Syngene

Putting Science to Work

Development and Manufacturing

Innovate | Integrate | Customize | Accelerate

Table of Contents

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

Our end-to-end platform

Allows us to offer an integrated as well as standalone services across the development continuum in one campus

Idea	Developability Assessment	Development Phase	Clinical Phase			Registration/ Process Validation	Commercial Batches	Patient
			Phase I	Phase II	Phase III			
Safety Assessment	Early PK, MTD/DRF studies, Exploratory Tox	• IND enabling GLP Tox studies: Ames, chromosomal aberration, micronucleus tests, pivotal repeat dose (rodent and non- rodent) • Safety pharmacology: CNS, Respiratory, CV Telemetry, hERG		• NDA enabling studies: Sub- chronic and Repro-tox studies • Local Tolerance study	Chronic and Carcinogenicity study			
Drug Substance Dev and Mfg.	• Route scouting • Process safety evaluation • Scalability	• Fit to purpose Process dev • Material supply • Impurity identification • Enable and scale • Tox material delivery	• Process dev , robustness and Safety study • Unit operation studies • Impurity synthesis and characterization • DS clinical batch supply			• Process DOE, QBD and scale up studies • Process risk assessment • FMEA analysis • Registration and process validation batches manufacturing.	Commercial batches manufactu ring. and packaging	
Drug Product Dev and Mfg.	• Pre-formulation • Salt polymorph screening • Excipient compatibility	• Solid Oral & Injectable dosage forms • Enabling formulation technologies	Clinical supplies for all phases • FIH formulation for phase 1/2A • Final dosage form for phase 2B/3 and onwards		Sterile Fill Finish facility*			
Analytical Services	Methods for pre-formulation and Bio-analytical	• Methods for intermediate, final DS, DP • Forced degradation studies • Solid state characterisation	• Phase appropriate method validation for DS & DP (microbial methods) • Specifications for DS and DP • In process and finished product analysis • Final batch release with COA • Reference standard , Impurities, Isolation and characterisation			Robustness of analytical methods and full validation as per ICH	Analysis of commercial batches	
Stability Services	Selection of suitable container closure system and packaging	• Development Stability studies	• ICH stability for all phases • Shelf life estimation • Re-test extension			Stability study of registration/ process validation batch	Stability study of commercial batches	
Clinical Development			• Human Pharmacology Unit (Phase I/BE studies) • Clinical trial services – full solution provider for conducting trials in India • Central Lab services including regulated bioanalytical lab • Clinical data management, biostatistics and medical writing					

We deliver our services (both Integrated & Functional) via a range of proven collaboration models

