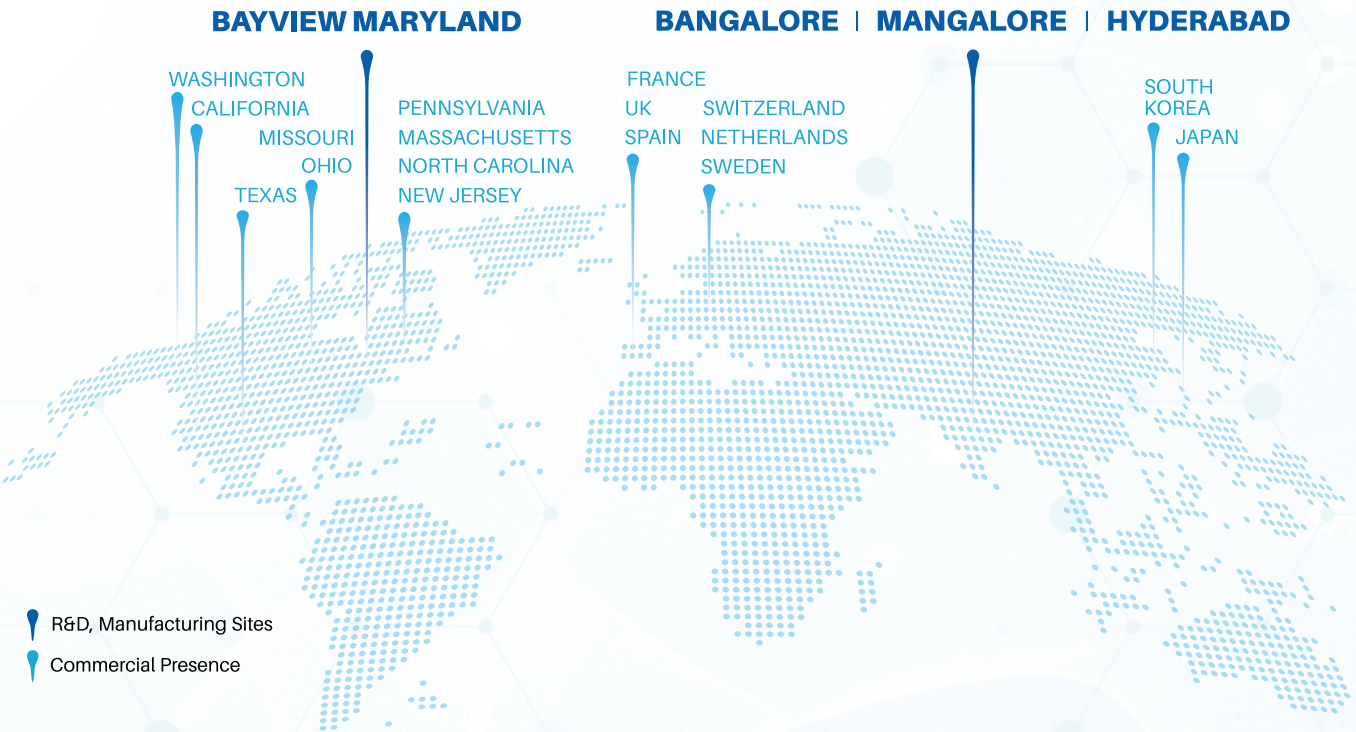
Syngene

Putting Science to Work

Your one-stop-shop for Biologics

with our manufacturing facilities across the U.S. and India



30+ years of delivering innovative scientific solutions to global markets

Syngene, a leading global CRDMO with over 30 years of experience in solving complex R&D challenges, delivers integrated drug discovery, development, and manufacturing services across small and large molecules, including niche modalities such as ADCs, peptides, and oligonucleotides.

Syngene's clientele includes world leaders across diverse sectors, ranging from global multinationals to small and medium-sized start-ups. As a strategic partner, Syngene offers innovative, flexible, and efficient approaches to scale rapidly, enabling faster go-to-market and improved access to patients.

