Syngene

Putting Science to Work

Your one-stop solution for Biologics

Target to Therapy

The Syngene advantage

Global

- 15 out of 20 top pharma are our customers
- 400+active customers around the globe
- Long term collaborations with Amgen, BMS, Baxter and Zoetis
- Clients distributed internationally in US, Europe and Japan
- Global Clinical and Commercial supply
- Validated worldwide cold chain shipping

Expert

- Three decades experience
- 6000+ scientists
- 400+ patents enabled for clients
- 140+ biologics projects delivered
- 25+ INDs enabled across multiple modalities
- Expertise in diverse modalities across therapeutic areas
- World-class facilities spread across 2.2 mn sq. ft.

Trusted

- US FDA, EMA, ANVISA and PMDA approved, GLP Certified, Ministry of Health of Russian Federation, AAALAC & CAP accredited/certified facilities
- 15+ successful regulatory and 160+ client audits in the last three years
- Transparency with real-time data sharing
- IT systems fully compliant with the ISO 27001 Information Security standards
- IP exclusivity to clients

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Why Syngene for Biologics?

Having a single partner with a broad suite of capabilities as opposed to multiple specialty partners, means being able to manage projects centrally, unhindered by logistical/shipping delays or dependencies on third-party deliverables. This enables timely completion of projects, efficiency, and cost savings.

Leading CRO/CDMO Syngene offers end-to-end Biologics Development and Manufacturing solutions for mammalian and microbial systems across modalities and therapeutic areas. We also offer Sterile Fill-Finish and Viral Testing services, making us a one-stop solution for all Biologics requirements – Target to Therapy!

Key benefits

Low risk of supply chain and logistics and multiple long-distance shipments
Low risk of Audit failure by having single site audit

Up to 3 months reduction in timelines by utilizing intracompany tech transfer
Up to 2 months reduction in timelines for development and manufacturing

Up to 50% cost reduction by increased titre
Up to 25% cost reduction by avoiding multiple tech transfers

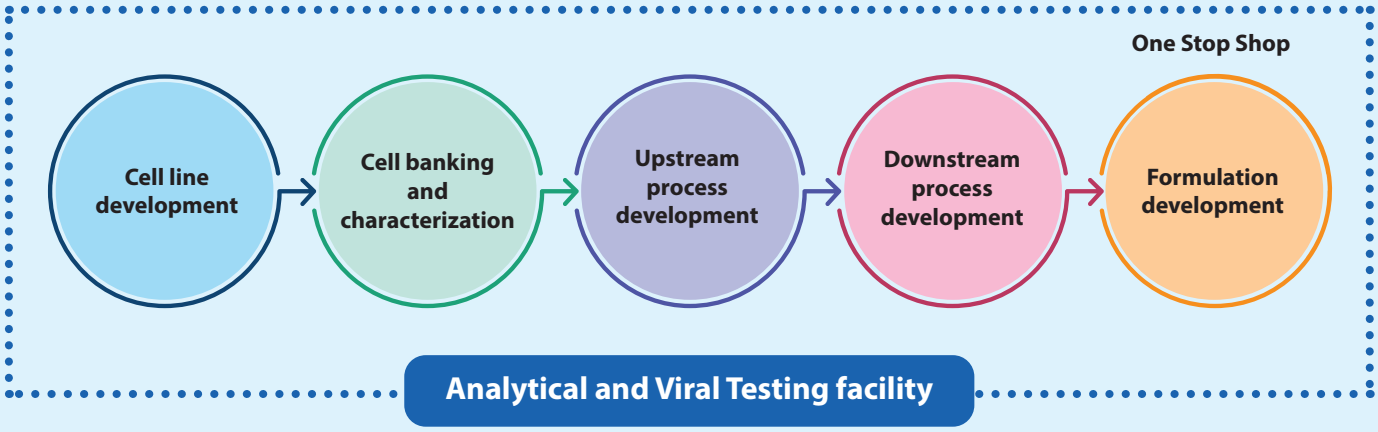
End-to-end Biologics services: Target to Therapy

	Capabilities	Mammalian and Microbial Expression Systems			
		Therapeutic Antibodies	Recombinant Proteins	Bispecific Antibodies	Biosimilars
Discovery	Bioinformatics	√	√	√	Not applicable
	Target Discovery	√	√	√	Not applicable
	Target Validation	√	√	√	Not applicable
	Immunogen Design, Engineering and Characterization	√	√	√	Not applicable
	Binding, Function, Developability assessment	√	√	√	Not applicable
	PK, efficacy and Toxicology Studies	√	√	√	√
Development (Clinical) Commercial Production	Cell line development	√	√	√	√
	Cell Banking	√	√	√	√
	Upstream Operations	√	√	√	√
	Downstream Operations	√	√	√	√
	Bioconjugation	Not applicable	Not applicable	Not applicable	√
	Bioassay Development	√	√	√	√
	Analytical Methods	√	√	√	√
Drug Product	Formulation	√	√	√	√
	Fill & Finish liquid vials	√	√	√	√
Clinical Trials	Phase 1 Early Phase	√	√	√	√
	Phase 2,3,4 Late Phase	√	√	√	√
	PK, PD, Biomarkers, immunogenicity	√	√	√	√