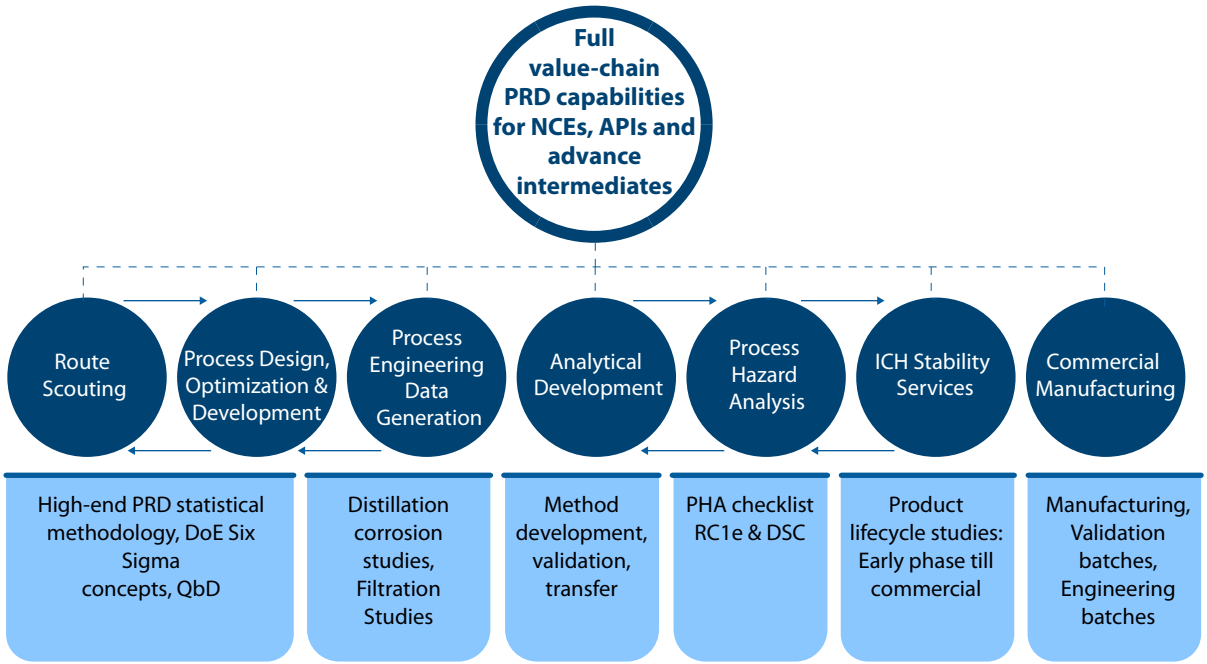
Dedicated R&D Labs | FTE | FFS

Syngene

Putting Science to Work

Small Molecule Development & Manufacturing

Chemical Development



Highlights

- 125+ fume hoods in multiple suites
- Automated lab scale jacketed reactors (-70- to 180 °C)
- Flow Chemistry
- Dedicated process engineering and safety lab
- HPAPI development from lab to Manufacturing scale
- Therapeutic and Diagnostic Oligonucleotide- from Lab to Manufacturing scale
- Performance and Speciality Materials - synthetic organic chemistry, polymer chemistry and scale-up activities
- Integrated analytical services- analytical method development, validation, transfer and reference standard qualification
- Regulatory Support

Process Engineering and Scaleup

Capabilities

- Design of experiments (DoE)
- Quality by design (QbD)
- Reaction Kinetics studies
- Process Modelling and Simulation
- Reaction Optimization studies
- Unit operation and processes
    - Filtration, Distillation, Extraction, Drying, Corrosion studies etc
- Process crystallization studies
- Advanced PAT tools for Process understanding (FBRM, PVM, React-IR etc)
- Flow Chemistry development
- Mass & Energy Balances
- Technology absorption and transfer

Process Safety Management

Capabilities

- Process Safety studies (DSC, RC1e, ARC, Vent Sizing etc)
- Powder safety studies (Fall Hammer test, MIE, MIT, Ignition test, MEC, LOC etc)
- Process Safety Information
- Process risk assessment (What-if, HAZOP, PHIRA, FMEA, Qualitative and Quantitative risk assessments etc)
- Pre-startup safety reviews
- Asset Integrity and reliability studies

Oligonucleotides

Salient Features

Process Development

- Natural & Modified | siRNA | ASOs | Anti-microRNA | Aptamer | CpG
- Conjugated oligos | Molecular beacons | Fluorescent oligos | Probes & Primers
- Backbone modifications | Base modifications | Sugar modifications
- Synthesizer & Scale: ÄKTA oligopilot 100 | 250 µmol - 6 mmol (100 mg - 5 g / batch (non-GMP))

Analytical Support

- Comprehensive analytical support | Method Development & Validation
- Combination of orthogonal techniques
- Impurity Analysis | Identification | Sequencing | Characterization
- Release specifications – General | Compendial | Oligo-specific methods
- Forced degradation | Informal stability | ICH stability

Manufacturing

- cGMP facility of 1500 sq. ft. | Fully qualified equipment and area
- Controlled environment to limit Endotoxin & Bioburden
- Located in a GMP certified/ USFDA inspected facility
- Synthesizer & Scale: ÄKTA oligopilot 400 | 4 mmol - 45 mmol (5 g - 135 g / batch (GMP/non-GMP))
- Support for regulatory filing | CMC documentation suitable for Phase 1/2 IND

Formulation

- Drug substance characterization and method development
- Formulation development and optimization
- Analytical methods development and pre-validation for the Drug Product
- Supportive stability study
- Component compatibility study and miscellaneous studies

