

Syngene

Putting Science to Work

Biologics CDMO Services

Science
For People
**ADVANCING
INNOVATION**

With Manufacturing Facilities
across the U.S. and India

Bayview
Maryland, U.S.

Bangalore
India



32+ 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 2900+ 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

- 32+ years of scientific expertise
- ~6000 scientists
- 400+ patents enabled for clients
- ~200 KL Global GMP DS capacity
- Integrated DS-DP for consistent quality and faster scale-up
- Expertise in diverse modalities across therapeutic areas
- World-class facilities spread across ~3 Mn sq. ft.



Trusted

- IP exclusivity to clients
- USFDA, EMA, ANVISA, and PMDA approved, GLP Certified, Ministry of Health of Russian Federation, AAALAC, and 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 standard

Accelerating Biologics Across Modalities and Markets

Syngene helps biopharma companies accelerate biologics to market through integrated 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

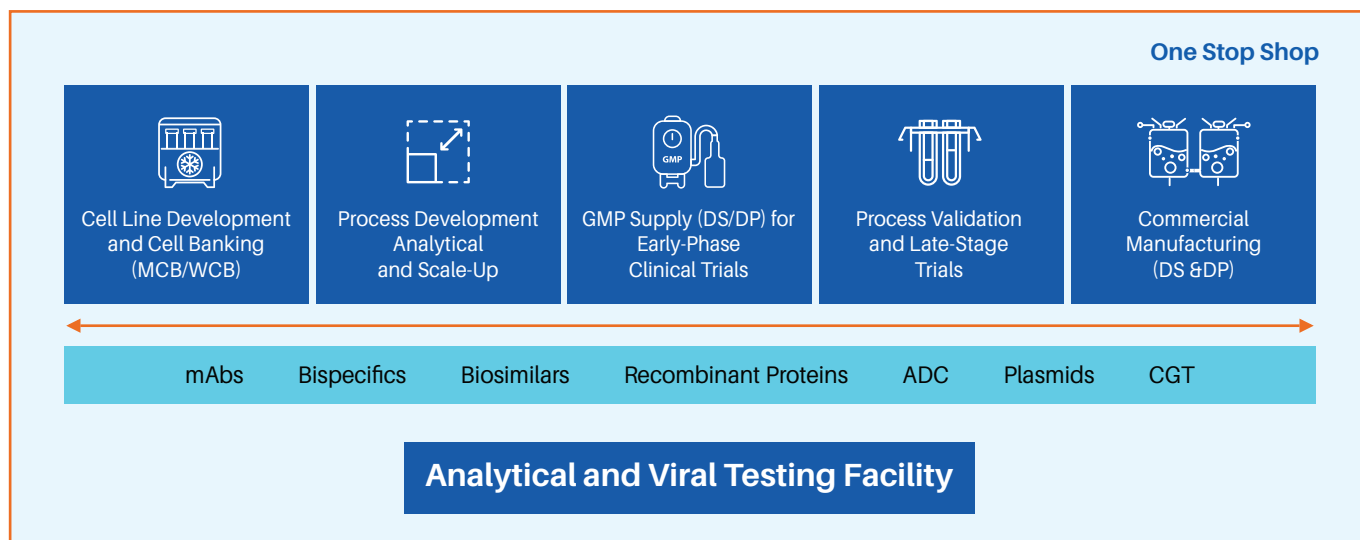
1 Mn vials/day

DP Capacity

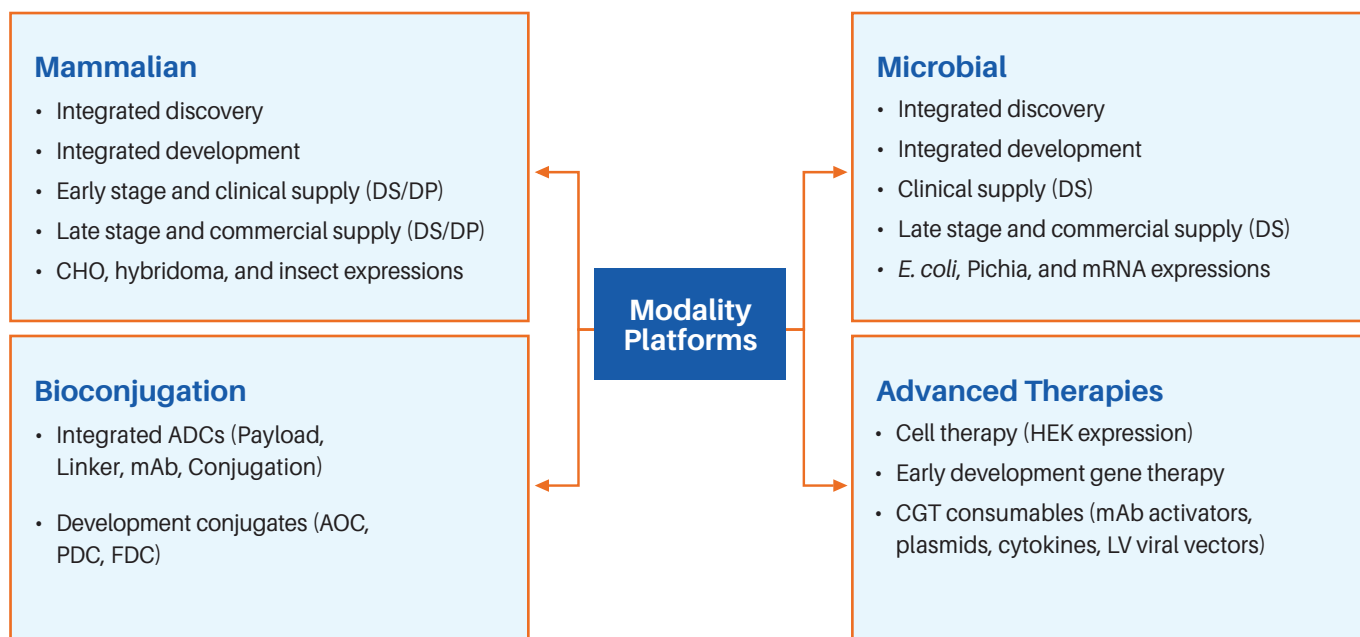
> 80 %

Green Power

Our Integrated Biologics Offerings Are Designed to Accelerate Molecules to Market



