A GLOBAL CDMO IN THE MAKING

Drug Substance

- Microbial
- Mammalian

Drug Product Fill Finish

- Biologicals
- Pharmaceuticals
- Vaccines

Stelis BioSource | August 2020

STELIS BIOSOURCE™ IS THE CDMO DIVISION OF STELIS BIOPHARMA

Stelis Biopharma is a vertically integrated biopharmaceutical company committed to developing and manufacturing high-quality, affordable biotherapeutics. Stelis aspires to be globally recognized as a leader, preferred partner and disruptive force in the biotherapeutics market, delivering affordable medicines complying with global standards

OVER $100M INVESTED TO BUILD A GLOBAL PLATFORM FOR BIOLOGICS , VACCINES AND PHARMACEUTICAL DRUG PRODUCTS

INFRASTRUCTURE

- 30,000 sq.ft. state-of-the-art process development; pilot/scale-up and **small-scale biopharma CGMP facility**
- 200,000 sq. ft. integrated commercial biopharma manufacturing facility catering to **Biologics Drug Substance, and aseptic Drug Product fill finish in different formats**
- Both facilities located in Bengaluru, India, with easy access from international airport

CAPABILITIES

- One-stop shop from cell line and process development to commercial manufacturing in biopharma
- One among few independent facilities in Asia-Pacific to offer full-service, end-to-end development and manufacturing of DS and DP
- **Facility adaptable to vaccine manufacturing**
- Sterile Injectable fill/finish for complex small molecules

FACILITY DESIGN

- **Mammalian Cell Culture**
  - 200L Pilot SUB
  - 2x 2,000L SUB process trains
- **Microbial**
  - 50L, 300L and 1,000L SS
- **Fill/Finish**
  - Vials/Vaccines
  - Prefilled Syringe, Cartridges,
  - Lyophilization
  - Drug-device combos
  - Packaging

CORE TEAM

- **Talented** scientific and technical teams with experience in high-end biopharma development and manufacturing.
- **Quality and regulatory expertise** with demonstrated experience in global compliance
- Experience from companies such as **Merck, AGC, Amgen, Patheon, Fuji Diosynth, Selexis, Biocon, Strides, P&G, Mallinckrodt, Pfizer, Lonza, Allergan amongst others**

BEST-IN-CLASS CDMO HUB FOR COST-EFFECTIVE DEVELOPMENT OF BIOLOGICS MEETING GLOBAL STANDARDS

ONE STOP SOLUTION FOR END-TO-END BIOPHARMA & PHARMACEUTICAL SOLUTIONS

PROCESS DEVELOPMENT

- Cell Line & Strain Development
- Upstream Development
- Downstream Development
- Formulation Development
- Analytical Development (Inc. Bioassays)
- ICH Stability Studies

PROCESS SCALE-UP

- Microbial 50L CGMP upstream
- Mammalian 200L CGMP upstream
- Down stream process scale-up
- Formulation - fill and finish (large and small molecule)
- CGMP Cell Banking

MANUFACTURING

- **DS CGMP manufacturing**
  - 2x2,000L Mammalian
  - 1x1,000L Microbial
- **DP CGMP formulations** for biopharma and pharma- aseptic fill and finish in cartridges, pre-filled syringes, vials and lyophilized vials
- **Commissioning a state-of-the-art vaccine suite for multiple vaccine types , going on stream from December 2020**

IN-HOUSE PROCESS DEVELOPMENT DELIVERING ROBUST, COMPLIANT & COST-EFFECTIVE PROCESSES

- Clone development & optimization for both microbial and mammalian expression systems
- Expertise in optimizing bioprocesses to establish high expression yields of target protein and high throughput processes
- Production clone finalization and optimization of cell culture/fermentation process based of DOE studies
- Cell line characterization
- Comprehensive analytical development & product characterization (including biosimilar pckages)
- Full bioassay capabilities
- Master and Working CGMP Cell Banking
- Professional Project Management systems

Scientists
Houses 300+ people with 200+ scientists

Laboratory area
Occupies 30,000+ Sq. ft. of lab area

Merck Partnership
Partnered with Merck Millipore for process scale-up lab

ADVANCED PROCESS SCALE-UP LAB (PSL) FACILITY - BRIDGE TO COMMERCIAL SCALE

DESIGNED WITH BEST-IN-CLASS TECHNOLOGIES FOR SMOOTH SCALE-UP AND TECHNOLOGY TRANSFER THROUGH PROCESS OPTIMIZATION & CHARACTERIZATION

Key Capabilities

- Designed for process scale-up studies of microbial 50L and mammalian 200L scale
- Equipment with same geometric aspects and control systems as in commercial manufacturing facility
- Capability to generate material for pre-clinical studies including animal efficacy and toxicology studies
- CGMP manufacturing in support of clinical studies
- Flexibility in operations - single use or multi use depending on process requirements
- Execution of process characterization studies through statistical DOE approach

