Stelis Biopharma

Unit 2

Integrated state-of-the-art manufacturing facility levarages microbial and mammalian platforms for development and commercial manufacturing of biologics and biosimilars in multiple fill-finish formats.

As a CDMO partner for the global biopharmaceutical industry, Stelis is committed in helping you achieve your project goals and timelines by accelerating development and commercialization of biologics for unmet patient needs, mutually benefiting in the growth trajectory. Our highly automated CGMP compliant facilities offer process development through clinical and commercial manufacturing, at various flexible scales to fit individual client and product requirements.

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

With deep technical expertise and capabilities coupled with marquee partnerships, Stelis has developed biologics for diabetes, osteoporosis and hemorrhoids using mammalian and/or microbial systems from pre-clinical stage through commercialization. We remain a preferred choice for our clients because we offer customized services according to their requirement in size, scale, design, and business model.

Manufacturing Capacity

Drug Substance

Microbial Facility

- 1 X 1000L stainless steel fermenter
- Homogenizer (GEA) and centrifuge (GEA) integrated with fermenters
- Capable of handling bacterial and yeast strains
- Flame proof area with high pressure chromatography system
- Filtration: viral filtration,ultrafiltration and dia-filtration
- Dedicated area for conjugation, bulk filtration & lyophilization

Mammalian Facility

- 4 X 2000L bioreactors
- Single use bags-based drug substance manufacture
- Dedicated pre-culture suites, media & buffer preparation rooms
- Controlled freeze and thaw system
- Production, testing and storage of master and working cell banks
- Filtration: viral filtration, ultrafiltration and dia-filtration

Drug Product

- Drug product capacity - 40 million cartridges, 28 million pre-filled syringes, 70 million vials (liquid and lyophilized)
- Tofflon filling line integrated with isolator and lyophilizer
- High speed vial lines attached to vial filling machine
- Bausch Strobel filling line integrated with steriline isolator
- 2 Boilers of capacity 3000 kg/hr and one of 5000kg/hr, cooling tower with capacity 180 TR and 4 HVAC chillers of capacity 180 TR
- Secondary packaging operations at a capacity of 100 cartons/ min
- High-capacity warehouse with cold chain inventory management

Quality Control

- On-site analytical and microbiology labs to support in-process and release testing
- Comprehensive monitoring of all in-process product quality parameters, drug substance and drug product release testing
- Usage of fully automatic packaging line and 100% visual inspection of the entire process
- Routine facility contamination controls by utilities testing and environmental monitoring activities by active air sampling, passive monitoring by settle plate and 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 are identified up to species level

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