High Potent API

Capabilities

- Integrated solutions from Discovery, Process R&D, Optimization, Scale-up & Clinical supplies to Commercialization
- OEL determination toxicity studies
- cGMP manufacturing
- Facilities designed to handle cytotoxic, cytostatic, and high potent compounds with OEL values in the range of >100 µg/m^3 to 0.01 µg/m^3
- Isolators for full spectrum of unit operations from Sampling, Dispensing and Weighing, Reactor charging, Filtration, Drying, Milling & Sieving to Packing
- Broad range of Reactors (Stainless steel, Glass lined, Hastelloy)
- Dedicated facility for Prep-HPLC and lyophilization of HPAPI molecules
- Development and manufacturing of ADCs, including the linker development, optimization, and characterization

Highlights

- Highly experienced process chemists, analytical chemists, process engineers, manufacturing and QC team
- cGMP facility for lab-scale to commercial-scale manufacturing including registration and validation batches for regulated market
- Integrated with a separate cGMP facility to manufacture non potent compounds.
- Provision to add reactor & matching downstream equipment to enhance capacity/capability
- PAI inspection for the API registration and validation batches

Performance and Specialty Materials

Capabilities

- Synthesis and Purification of Monomers/Polymers
- Functionalization chemistry
- Material Characterization
- Process Development & Process Engineering
- GMP and Non-GMP manufacturing capabilities

Monomers	Polymers	Materials
Acrylates; Schiff bases; Ionic liquids; Radical compounds; Macrocycles; Heterocycles, End functionalization of polymers; Light and air sensitive compounds	Supramolecular Polymer; Conducting Polymers; Polymer Self Assembly; Self-healing Polymers; Hydrogels; Silicones; Random/Block/star/comb copolymers	Inorganic Materials; Additives; Catalysts; Biomaterials; Nanomaterials-Nanofibers, CarbonNanoTube (CNT)

Highlights

- Excellent track record of continuous supply of polymers & specialty materials (250-500 kg/batch), Nano materials (1-2 kg) and additives (10-100 kg scale)
- cGMP compliant facilities inspected by USFDA and audited by global customers and QPs from Europe
- Innovation on specialty materials and polymers from lab scale to commercial manufacturing level

Formulation Development

Capabilities

- Pre formulation profiling including salt and polymorph screening
- Preclinical formulation development
- Drug-drug and drug-excipient compatibility study
- Formulation development – oral solids, liquids, semisolids (OEL up to 1 µg/m^3)
- Formulation development – injectables (OEL up to 0.1 µg/m^3)
- Ready to use and lyophilized injectable product development, including nanosuspensions
- High potent injectable dosage form development
- Development of palatable dosage forms for companion animals (hard chews and soft chews), spot on formulations
- Formulation Development of oral solids (modified release, controlled released, timed release, delayed release
- Novel drug delivery systems (liposomes, nano-emulsions, biodegradable polymers-based microspheres, nanoparticles and in situ depots)
- Enabling formulation approaches – spray-dried dispersion (SDD), hot melt extrusion (HME), lipid based, complexation-based self-micro emulsifying drug delivery system (SMEDDS) and nanosuspensions
- Analytical method development and validation
- CGMP manufacturing and clinical supplies
- Clinical supplies manufacturing for solid orals (OEL up to 1 µg/m^3)
- Scale-up and technology transfer
- Phase I/phase II and phase III clinical supplies/registration batches / process validation batches
- Small scale commercial supply
    - Niche and orphan drug products (current batch size up to120 kg batch size (upscaling up to 200-400 kg scale by 2023)

Integrated CMC Development Services – Lead to FIH

- Salt and fit for purpose polymorph screening for first- in- human (FIH) studies
- Pre-formulation package to assess the physico-chemical properties and design
- Identification of the right enabling approach by screening different enabling approaches using scientific rationale post drug developability assessment
- Advantage of multidisciplinary scientific team in the same campus
- Fit-for-purpose analytical method development and validation

Highlights

- Quick-to-clinic approaches for phase 1 clinical studies (FIH)
- Expertise in animal health care formulation development
- Expertise in parenteral formulation development and small-scale clinical batch manufacturing (ready-to-use vials and prefilled syringes)
- Delivered over 20 integrated CMC projects in last five years
- Can involve in 505(b)(2) programs as early as ideation process, repurposing of molecules and identifying unmet medical need
- Clean regulatory track record with different regulatory bodies across the globe (USFDA and Russian Regulatory Agency- approved, oral solid manufacturing facility)