With a strong focus on client satisfaction, quality, safety, ethics, and data integrity, Syngene is supported by a global supply chain of 2,900+ suppliers across 30 countries. Its ESG strategy prioritizes sustainability, employee well-being, and community investment achieving 82% renewable electricity use, zero waste to landfill, and zero liquid discharge at key sites.

The Syngene Advantage

Global

- 15 out of 20 top pharma are our customers
- 400+active customers around the globe
- Long term collaborations with BMS, Baxter and Zoetis
- Biologics manufacturing facilities across the U.S. and India
- Global clinical and commercial supply
- Validated worldwide cold chain shipping

Expert

- 30+ years of expertise
- 6000+ scientists
- 400+ patents enabled for clients
- 150+ 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

- IP exclusivity to clients
- USFDA, 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

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Accelerating biologics across modalities and markets

Syngene helps biopharma companies accelerate large molecule therapies to market through integrated biologics CDMO services, with manufacturing facilities across the U.S. and India. With a GMP capacity of 50 KL in single-use bioreactors, featuring 500 L, 2000 L and 4000 L units designed to deliver economies of scale, Syngene offers innovative, flexible, and efficient solutions to its clientele.

Syngene provides end-to-end services for mammalian and microbial systems, covering diverse modalities and therapeutic areas, including mAbs, recombinant proteins, bispecifics, biosimilars, and ADCs.

Our global infrastructure, regulatory expertise, and commitment to innovation enable faster development, seamless tech transfer, and consistent product quality. Solving complex manufacturing challenges is at the heart of our long-term client partnerships.

150+
Successful projects

25+
INDs enabled

250+
GMP batches

4
Manufacturing facilities across the U.S. and India

50 KL
Global SUB capacity

2 KL & 4 KL
SUBs across the U.S. and India

7-12 g/L
Titer with SynWeave™ platform

1 M vials/day
DP capacity

>80%
Green power

Our integrated biologics offerings are designed to accelerate molecules to market

One Stop Shop

Cell Line Development and Cell Banking (MCB/WCB)	Process Development Analytical and Scale-up	GMP Supply (DS /DP) for Early-Phase Clinical Trials	Process Validation and Late-Stage Trials	Product Launch, Commercial Mfg. and Post Marketing

mAbs Bispecifics Biosimilars Recombinant Proteins ADC Plasmids CGT

Analytical and Viral Testing facility

We focus on 4 platforms to align with our customer needs

Modality Platforms

Mammalian

- Integrated discovery
- Integrated development
- Early stage and clinical supply (DS/DP)
- Late stage and commercial supply (DS/DP)
- CHO, hybridoma, insect expressions

Microbial

- Integrated discovery
- Integrated development
- Clinical supply (DS)
- Late stage and commercial supply (DS)
- E-Coli, Pichia, mRNA expressions

BioConjugation

- Integrated ADCs (Payload, Linker, mAb, Conjugation)
- Development Conjugates (AOC, PDC, FDC)

Advanced Therapies

- Cell therapy (HEK expression)
- Early development gene therapy
- C&GT consumables (mAb activators, plasmids, cytokines, LV viral vector)

