Stelis Biopharma

Unit 3

A multipurpose facility with an ability to cater to multiple vaccine types including viral vectors, protein subunits, mRNA & DNA.

As a full-service CDMO player and the go-to partner for global biopharmaceutical companies, we excel in process development across modalities, scale-up, and manufacturing of biologics and sterile injectables. The state-of-the-art Unit 3 facility enables end-to-end biopharmaceutical manufacturing and is completely separated from the other two facilities to eliminate any cross-contamination.

By leveraging our world-class infrastructure and manufacturing capabilities, our technical specialists emphasize on developing and supplying vaccines for a broad range of infectious diseases. The scientifically sound and knowledgeable team of Stelis has successfully developed the world's first plasmid DNA vaccine used for COVID-19 (ZyCoV-D), Etanercept and Rubella vaccines.

We embrace quality at every step of integrated process development and manufacturing.

Our Unit 3 facility is designed to support the entire product lifecycle of various drug substances and drug products ensuring compliance with the strict pharmaceutical regulations required for cGMP manufacturing.

Manufacturing Capacity

Drug Substance

- Process development capacity - upstream and downstream: 4L, 20L and 100L
- Process Scale-up-10 X 200 L
- Process validation & commercialization: 20 X 2000 L
- Use of single-use and disposal bioreactors
- Capable of handling and developing processes using adenovirus and lentivirus
- Cell manipulation and engineering using viral vectors

Quality Management System

- We are committed to maintaining an effective quality management system (QMS) modelled around US FDA 6-systems which complies with the ICH guidance, Indian Regulations, EU GMP guidance, US FDA guidance, ISPE and PDA guidance and current industry \ standard
- Routinely involved in facility contamination controls by utilities testing and environmental monitoring activities by active air sampling, passive monitoring by settle plate and by surface monitoring for classified areas and inbuilt active air samplers within isolators in line with regulatory requirements. Environment isolates and organisms recovered from investigational samples were identified up to species level
- Usage of a fully automatic packaging line and 100% visual inspection of the entire process

Drug Product

- Formulation development
- High-speed two vial lines for high volume products with an annual production capacity of 400 million vials (liquid and lyophilized)
- Secondary and tertiary packaging
- Cold chain inventory management
- Preparation of cold packs & shippers
- Tertiary packing (bundling, palletization)
- Finished goods dispatch

List of Abbreviations

- ICH- International Council on Harmonisation
- ISPE- International Society of Pharmaceutical Engineering
- PDA- Parenteral Drug Association

No.68/A, 1st Phase,
Bommasandra Industrial Area,
Opp to Sai Visharam Hotel,
Bangalore, Karnataka, India -560099.

Email : info@stelis.com
Phone: 080-35079111