Oral Solid Dosage Forms

Capabilities

- State-of-the-art GMP manufacturing facility for solid orals (phase 1 to low volume commercials)
- APIs having OEL up to 1 µg/m^3 can be handled for drug product manufacturing
- Batch sizes of up to 120 kg can be handled currently, upgradable up to batch of 200-400 kg by 2023
- Unit operations such as dry and wet granulation, wurster coating, blending, spray drying, Tablet compression, tablet coating, encapsulation, extrusion and spheronization
- Automatic capsule filling machine for pellets, powders and mini tablets
- Blister packing machine; ALU- ALU, PVC-ALU, PVC/PVDC-ALU and automatic bottle packing machine for tablets and capsules

Highlights

- Expertise in enabling technologies (spray drying, hot melt extrusion, nanosuspension, SMEDDS) and modified release formulation development
- Successfully completed "ideation to PoC " for a hybrid application for EU/505(b)2 for U.S.
- Strong track record of consistently delivering integrated CMC programs year-on- year (18 projects over the past five years)
- Experienced in late-phase product development requirements and USFDA query responses
- US FDA and Russian Regulatory- approved manufacturing, quality control and stability facility
- Consistently delivering 35-40 GMP campaigns per year

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

Formulation Development for Animal Health

Supporting drug product development and clinical supply manufacturing for four out of top 10 Animal Health companies in the world

Capabilities

- Dedicated GMP facility for animal health products (up to OEL 1µg/m^3)
- Pre formulation, formulation development and manufacture of oral solids chewable dosage forms for standalone or combination products
- Manufacturing and packing of conventional and bolus tablets
- Development of injectables, spot-on/pour-on formulations
- Development of palatable hard and soft chews tablets for API requiring masking of taste
- Blister packaging capability for small and bolus tablets; PVC-ALU, PVC-PVDC/ALU, Alu-Alu, & Aclar and bottle packaging
- Experienced team dedicated for analytical activities for animal health products

Highlights

- Drug product development, clinical batches, VICH stability studies for multi API combination multi-drug hard chew and soft chew tablets
- Manufacturing and packaging of clinical supplies for companion animals
- Drug product development and lab stability studies for topical and injectable dosage forms
- Robust analytical methods development and validation for combination products and stability studies

Analytical Development

- Method development
- Method verification/validation
- Structural characterization and elucidation
- Reference and working standards qualification
- Identification and characterization of impurities
- Prep HPLC/chiral purification
- Residual Solvent Analysis
- Elemental impurities analysis
- Impurity analysis
- Method transfer
- Stability studies
- Phys-Chem studies/5-batch analysis

Analytical capabilities for Drug Products

Tablets capsules:
Assay & content uniformity, related substances, water content, drug excipient compatibility studies, filter compatibility, solubility, degradation studies, antioxidant and preservatives, DT, dissolutions (release media, multimedia & bio-relevant media), PSD, pXRD and residual solvents.

Powder for Injection (lyophilized / dry powder, microspheres, liposomes):
Assay, related substances, residual solvents, reconstitution stability study, diluent/component stability compatibility, assay of encapsulated/free drug, polymer characterization, lipid characterization, assay of antioxidant/preservatives, dissolution, particle size distribution.

Suspensions, Solutions:
pH, viscosity, light transmission matter/color, Density (Wt/mL), solubility, AET, assay & CU, degradation studies, drug excipient compatibility studies, related substances, antioxidant and preservatives, dissolutions and PSD.

Suspensions (ophthalmic suspensions, vial suspension for injection):
Assay, related substances, residual solvents, component stability compatibility, assay antioxidant and preservatives, dissolution, particle size distribution, *Invitro* comparative nasogastric feeding tube studies for vial suspension.

Liquid Injections (ampoules, prefilled syringes, vials):
Assay, related substances, residual solvents, diluent and component stability compatibility, particulate matter.

Semisolid dosage forms:
pH, viscosity, physical appearance, density (Wt/mL), AET, assay & CU, degradation studies, drug excipient compatibility studies, related substances antioxidant & preservatives, IVRT, texture analysis.

