Syngene

Putting Science to Work

Biologics Development & Manufacturing

Innovate | Integrate | Customize | Accelerate

30 years of Putting Science to Work

A Global CRO/CDMO

- Integrated Drug Discovery, Development and Manufacturing service provider
- Small Molecules and Biologics, ADCs, Oligonucleotides
- Listed on Indian Stock Exchanges (NSE and BSE)

Scientific Ecosystem

- 2 Mn sq. ft. world-class R&D and Manufacturing infrastructure
- 5200+ qualified scientists
- Ongoing $510Mn (423.15 Mn Euro) investment program
- Highly effective supply chain practices

IP Position

- IP assigned to clients
- Strong track record of Data Integrity and Security
- Over 400 patent assignments by clients recognizing Syngene

Marquee Clients

- 400+ active clients last FY
- Partnering with large / mid-size / emerging BioPharma (EBP) and other industries
- Clients concentrated in US, Europe & Japan
- Track record of working with diverse industry sectors

Quality Focus

- Quality driven organization
- Excellent track record of compliance with global regulators
- US FDA, EMA, ANVISA and PMDA approved, GLP Certified, Ministry of Health of Russian Federation, AAALAC & CAP accredited/certified facilities
- 15+ regulatory and 160+ client audits in the last 3 years

Track Record

- Collaborations and partnerships to deliver numerous clinical candidates
- Delivery history for integrated CMC programs towards FIH and beyond

When you select Syngene for your biologics program, you partner with a 30 years industry leader solving complex R&D and Manufacturing challenges. With our highly experienced team, state-of-the-art infrastructure, proven track record and a portfolio of product experience, we help you navigate the complex Journey from Discovery to Commercial Supply

One-stop service

30+ Global customers

Global Clinical and Commercial supply

360+ Technical staff

Dedicated Program Leader and Project Management

High yield processes 4-5g/L

Experience in Animal Health

9 Months from Clone to clinical supply

Our experience base

- Recombinant Proteins, Protein subunit vaccine, Glycoproteins
- mAbs, Antibody Fragments, Bispecifics
- r – protein vaccine in Baculovirus expression system, mRNA vaccine
- Microbiome (Live Biotherapeutics)

Biologics development and biomanufacturing solutions in both mammalian and microbial systems

Development services

- Developability assessment
- Upstream development
- Formulation screening
- Process characterization
- Viral clearance studies

Integrated FIH development

- DNA sequence to IND supply
- Platform process for mAbs
- CMC regulatory support