End-to-end Biologics services: Target to Therapy

	Capabilities	CGT / ATMP		Vaccine	Bioconjugates	
		Plasmid DNA	mRNA	Recombinant	ADC	Peg/Other
Discovery	Bioinformatics	√	√	√	√	√
	Target Discovery	Not applicable	Not applicable	Not applicable	√	√
	Target Validation	Not applicable	Not applicable	√	√	√
	Immunogen Design, Engineering and Characterization	√	√	√	√	√
	Binding, Function, Developability assessment	√	√	√	√	√
	PK, efficacy and Toxicology Studies	√	√	√	√	√
Development (Clinical) Commercial Production	Cell line development	√	Not applicable	√	√	√
	Cell Banking	√	Not applicable	√	√	√
	Upstream Operations	√	√	√	√	√
	Downstream Operations	√	√	√	√	√
	Bioconjugation	Not applicable	Not applicable	Not applicable	√	√
	Bioassay Development	√	Not applicable	√	√	√
	Analytical Methods	√	√	√	√	√
Drug Product	Formulation	√	√	√	√	√
	Fill & Finish liquid vials	√	√	√	√	√
Clinical Trials	Phase 1 Early Phase	√	√	√	√	√
	Phase 2,3,4 Late Phase	√	√	√	√	√
	PK, PD, Biomarkers, immunogenicity	√	√	√	√	√

Accelerating Biologics development with expert knowledge and platform technologies



Capability highlights

- Cell line development (Transposon based platform and UCOE along with CHOZN platform)
- Single clone selection (Cytena, Solentim Cellmetric and Octet HTX).
- N-1 perfusion process to enhance titre by 3x (Fig.1)
- DASbox/Ambr 250, shake flasks > 2L, 10L & 50L bioreactors > 200L, 500L, 2KL fermenters
- DoE studies for Upstream and Downstream process development (Fig. 2)
- 10 months Gene to GMP (Fig.3)
- Formulation development & fill-finish, process simulation

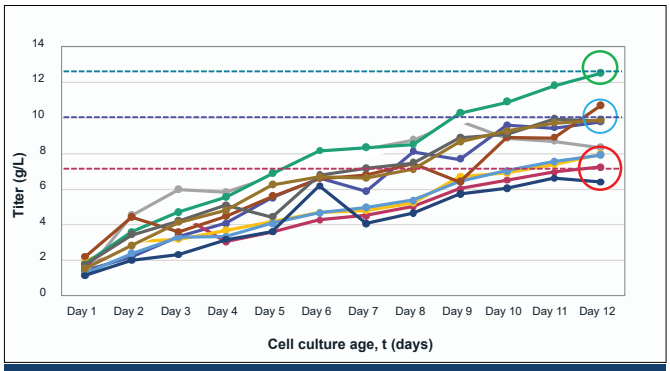


Figure 1: N-1 perfusion process enhances titer by 3x

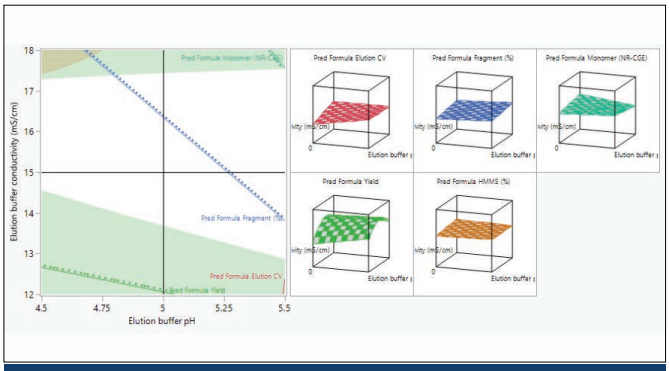


Figure 2: Design space and response surface plots for downstream process characterization studies using DoE