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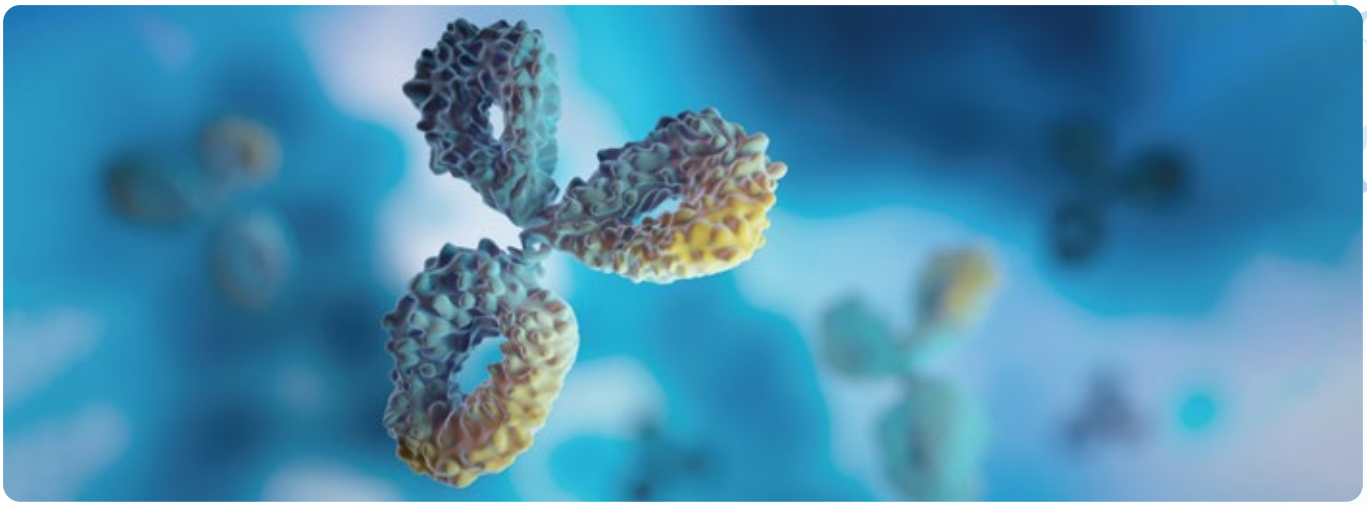
Get a 4-month head start with Syngene's mAb Accelerator Program

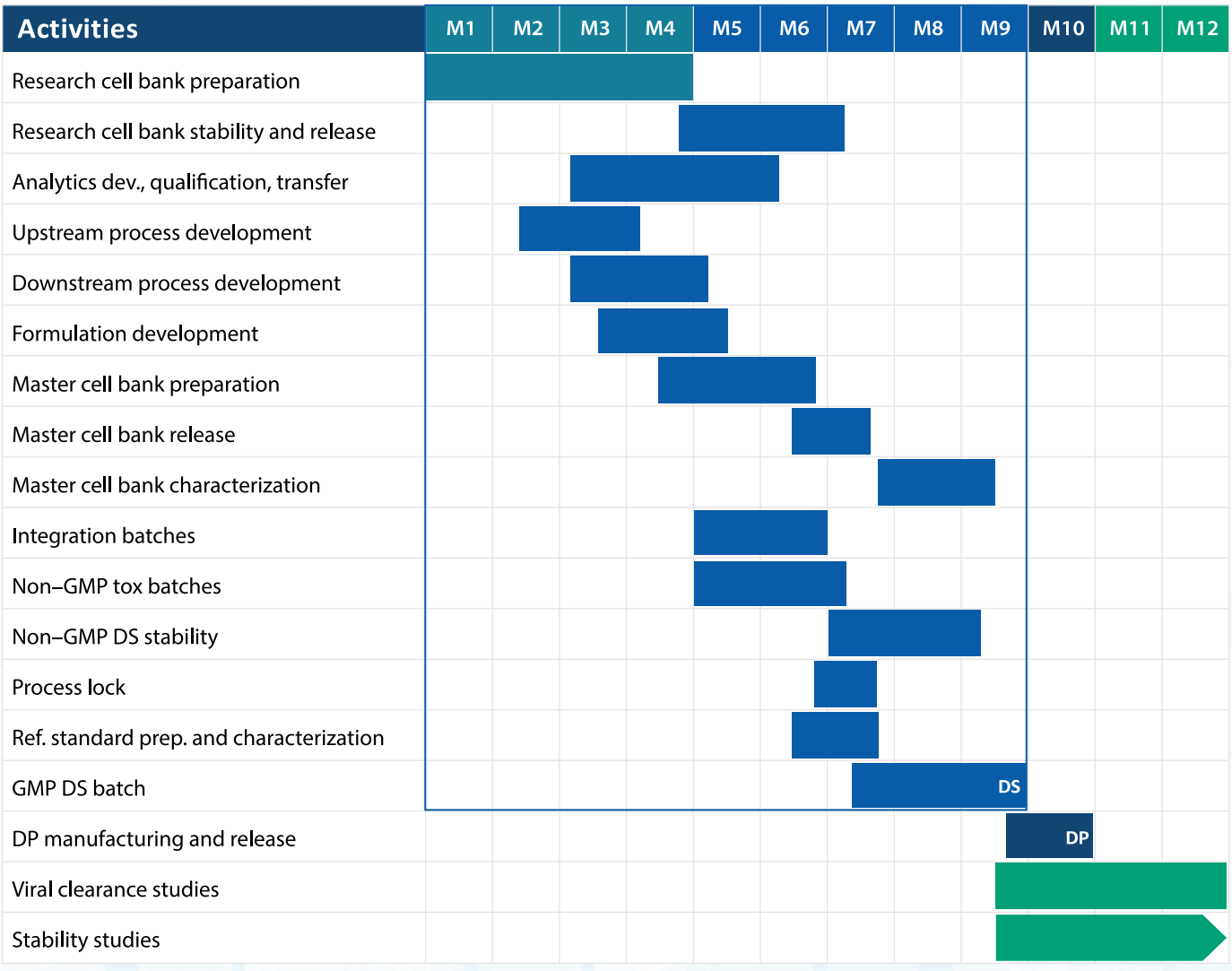
Every biologics journey begins with uncertainty. That's why, at Syngene, we take the first step for you.