Commercial biomanufacturing

- Mammalian mfg to 2kL scale
- Microbial mfg to 500L scale

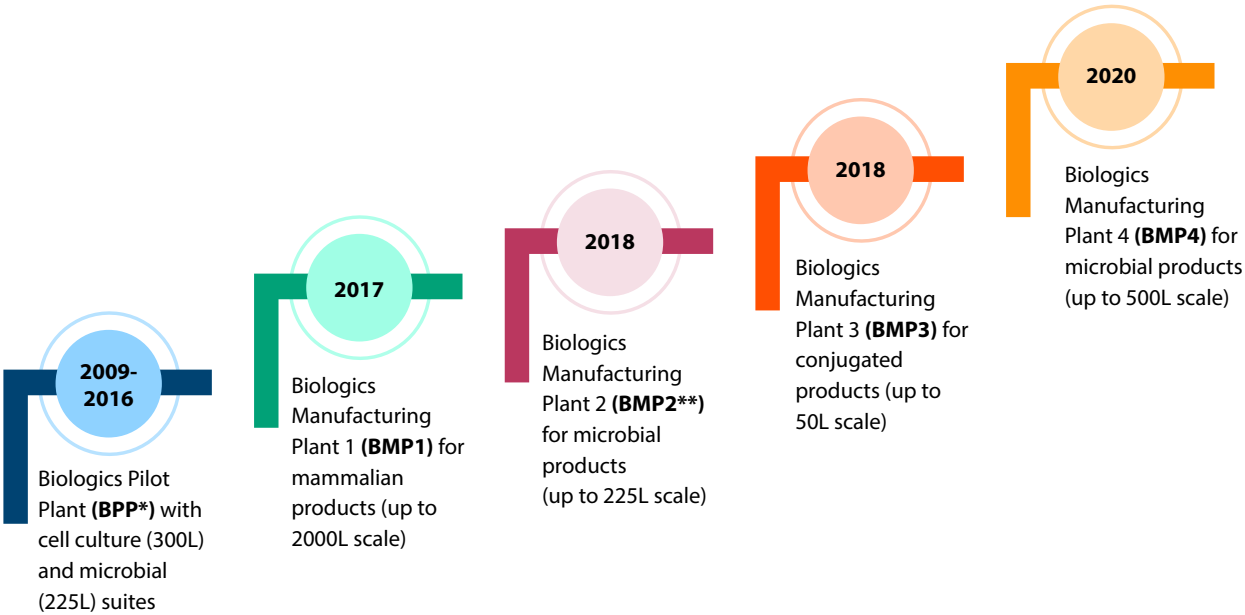
Cell Line & Process Development

- Mammalian (Freedom™ CHO-S™ Expression and CHOZN®)
- Microbial (E. coli, Pichia P.)
- Clone Pix, Solentim (for Monoclonality) Upstream process: Multi-reactor system for DOEs, 1-50L Bioreactors, ambr® 250, perfusion (ATF), Metabolite profiling, Spent media analysis
- Harvest: Depth & Polymeric Filtration & Centrifugation, Flocculation and filtration in filter-press mode, Microfluidizer
- Downstream: Column Chromatography (IEX, Affinity, HIC, Mixed-mode, AKTA Explorers and Purifiers)
    - Virus reduction steps and clearance studies

Analytical Development and Product Characterization

- Product Characterization: Mass Spectrometry, LC-MS (Glycan and product variants), MALDI-TOF, MS/MS (Ion-trap), CD, Fluorescence, SPR (Biacore), PAMAS (sub-vis), Solo VPE, Flowcam, Maurice (cIEF), HIAC, SEC-MALS, AUC
- Stability Studies: Exploratory, Freeze-thaw, Real-time, Accelerated and Stress (forced degradation)
- Bioassays: cell based, Non-cell based, In vivo, Proliferation, Inhibition, Reporter Gene, Effector Function, Secondary Signaling

cGMP Manufacturing



*Decommissioned

**Leased to a client

End to-End Biomanufacturing from Clinical to Commercial Supply

Mammalian:

- Scale: Single-Use bioreactors 100→500→2,000L trains
- USP: Shake flasks, 1L-50L bioreactors, ambr® 250, perfusion (ATF), Depth and polymeric filtration and centrifugation
- DSP: Column chromatography (IEX, Affinity, HIC, Mixed-mode, AKTA- Process, Explorers and Purifiers) – Up to 800mm column and 2000LPH flow rate

Microbial:

- Scale: Up to 500L (SS) fermentation, 1000L refolding, 60 cm column chromatography and 10 sq.m. tangential flow filtration
- USP: Continuous centrifuge, Cell homogenizer
- DSP: Chromatography systems, TFF systems

Sterile Fill Finish Facility

Clinical supplies and small-scale manufacturing

Capability to manufacture ready-to-use solutions and lyophilized products (pre-sterilized vials and prefilled syringes)
OEL: ≥ 1 µg /m3 in GMP environment

- Aseptic filtration and filling
- Terminal sterilization
- Batch size of 500 to 25,000 vials, 5L- 50L
- Lyophilization capability for vials (3500 vials of 10R size)
- Capability to handle clinical batch manufacturing of small molecules and biologic products
- Storage chambers of 2 – 8°C and - 30°C

Equipment:

- Vials+ PFS combi filling line under isolator (Make: MAR Italy)
- Isolator-based robotic filling machine for vials and PFS
- Ready-to-use nested vials: Liquid and lyophilized vials with ll volume of 0.5 ml to 50 ml (ISO 2R to ISO 30 R)
- Ready- to- use nested prefilled syringes: Fill volume of 0.1 ml to 10 ml
- Terminal sterilizer; jacket cooling available after sterilization cycle.
- Lyophilizer: Toon China (Model: Lyo-3), Grade B area

We are 21 CFR-compliant wherever applicable

Viral Testing Services

A 4000 sq. ft and ISO 9001:2015 certified state-of-the-art BSL-2 laboratory

- GLP virus Clearance studies for biologics manufacturing processes for phase 1, phase 3 and commercial license
- Model viruses as per ICH Q5A
    - RNA (Enveloped & Nonenveloped) – XMuLV, Reo3
    - DNA (Enveloped & Nonenveloped) – MVM, HSV1
- Testing of Unprocessed bulk harvest and Cell bank
    - 28 day in-vitro adventitious virus detection
    - Retrovirus detection by cell-based assay
    - MVM detection by QPCR
    - Mycoplasma detection by QPCR (EP & USP compliant)
    - TEM analysis

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About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical sectors. Syngene's more than 4700 scientists offer both skills and the capacity to deliver great science, robust data management and IP security and quality manufacturing at speed to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb, as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK and Merck KGaA.

For more details, visit www.syngeneintl.com or write to us at bdc@syngeneintl.com

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