PSL FACILITY-SMALL SCALE FILL AND FINISH IN ALL INJECTABLE FORMATS

CAPABILITY TO CONVERT DRUG SUBSTANCE TO STABLE FORMULATIONS AND FILL AND FINISH IN ALL INJECTABLE FORMATS

KEY CAPABILITIES

- ✓ Capable of filling all injectable formats such as PFS, cartridges, vials & lyophilized vials in GMP conditions
- ✓ Completely automated combi-filling machine (up to 2000/hour for vials & 1000/hour for syringes and cartridges)
- ✓ Stability studies on DS and DP as per ICH guidelines
- ✓ Thorough characterization of reference products as well as quality comparison studies
- ✓ Technology transfer “in” from clients and “out "to Stelis manufacturing or customer facilities

Our integrated manufacturing setup is designed with modern flexible technologies that are amongst the best in APAC region

- The facility is designed to offer comprehensive CDMO services for pharmaceutical and biopharmaceutical companies
- Vaccine development readiness from December 2020 with integrated and highly automated capabilities
- The infrastructure is capable to meet all global regulatory compliance & offer operational flexibility with modern design

Click here for a virtual plant tour

MICROBIAL DRUG SUBSTANCE MANUFACTURING WITH HYBRID MODEL

Hybrid model with conventional SS fermenter for fermentation and single-use and conventional systems for downstream

| FERMENTATION CAPABILITY

- ✓ Stainless steel fermenters (sartorius) of capacity 50L, 300L & 1000L
- ✓ Homogenizer (GEA) and centrifuge (GEA) well integrated with fermenter for combination of operations
- ✓ dedicated pre-culture area
- ✓ dedicated autoclaves for sterilization and decontamination

| PURIFICATION CAPABILITY

- ✓ Flame proof area with high pressure chromatography system (Hanbon)
- ✓ Mix of single-use and conventional chromatography systems (Merck Millipore)
- ✓ High pressure chromatograph systems
- ✓ Filtration: viral filtration, ultra-filtration and Dia-filtration
- ✓ Dedicated area for conjugation, bulk filtration & lyophilization

| BENEFIT

- ✓ Cost efficient manufacturing and operation flexibility at manufacturing scale
- ✓ Better mixing and higher oxygen transfer rates

MAMMALIAN DRUG SUBSTANCE MANUFACTURING WITH END TO END DISPOSABLE SYSTEMS

End-to-end disposable systems offer better regulatory compliance, no product carry over, less turn around time between batches and operational efficiency

| FERMENTATION CAPABILITY

- ✓ 2 single-use trains up to 2000L
- ✓ Line-up: 50L→200L→2000L
- ✓ Capability of handling batch, fed batch and perfusion fermentation process
- ✓ Production, testing and storage of master and working cell banks
- ✓ Dedicated pre-culture suites, media and buffer preparation rooms

| PURIFICATION CAPABILITY

- ✓ Pre and post viral segregation
- ✓ Single use flow path - chromatography systems
- ✓ Filtration: viral filtration, ultrafiltration and Dia-filtration
- ✓ Dedicated autoclaves for sterilization and decontamination
- ✓ Controlled freeze and thaw system

| BENEFIT

- ✓ Multi-product CGMP manufacturing

STATE-OF-THE-ART DRUG PRODUCT INFRASTRUCTURE WITH SIGNIFICANT OPERATIONAL FLEXIBILITY

Key Capabilities

Capability to convert drug substance to stable formulations and fill and finish in all injectable formats

| FILL FINISH

- ✓ Aseptic liquid filling in all formats:
  - ✓ PFS
  - ✓ Cartridges
  - ✓ Vials under isolator
  - ✓ Lyophilization in vials with automatic loading/ unloading systems and capping machine
- ✓ 100% visual inspection
- ✓ Cold rooms for storage of product at various stages

| PACKING

- ✓ Fully automatic packaging line with labeler, syringe assembling systems, blistering and cartoning machines
- ✓ Tertiary packaging area
- ✓ Track and trace systems
- ✓ Pen device assembly capabilities
- ✓ High capacity warehouse with cold chain inventory management

NEW DEDICATED SUITE FOR VACCINES WITH INTEGRATED CAPABILITIES

Type	DS Capabilities	DP Capabilities
Viral vector	Yes	Yes
Protein subunit	Yes	Yes
RNA	No	Yes
DNA	No	Yes
Inactivated	No	No
Live-attenuated	No	No

Key Capabilities

- Nanoparticle fill finish capability
- The vial line is equipped with lyophilizer
- Area classification Class A and B
- Use of single use manifold system
- High speed filling lines with yearly capacity of 60 Mn
- Manufacturing of Drug Substance and Drug Product for recombinant Antigen