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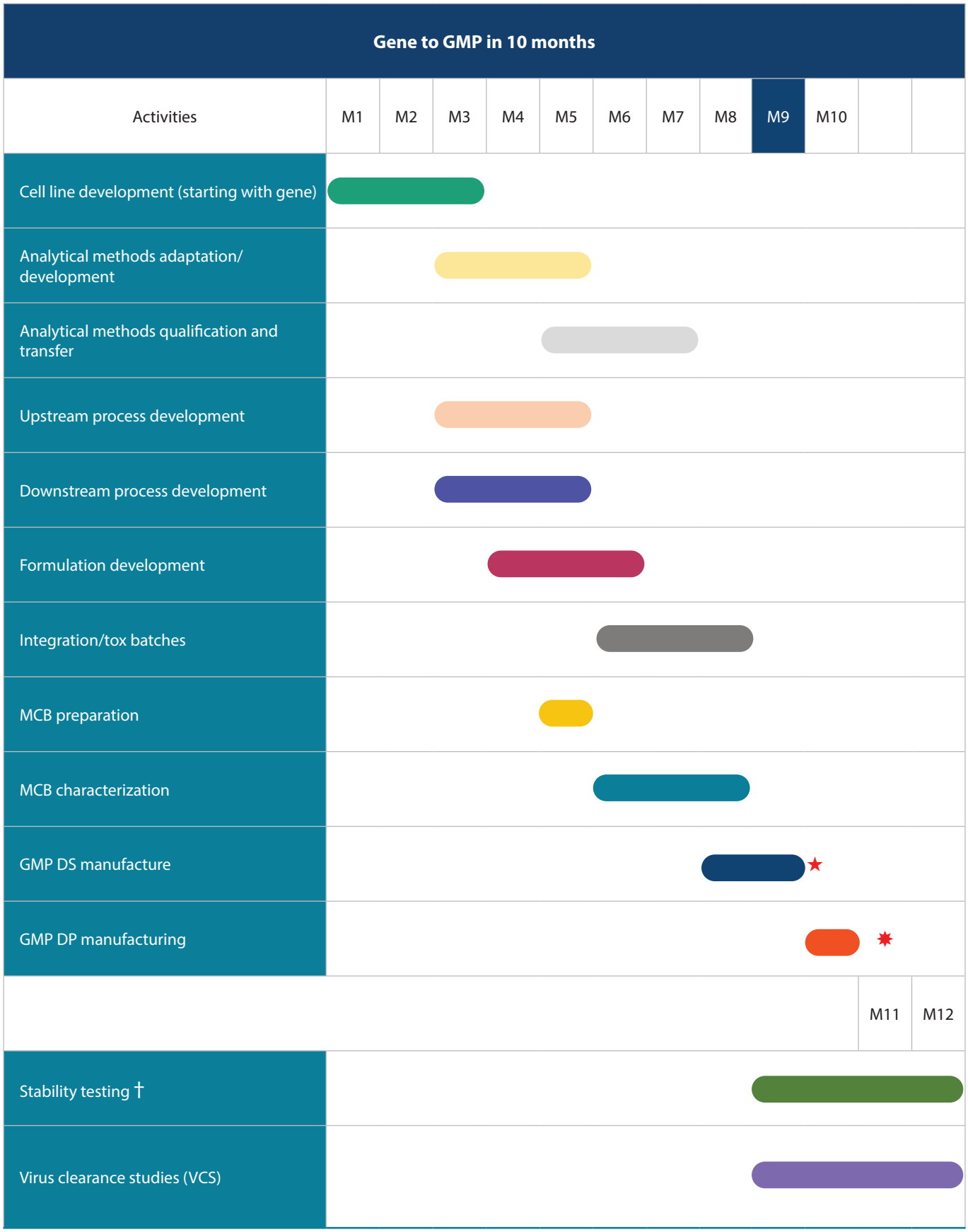


★ *Supply of GMP Drug Substance*

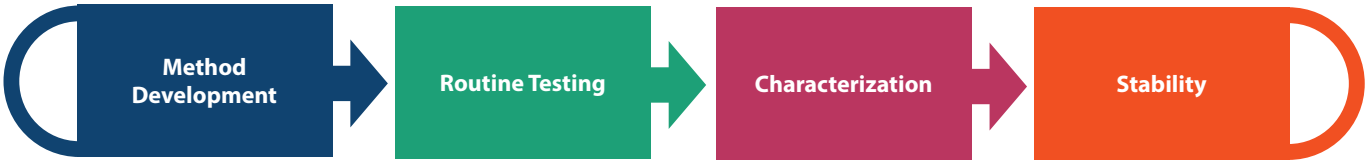
✸ *Supply of GMP Drug Product*

† *Ongoing process*

Figure 3: 10 months Gene to GMP DS manufacturing

Analytical facility: Features & Services

- World class Development and QC lab, supporting non-GMP and GMP release / stability testing
- Characterization using high-resolution mass spectrometer: Orbitrap and Q-TOF LC-MS systems
- Other advanced techniques for characterization include SPR, NMR, SEC-MALS, Flow cytometry, CD, AUC, DSF and DLS
- Wide range of functional assays including ADCC, CDC and apoptosis