We initiate Cell Line Development immediately, saving you up to four months while you secure approvals and funding. This early action places your program on solid footing, reducing both technical and timeline risks. This isn't just a service, but a clear signal that we're already invested in your success at scale.

Lets accelerate your molecule to market – together.



Gene to GMP in 9 months



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Capability Highlights

SynWeave™: Redefining cell Line development for advanced biologics

SynWeave™ is created by combining:

- Transposon based gene integration technology from Excellgene
- Extensive process development experience of Syngene's scientific team

It's a cutting-edge platform developed to:

- Produce high titer clone optimized for maximum yield
- Shorten the timelines to accelerate development and production
- Create clones with high manufacturability to reduce the risk for manufacturing scale production

N-1 Perfusion process enhances titer by 3x

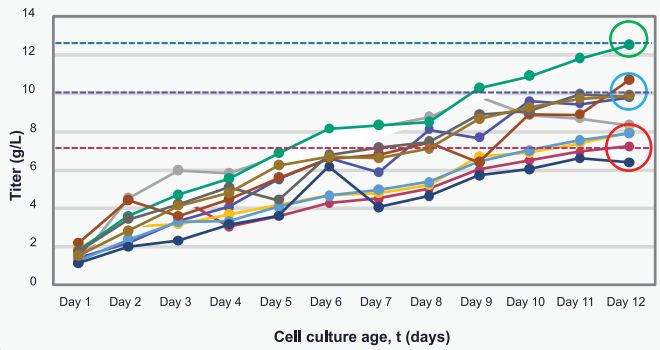

Figure 1: N-1 perfusion process enhances titer by 3x

DoE studies for upstream and downstream PD

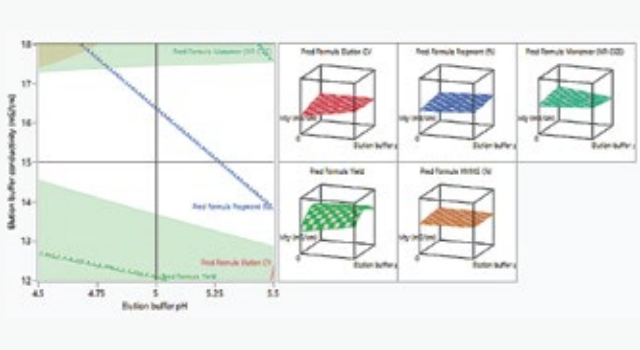

Figure 2: Design space and response surface plots for downstream process characterization studies using DoE

