Stelis Biopharma

Stelis BioSource™

DELIVERING BIOPHARMACEUTICAL EXCELLENCE

A ONE-STOP SOLUTION FOR
BIOPHARMACEUTICAL MANUFACTURING

Stelis BioSource™

Single-cycle development track: preclinical to commercial, for development and manufacture of Biologics.

We are a fully integrated, multi-product, Contract Development & Manufacturing Organization (CDMO), located in Bangalore, India. We offer comprehensive services from early-stage cell line development to commercial sterile drug product manufacturing of biologics.

The manufacturing facility have separate dedicated suites for microbial and mammalian (coming soon) drug substance. We offer end-to-end cGMP manufacturing solutions for Biologics and fill & finish in all formats viz. pre-filled syringe, cartridges and vial manufacturing and secondary packaging for drug droduct.

We can support your needs in:

- Early stage development
- Clinical trial material generation
- Process validation
- Commercial supply

We offer on-site quality assurance, full release testing (including cell based assays), for raw materials, intermediate, Drug Substance, formulation, fill and finish (in all sterile formats) and packaging of Drug Product to support your requirements at each stage in the drug development life cycle.

R&D

The R&D facility leverages latest technologies for developing easily scalable processes in microbial and mammalian systems and biological formulations in all injectable formats. We also offer analytical services including characterization, formulations & lyophilization cycle development.

ANALYTICAL DEVELOPMENT

Analytical development services are offered for development of in-process analytics, bioassays, product characterization and stability analysis, meeting guidelines set by ICH, US-FDA and EMA

SCALE-UP

The scale-up facility (50L) is designed for seamless technology transfer to Manufacturing. The scale-up facility also offers formulation and fill & finish in all injectable formats for pre-clinical studies and cGMP supply for all phases of clinical studies.

cGMP MANUFACTURING

The cGMP manufacturing facility incorporates latest technologies to meet US-FDA and EMA requirements for manufacturing of clinical and commercial supplies.

STATE-OF-THE-ART FACILITIES

PROCESS DEVELOPMENT (PD)

The 22,000 sq.ft. R&D facility is designed to handle microbial biopharmaceutical development.

Our microbial PD can develop processes up to 10L fermentation scale. We offer expertise in microbial protein expression in different forms - inclusion bodies, soluble proteins & periplasmic proteins.

Our purification expertise includes development of low & high pressure chromatography, filtration operations, protein modification techniques such as conjugation, refolding and enzymatic conversion.

The Process Development follows a systematic approach incorporating Quality by Design principles like DOE, Design Space, Control Strategy, PAT, Risk Management etc.

PROCESS SCALE-UP

Our cGMP facility is designed for scale up of microbial (50L) processes sufficient to deliver pre-clinical and phase-1 requirements.

For purification operations, the facility offers both conventional and single-use technologies.

We offer optimization of continuous centrifugation and filtration technologies for product separation.

We have a dedicated combi filling machine for fill & finish in all injectable formats: pre-filled syringes, cartridges and vials including lyophilized forms.

The in-house analytical team supports the in-process and release testing.

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cGMP MANUFACTURING

The 2,00,000 sq.ft. cGMP facility produces recombinant biotherapeutics from microbial systems in compliance with US-FDA and EMA requirements.

The microbial DS suite has manufacturing lines with 50L, 300L & 1000L conventional SS fermenters supported by corresponding downstream processing capacities using single-use technologies.

The cGMP Drug Product facility offers filling in all injectable formats. All filling lines- PFS, Cartridge and Vial line have integrated isolators to maintain continuous aseptic conditions during filling. The DP facility is supported by a fully automatic packaging line with labeller, syringe assembly, blistering, cartoning machines, pen devices, testing and assembly lines.

We also have a dedicated warehouse with cold chain management for drug substance & product.

IF YOU ARE LOOKING FOR A RELIABLE PARTNER TO SUPPORT YOUR NEEDS AT ANY STAGE OF PRODUCT DEVELOPMENT, PLEASE CONTACT US AT:

STELIS R&D AND SCALE-UP

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