LARGE SCALE CAPACITIES WITH LATEST EQUIPMENT AND MODERN ENGINEERING DESIGN

Presentation	Working Range	Annual Capacity on 2 shift basis	Status
Cartridge Filling with pen assembly for pharma and biopharma products	Diameter 7mm to 14mm Height 40mm to 90mm	40 million	Validated and available for commercial production
Pre-Filled Syringe Filling for pharma and biopharma products	0.5ml to 10ml	28 million	Validated and available for commercial production
Vials and lyophilised vials for pharma and biopharma products	1ml to 100ml Lyophilization - Commercial: 9.2 sq. m and Clinical: 5.11 sq. m	10 million vials and 4 million Lyophilised vials	Going on stream from December 2020
Vaccine dedicated vial line	1ml to 30ml	60 million	Going on stream from December 2020

ON-SITE ANALYTICAL AND MICROBIOLOGY LABS

On-site analytical and microbiology labs to support in-process and release testing

| KEY CAPABILITIES

- ✓ Qualification and validation of raw material, consumables and packaging material
- ✓ Comprehensive monitoring of all in-process product quality parameters drug substance and drug product release testing
- ✓ Generation and characterization of reference material
- ✓ Stability studies for active ingredients, intermediates & finished products

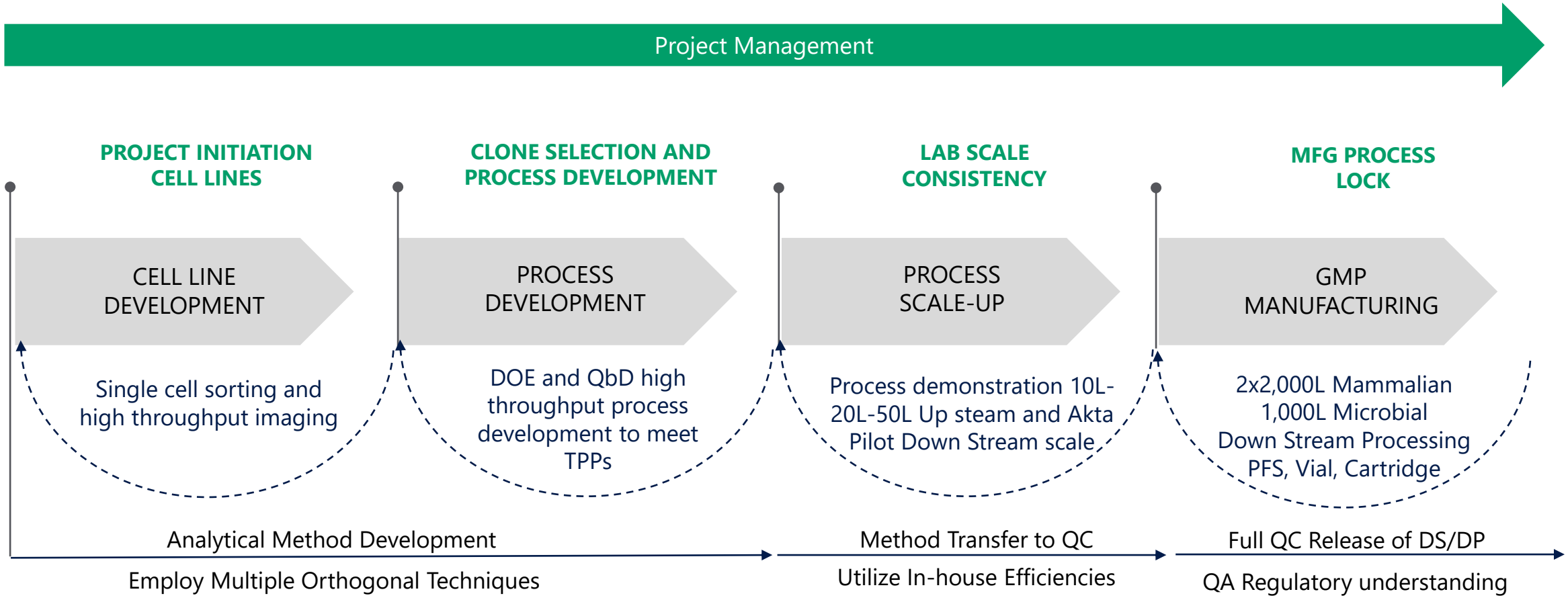
ON-SITE QUALITY COMPLIANCE AND REGULATORY SUPPORT

Designed, built and validated to meet regulatory market standards

| KEY CAPABILITIES

- ✓ In-process QA team- process assurance of ds and dp manufacturing
- ✓ Product release QA team - RM & PM and product release group
- ✓ Quality control release QA- quality control related activities
- ✓ Quality management system(QMS)
- ✓ Training and compliance group
- ✓ Validation –equipment , systems and process.
- ✓ Internal audit management team
- ✓ Vendor management team and documentation cell

STELIS IS A ONE-STOP SOLUTION WITH CAPABILITIES FOR SINGLE CYCLE DEVELOPMENT



Gated activities for all programs with iterative analytical methods for Client programs

THANK YOU

Contact Us

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