hsin-Chu, Taiwan for the production of our proprietary and generic products and providing contract manufacturing services as well. The UBI-Asia facilities are capable of producing biopharmaceuticals and all types of formulations including sterile injectables, which fully comply with international quality standards. Our Biologics Pilot plant for production of mammalian cell based monoclonal antibodies and other protein products has been validated to allow the supply of clinical trial materials. We provide a wide range of product development and manufacturing services from cell line establishment and process design to development of full-scale cGMP protein production, purification and aseptic filling, in addition to corresponding testing, validation, analytical and regulatory support.

Facility

The Biologics Pilot Plant encompasses 9,000 square feet of manufacturing area and maintains stainless stirred-tank bioreactor systems, recovery, purification systems, and clean room work zones of class 100, 10,000 and 100,000. The facility is supported by a dedicated HVAC system, water for injection and clean steam systems. The other GMP support systems and QC/QA are provided by the long-term established main pharmaceutical plant, which was acquired from Glaxo Welcome, Taiwan in 2001.

Current manufacturing capacity include two 30 liter bioreactors and a 150 liter bioreactor systems, recovery and purification systems, and clean room work zones up to class 100 for terminal filter sterilization. The recovery and purification systems are controlled by software systems that are capable of compliance to 21CFR Part 11 requirements. A validated and constantly monitored cell storage system has the capacity for thousands of cultures in a secure, documented environment.

The design of work stations within the Biologics Pilot plant follows linear flow concepts. Separate restricted and unrestricted corridors are designated for personnel, material and waste flow with no return movement in order to reduce the risk of cross contamination.

Production staff will perform a general garment change area before entering the facility and may be required to robe in full body coverage when working in class 100 zones. Cleaning procedures are validated and rigorously enforced and monitored to minimize the risk of cross-lot contamination.

Quality Control & Quality Assurance

UBI Asia's facility is equipped to perform all analytical methods to support environmental monitoring: raw material, in-process, bulk drug substance and finished product release testing and stability study. Our analytical team is qualified and highly trained on the battery of techniques required to ensure accurate testing and characterization of our clients' protein therapeutics.

Our Quality Assurance unit that is independent from Operations and has the responsibility to establish, plan and implement the quality program throughout the company to assure that all products are manufactured in compliance with product specifications for safety, identity, purity and potency. The goal is to establish and implement systematic quality management activities to meet the needs of customers and regulatory authorities.

cGMP Compliance

The Biologics Pilot Plant has completed full implementation of cGMP compliance and its cGMP status was approved by Department of Health (DOH), Taiwan on October 04, 2007.

Our facility was designed, built and validated to be in compliance with cGMP requirements for biopharmaceuticals and active ingredient production. Initiation activities include "3Q"–the performance of Installation, Operational and Performance Qualification studies based on pre-defined protocols. Additional validation programs for processes and equipment systems are built into the quality system program for biologics and active ingredient production, supply and distribution. Our entire staff is dedicated to the highest standard of maintaining cGMP compliance.

Accelerating Your Product Development Pipeline

Technology and Services

UBI-Asia provides total solution from cell line development to clinical trial development including research and development of high yielding cell line, media optimization, cell culture and purification, scale-up and analytical method development, product characterization, supplying and manufacturing clinical grade material under cGMP compliance and providing regulatory support. Therefore, with process development expertise, manufacturing capacity, regulatory support, timely service and competitive service charge, UBI Asia is your best partner for early clinical development in Biologics. We are highly motivated to collaborate with other biotech and biopharmaceutical companies not only for providing manufacturing services but also product development.

Cell Line and Process Development

- Genetic engineering and expression vector construction.
- Establishment of high yielding and stable recombinant clones.
- Serum-free suspension culture adaptation and medium optimization.
- Fed-batch suspension cell culture process development and scale-up from 2, 5, 30, to 150 L.
- Purification process development and laboratory scale production.
- Methods development for quality control of protein drugs

Product Characterization

- Genetic analysis of recombinant cell lines
- Assays to detect contamination, spectrometry, isoelectric focusing, protein sequencing, mapping, amino acid analysis, monosaccharide analysis, carbohydrate structure and disulfide bond patterning for protein characterization.

Cell Bank Production

- Class 100 clean room for manufacturing mammalian cell banks.
- With all appropriate monitoring and documentation to meet international regulatory requirements.
- Secure, segregated Cell Banks in locked containers with access control.
- Cell Bank Vials are stored in constantly monitored liquid nitrogen storage tanks in liquid phase.
- Level of liquid nitrogen is monitored and auto-filled to a set level.

Clinical Grade Protein Drug Manufacturing

- Production of bulk quantities of protein drug for clinical development.
- Thirty and 150 Liter stainless stirred-tank bioreactors for cell culture.
- Fully traceable multi-step chromatography and ultrafiltration/diafiltration systems for purification.
- Class 100 clean room for terminal sterile filtration of antibody
- Class 100 clean room for aseptic fill packaging of bulk quantities
- With all appropriate monitoring and documentation to meet international regulatory requirements.
- Assist customers with new product registration and license applications.
- Provide services in logistics management, production planning, procurement of raw materials and packaging components, warehousing, and distribution.

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