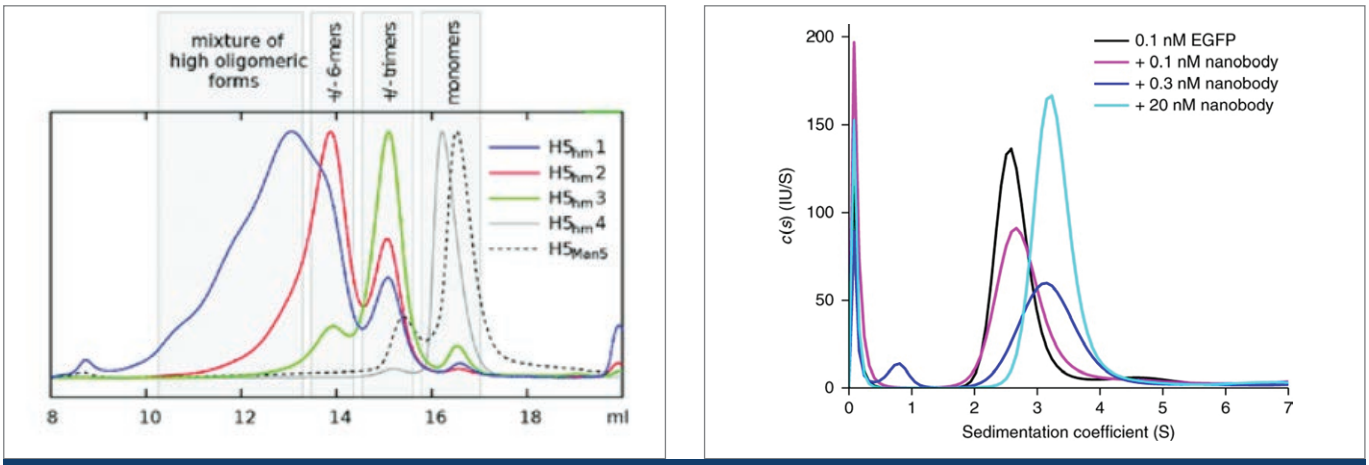


Figure 4: Aggregation analysis of mAbs using SEC-MALS and AUC

Viral Testing Facility: Features & Services

- India's only GLP-certified lab, ISO 9001-2015. State- of- the-art BSL-2 laboratory infrastructure for viral testing, spread over 4000 sq. ft.
- Offerings include Cell Bank Testing, Unprocessed Bulk Harvest Testing and Viral Clearance studies to support Phase I, Phase III CT submissions and commercial license applications
- Studies fully compliant with ICH, FDA and EMA regulations. Multiple client studies conducted to support application-filing in US, EU and India.
- Have cleared several audits conducted by clients and inspectors
- Experience and expertise across diverse products and process steps for virus clearance

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cGMP Biologics manufacturing plant (microbial): Features

Our microbial biologics manufacturing capacity encompasses a wide range of drug products. It comprises 300 and 500L (stainless steel) fermenters, 1000L refolding capability, a continuous centrifuge with a capacity of 200 LPH, a cell homogenizer with a capacity of 300 LPH, AKTA chromatography systems in both 600 and 2000 LPH variants, and an automated tangential flow filtration system.

Our manufacturing capabilities encompass diverse modalities, including the production of recombinant proteins from microbial sources, live biotherapeutic products (LBP), and plasmid DNA and mRNA products.

Figure 5: Manufacturing workflow in our dedicated microbial facility from counterclockwise: SS microbial fermenter, AKTA chromatography system, and automated tangential flow filtration system.

cGMP Biologics manufacturing plant (mammalian): Features

Our biologics manufacturing facilities have a total installed, single-use bioreactor capacity of 28KL (expandable to 48KL). We maintain four parallel isolators and oRABS type lines for sterile fill-finish which has a total capacity of 1 million vials/day. The facility includes various container closure system configurations including vials and pre-filled syringes with the capability to carry out lyophilization and terminal sterilization

Figure 6: Our dedicated Biologics (mammalian) manufacturing facilities, with our single use bioreactors and an isolator line for fill and finish

To know more about our Biologics services, **contact our experts**

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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 6000 scientists offer both skills and the capacity to deliver great science, robust data 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 2.2 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, Zoetis and Merck KGaA.

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

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