Viral Testing 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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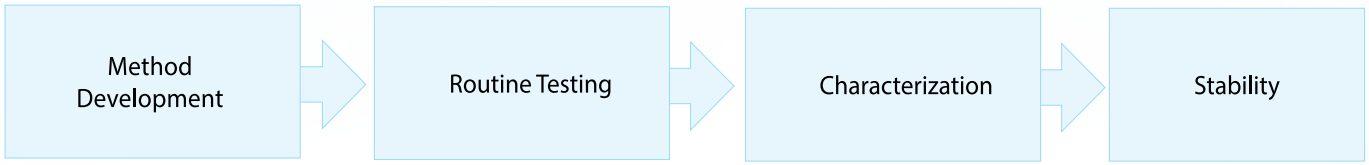
Analytical Services

- 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



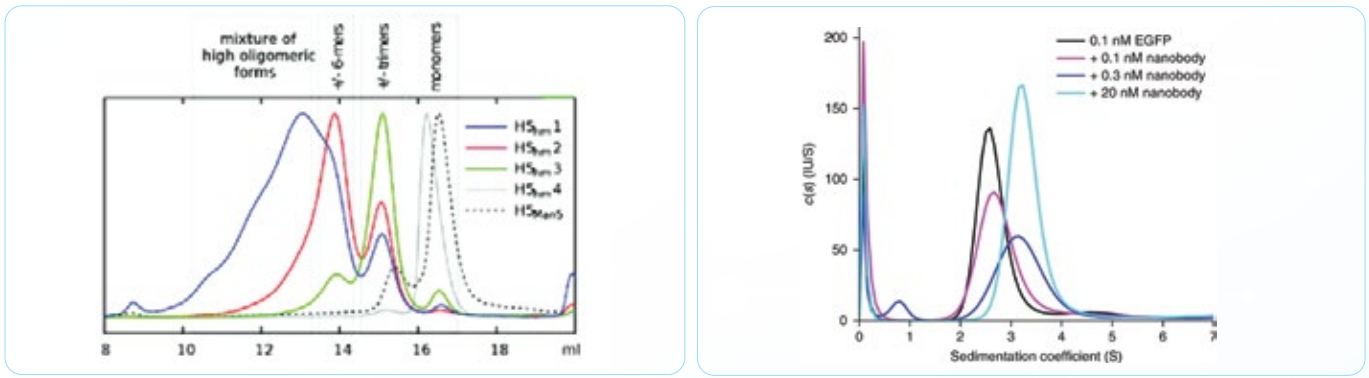


Figure 3: Aggregation analysis of mAbs using SEC-MALS and AUC

Our global manufacturing experience at multiple scales for DS and DP across modalities

Mammalian

- 500 L, 2000 L and 4000 L SUBs
- Dedicated suites for multi-product handling
- Downstream Harvest (centrifuge or depth filtration)
- GLP-certified virus testing and clearance
- USFDA, EMA, MHRA approved facilities

Microbial

- 200 L and 500 L Stainless Fermenters
- Continuous centrifugation
- 60 cm Chromatography
- Automated Tangential Flow Filtration (TFF)
- Plasmid DNA & mRNA production system

Drug Product Formulation

- Commercial: 2 High-Speed 500 vials/min
- Clinical/Small Scale: Multi-product clinical line (vials / PFS1) w/ Lyophilization
- Vial filling size (2R-100R / 0.5 ml – 100 ml)
- PFS filling size (0.3 ml – 1 ml)
- Auto visual inspection, serialization, semi-auto packing

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
	Immunogen Design, Engineering and Characterization	√	√	√	Not applicable
	Binding, Function, Developability assessment	√	√	√	Not applicable
	PK, efficacy and Toxicology Studie	√	√	√	Not applicable
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	√	√	√	√

Capabilities		CGT / ATMP		Vaccine	Bioconjugates	
		Plasmid DNA	mRNA	Recombinant	ADC	Peg/Other
Discovery	Bioinformatics	√	√	√	√	√
	Target Discovery	Not applicable	Not applicable	Not applicable	√	√
	Immunogen Design, Engineering and Characterization	Not applicable	Not applicable	√	√	√
	Binding, Function, Developability assessment	√	√	√	√	√
	PK, efficacy and Toxicology Studie	√	√	√	√	√
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	√	√	√	√	√