We Focus on 4 Platforms to Align with Our Customer Needs

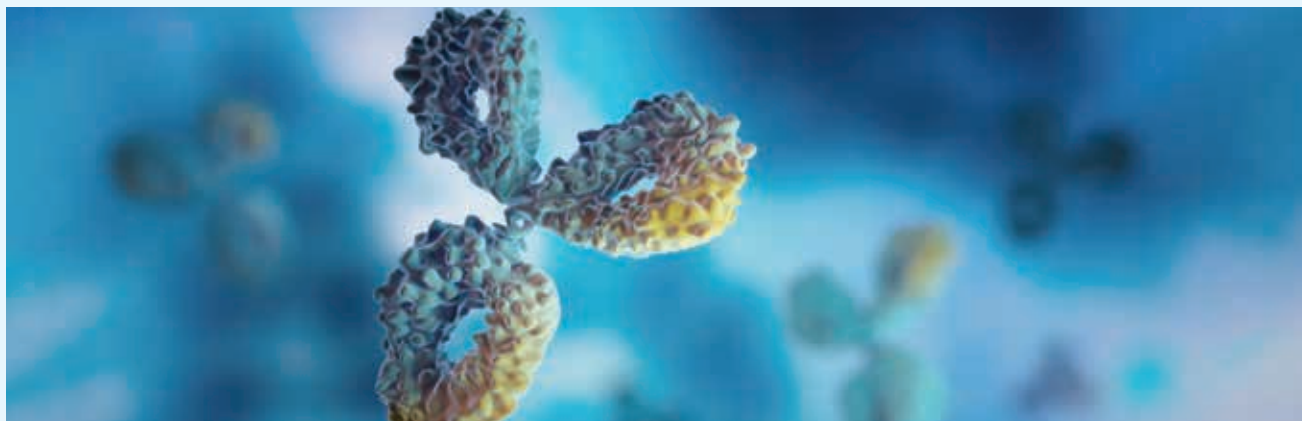


Get a 4-Month Head Start with Syngene's mAb Accelerator Program

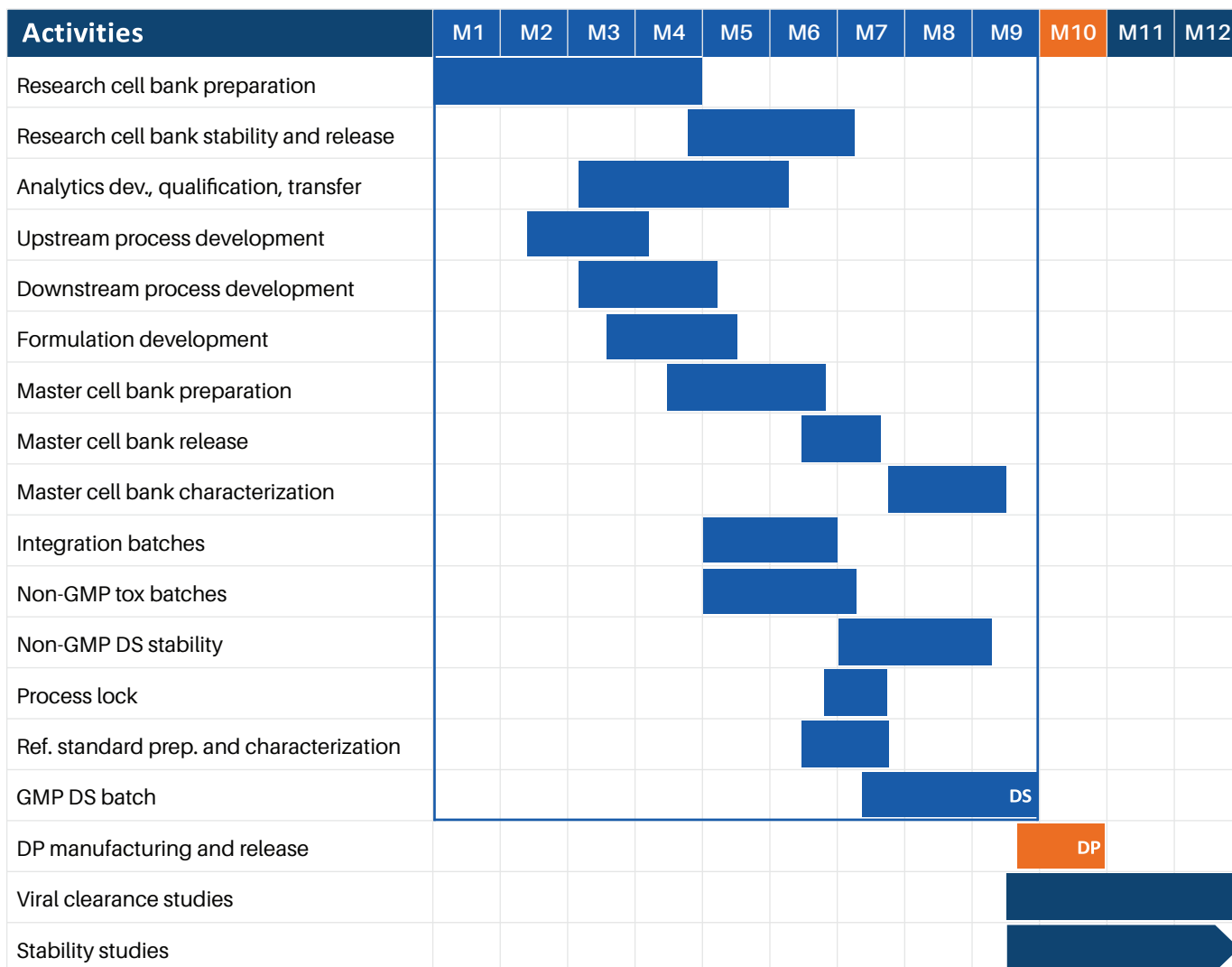
Every biologics journey begins with uncertainty. That's why, at Syngene, we take the first step for you.

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.

Let's accelerate your molecule to market, together.