Analytical capabilities for complex injectables

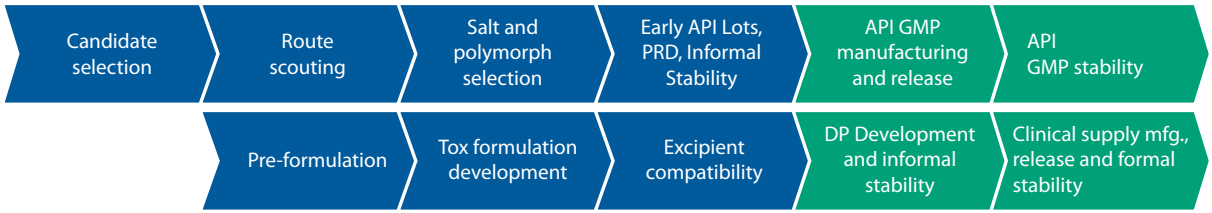
Pre-formulation studies	Liposomal injection	Injectable nanosuspension	Extended release injectable microspheres
• API characterization • API solubility • Excipient's evaluation • pH solubility and impact on stability • Impact of various parameters on API stability • Aggregate evaluation	• Assay; free/entrapped drug; other critical excipient • Related substances Phospholipid content (lyso forms) • Size and zeta potential • Internal environment (volume, pH, and ionic concentration): • State of encapsulated drug • *In vitro* drug release dissolution method using USP Type IV • Lipid degradation	• Dissolution method • Development – USP yype IV Assay • Related substances • Free fatty acid content • Phospholipid content • Drug partitioning • Globule size and zeta potential • Redispersibility	• Dissolution method development using Incubator orbital shaker or bottle rotating • Assay of free drug and encapsulated drug • Particle morphology size, shape • Molecular weight determi nation by GPC for polymer • Related substances • Polymer degradation

Analytical capabilities for Drug Substances

One-stop solution for all Analytical needs: Small molecules, oligonucleotides & performance and specialty materials (PSM)

Solid state characterization	Structural characterization	Method development/ validation	Extraction and purification
• Optical microscopy • XRPD • DSC/ TGA • DVS • Particle size analyzer	• NMR • LC/MS • LC/MS-MS • HRMS • GC/MS	• HPLC, GC, IC • Quantitative NMR • Wet chemistry • LC/MS, GC/MS • Genotoxic impurity methods • Forced degradation studies	• Semi prep HPLC • SFC • Column chromatography • Flash chromatography

Integrated Analytical support: Non-GMP and GMP activities



Non GMP Activities

- Phase-appropriate API, intermediate, DP analytical method development
- Support to chemists/process scientists / formulators for:
    - Route scouting, PRD activities
    - Tox/clinical formulation development
- Salt and polymorph screening
- Preformulation and excipient -- compatibility support
- Development stability of DS and DP (in use, accelerated, follow-up)
- Processing and packaging component compatibility

GMP Activities

- Phase-appropriate method qualification/ validation
- Release of RMs/ Intermediates/ DS/ excipients/ DPs
- DS and DP GMP stability
- Use time study for injectable DP

Non- GMP activities

GMP activities

Stability services: Salient features

Our Study expertise

- Complete Product lifecycle studies: Early phase till commercial
- Developmental stability
- Follow-up stability
- Forced degradation
- Freeze-Thaw stability
- In-Use stability
- Photo stability
- Registration stability
- RLD stability
- Commercial stability
- Transport assessment studies

Formulation types we deal in

Drug substances, drug intermediates including HPAPIs

- Tablets
- Capsules
- Soft gels
- Injectables
- Creams
- Ointments
- Eye drops
- Parentrals
- Lotions
- Emulsions
- Gels
- Suspensions
- Patches
- Liquid Spray
- Aerosols
- Powders

Our State-of-the-art facilities

- Biometric chamber access
- Multi-client ICH stability facility with long-term and intermediate testing conditions
- Uniquely coded and appropriately labelled samples
- Chromatography data systems
- 24*7 Online Temp/RH monitoring with backup facility
- Data managed electronically with systems 21CFR, Part 11 compliant