Notes

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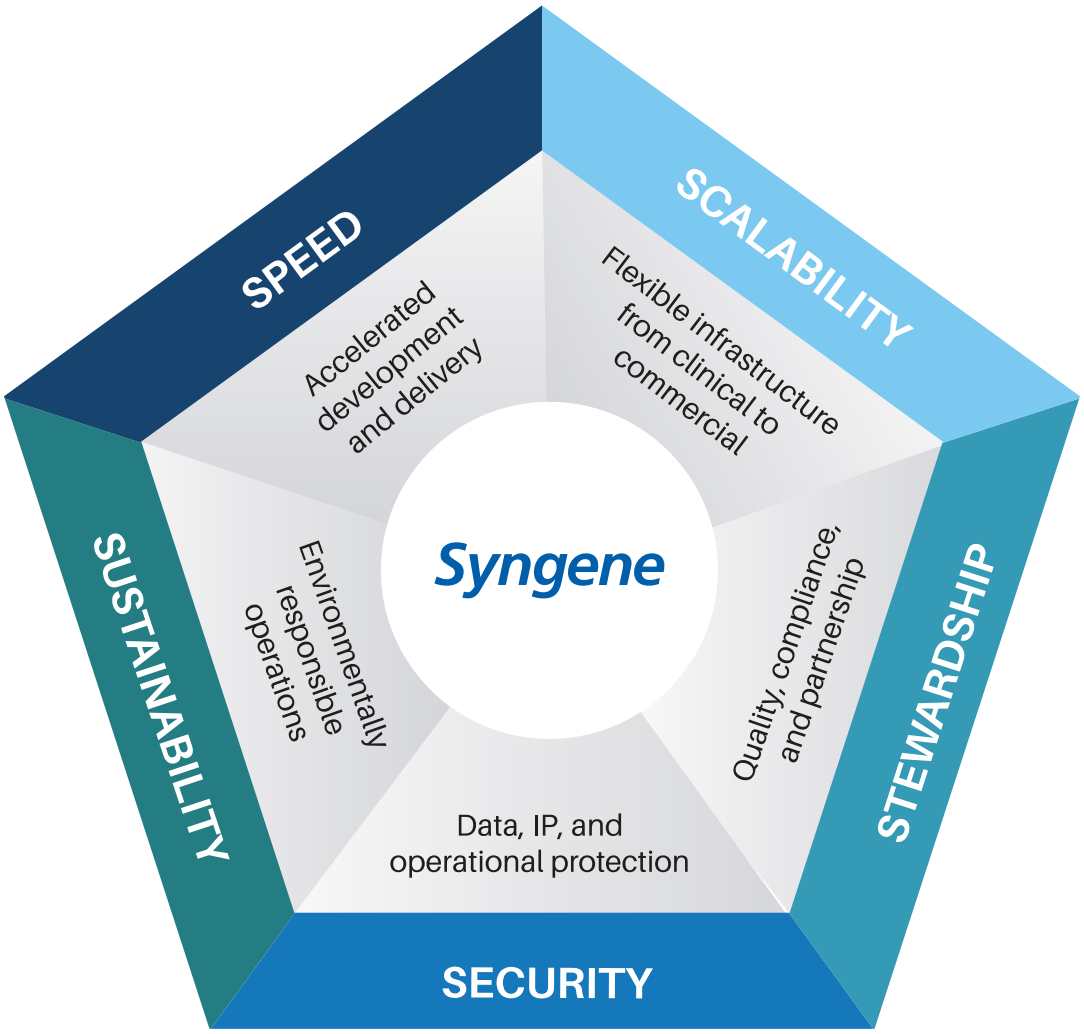
Notes

Fast track your Biologics with

Syngene's 5S formula



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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 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 Baxter, and Bristol-Myers Squibb, as well as 2.2 million 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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