Gene to GMP in 9 Months



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 clones optimized for maximum yield
- Shorten 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

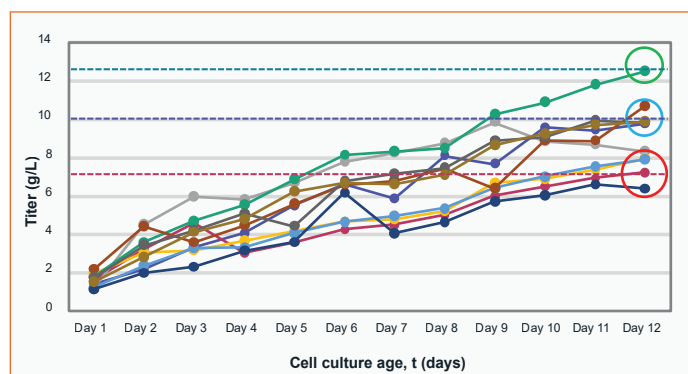


Figure 1: N-1 perfusion process enhances titer by 3x

DoE Studies for Upstream & Downstream PD

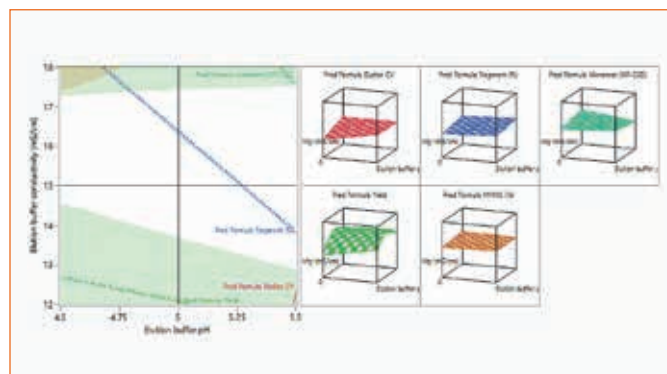


Figure 2: Design space and response surface plots for downstream process characterization studies using DoE

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 U.S., EU, and India
- Cleared several audits conducted by clients and inspectors
- Experience and expertise across diverse products and process steps for virus clearance