Commercial Manufacturing

Capabilities

Manufacturing of Regulatory starting materials, APIs, HPAPI, NCEs & Novel advanced intermediates

Mfg. facility	nGMP	S1 Kilo Lab	Unit 2 Kilo Lab	HPAPI	S14	Mangalore
Range	160 L - 5000 L	10 L - 20 L	10 L - 50 L	60 L - 630 L	60 L - 8,000 L	2000 L - 12,500 L
Total Capacity	26,640 L	120 L	90 L	2010 L	63,600 L	69,600 L
Largest reactor	5,000 L	20 L	50 L	630 L	8,000 L	12,500 L
# Reactors	15	3	4	5	32	11
Total number of reactors (Manufacturing Volumes)					**70 reactors (>161,000 L)**	

Salient Features

- 24/7 operations to ensure optimal utilization of resources
- Broad range of Reactors (Stainless steel, Glass lined, Hastelloy)
- Broad range of Chemistries (Asymmetry catalysis, halogenation, etc.)
- High potency expertise (Cytotoxic, Cytostatic compounds up to 0.1 µg/m^3 - 8h OEL)
- High vacuum (< 10 Torr) & high temperature (140°C) distillations
- Hydrogenator for highly acidic/basic reactions with capacity up to 4 KL and 26 bar pressure rating
- 12 KL cryogenic reactor operating within a temperature range of -90°C to 140°C
- Particle size reduction to < 10 microns with nitrogen and air in class 100,000 area
- Batch sizes range between 100kg (Bangalore) to 40 MT per annum (Mangalore)
- PMDA (commercial) and USFDA (RSM) approved Bangalore S14 manufacturing facilities

Syngene

Putting Science to Work

Clinical Development

Clinical Development

Capabilities

BA/BE Studies to Support Development of Generic Drugs

- Conducted over 600 BA/BE or PK/PD or Phase-1 trials [incl. FIH studies]
- Clinic with 190 ward care beds and 12 ICU beds
- Over 200+ validated methods available as per USFDA guidelines
- Total Mass Specs: 11 [API 4000s and API 6500s]
- State-of-the-art instrumentation [with qualification]
- Analysis of drug(S) and/or metabolite(s) in biological specimen [e.g. blood, plasma, serum, human aqueous humor etc.] to support TK< PK, early phase clinical development, BA/BE and TDM studies
- Team of 45 qualified and experienced researchers with experience in method development, validation and regulated Bioanalysis for a wide range of chemically diverse drug molecules

Clinical Trial Management (Phase I-III Trials) of Novel Drugs and Biosimilars

- One of the most experienced Indian CROs in conducting patient-based trials
- Over 100 clinical trials conducted for registering products in US, Europe, India and ROW countries
- Deep experience in Oncology, Diabetes and Auto-immune disorders
- Conducted multiple COVID-19 related trials in India
- Full service solutions, incl. Clinical Supplies Management, Central Lab and CDM & Biometrics

Central Laboratory Services Encompassing Clinical/ Safety Lab and Bioanalytical Services for Small Molecules & Biologics

- CAP accredited Central lab offering clinical testing services exclusively for Phase 1-IV clinical trials and BA/BE studies
- GLP-certified, FDA-inspected bioanalytical lab offering PK, ADA and Nab assays
- 21CFR-11 compliant laboratory information management system with customizable project management and reporting capabilities
- Supported over 100 NDAs/BLAs submitted to US FDA, EMA and PMDA
- r HbA1c

Regulated Bioanalytical Lab for Large Molecules

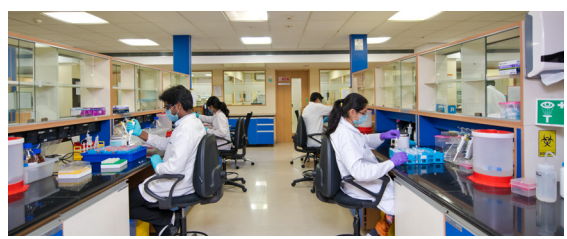
- 3 blockbuster MAbs approved by USFDA and EMA, based on the bioanalytical data submitted from this lab
- Experience with 7 Biosimilars, 22+ Monoclonal Antibodies and few vaccines
- 600,000+ samples imported (from various parts of the globe) and analysed till date, with a track record of Zero compromise on sample shipment
- Existing customers include 5 of the top 10 global Big Pharma/Biotech companies and 1 of the top Animal Health companies
- 15+ years of rich and diverse experience
- Adept at Method Transfer, Development and Validation based on FDA/EMA/WHO guidance
- Influenced favourable change in Indian Govt's policy on import of biological samples for testing – no wait period for license, ~4-6 days sample travel time from US/EU, no wait period for clearance from customs, expedited reporting can be handled, especially for Dose Escalation studies requiring 1 week TAT