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

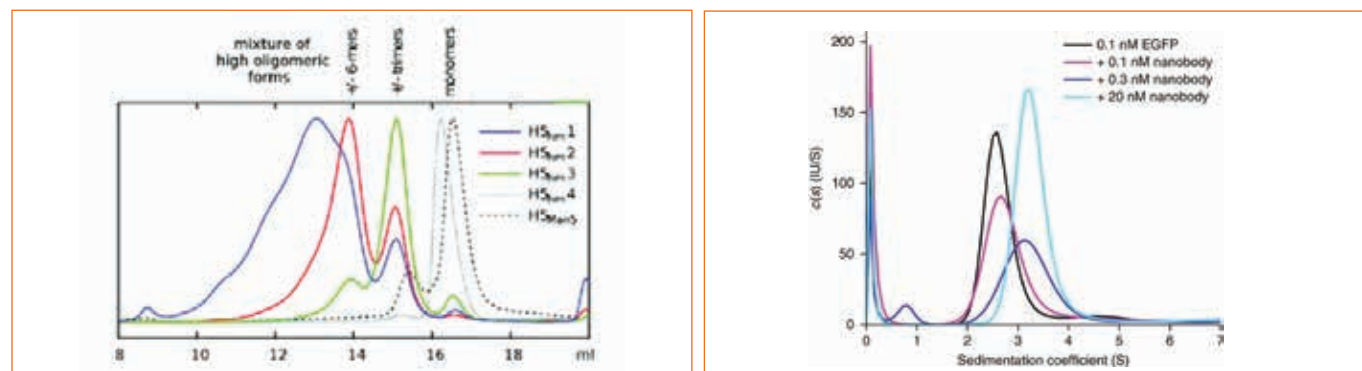
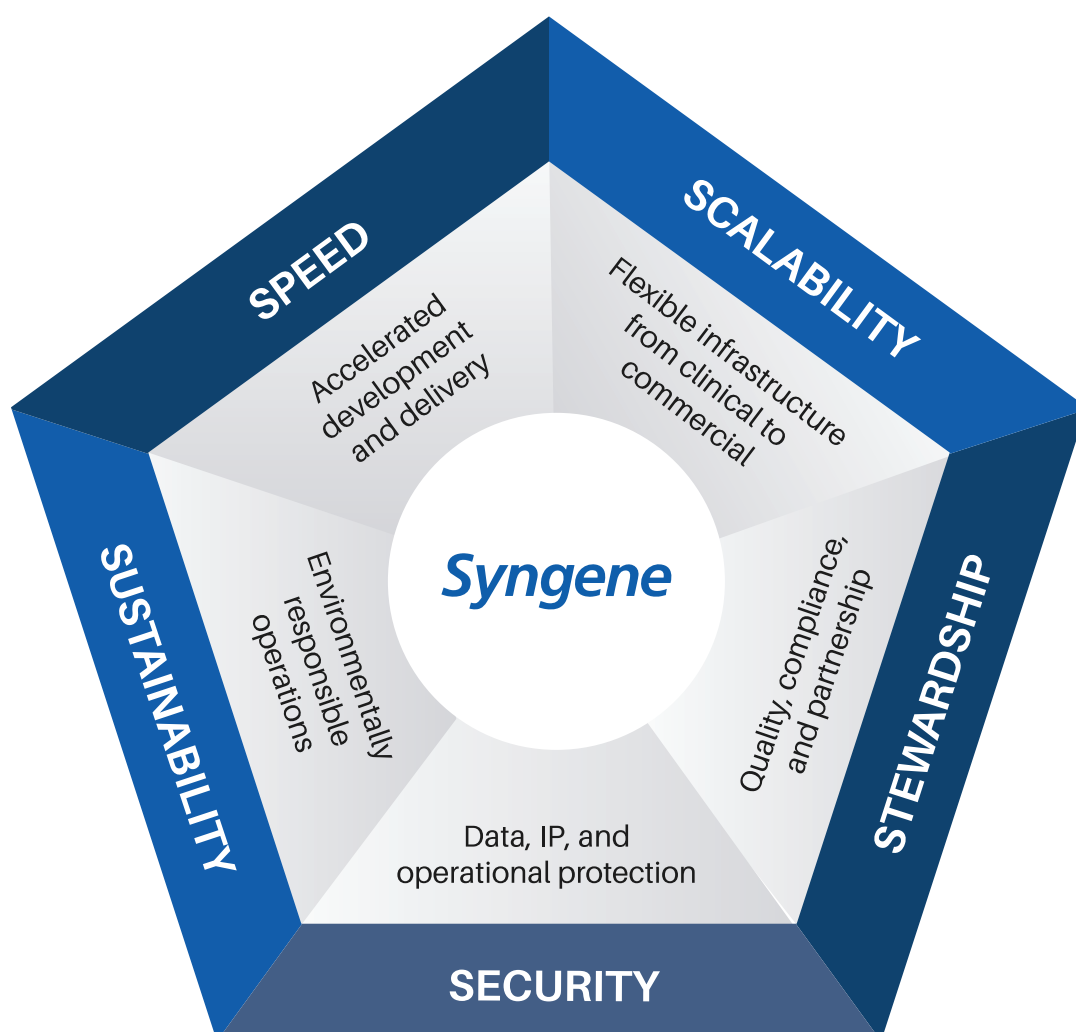


Figure 3: Aggregation analysis of mAbs using SEC-MALS and AUC

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 and mRNA production system	 Drug Product Formulation • Commercial: 2 high-speed lines at 520 vials/min • Clinical / Small Scale: Multi-product clinical line (vials / PFS1) w/ Lyophilization • Vial filling size (2 R - 100 R / 0.5 ml - 100 ml) • PFS filling size (0.3 ml - 1 ml) • Auto visual inspection, serialization, and semi-auto packing
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Fast-track your Biologics with
Syngene's 5S formula >>



Syngene
Putting Science to Work

About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated CRDMO (Contract Research, Development and Manufacturing Organization), serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's ~6000 scientists bring the skills and capacity to deliver great science, strong data security, and quality manufacturing, at speed, helping improve time-to-market and lower the cost of innovation. This is backed by ring-fenced dedicated centers, as well as ~3 Mn sq. ft. of specialist discovery, development, and manufacturing facilities.

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