Clinical Data Management and Biometrics

- Stand alone or integrated data management for Phase I-IV studies
- Statistics and SAS programming for Clinical and non-clinical development programs

Data Acquisition:

- Web based through in-house eCRF
- Paper CRF based data capture



Regulatory Track Record

- Audited by major life sciences Co's & Regulatory agencies from North America and Europe
- Certifications/ Accreditations: ISO 9001:2008, 14001, OHsAs 18001, AAALAC, GLP
- HPU & Bioanalytical labs are inspected by:
    - US-FDA – 9 audits
    - EMA – 3 audits
    - Thai FDA for GLP – 2 audits
    - ANVISA – Brazil – 3 audits
    - UK-MHRA – 1 audit
- Regulatory track record for Regulated Bioanalytical Lab for Large Molecules :
    - US-FDA – 1 audit
    - PMDA – 1 audit

Syngene

Putting Science to Work

Biologics Development & Manufacturing

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

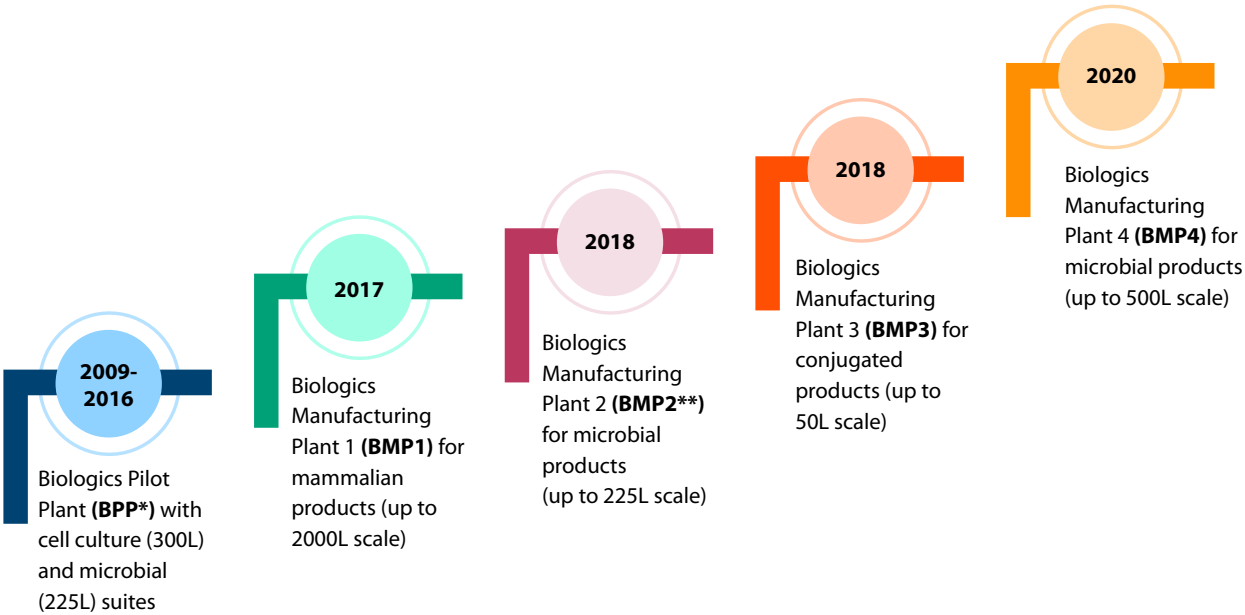
Cell Line & Process Development

- 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

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

Syngene
Putting Science to Work

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 5200+ 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

Stay Connected