Syngene

Putting Science to Work

Partnering for Precision in Small Molecule Drug Substance Development & Manufacturing

Integrated Capabilities for Small Molecule Success

Introduction

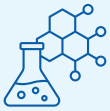
Syngene International is a globally recognized Contract Research, Development, and Manufacturing Organization (CRDMO), offering integrated services across the drug discovery, development, and manufacturing continuum. With over three decades of experience, Syngene supports pharmaceutical and biotechnology companies in solving complex R&D and manufacturing challenges.

- Integrated services across small and large molecules, HPAPIs, oligonucleotides, peptides, and ADCs
- One-stop partner for discovery, development, and commercialization
- Global client base with proven scientific and operational excellence

Small Molecule Drug Substance Development & Manufacturing

Syngene's small molecule drug substance development and manufacturing services are powered by a multidisciplinary team and robust infrastructure supporting a wide range of molecules including oligonucleotides, peptides, polymers, and HPAPIs.

Team of 1,150+ professionals including scientists, engineers, QA/QC, regulatory, SCM, and PM



Facilities for both GMP and non-GMP operations

Proven track record: 250+ route scouting projects, 200+ process developments, and over 300 MT of material delivered

Over 2,700 analytical methods developed, 5 joint patents filed, and 4 products successfully commercialized

Process Research and Development

To support scalable and robust manufacturing, Syngene's Process Research and Development (PRD) capabilities include complex organic synthesis, flow chemistry, and advanced purification systems.

- Expertise in heterocycles, natural products, peptides, oligonucleotides, and ADC payloads
- Advanced tools: automated jacketed reactors, parallel synthesizers, PAT tools (FBRM, PVM, React-IR)
- Photochemical and cryogenic reactor setups for sensitive reactions

Analytical and Process Safety

Syngene provides comprehensive analytical development and rigorous process safety protocols to ensure quality and compliance throughout the development lifecycle.

- Extensive analytical capabilities: LC-MS, GC-MS, NMR, SFC, Prep HPLC
- Services include method development, impurity profiling, and ICH stability studies
- Process safety tools: calorimetry (DSC, ARC), gas quantification, powder safety assessments
- CCPS-based safety protocols implemented across all laboratories

Engineering and Commercial Scale-Up

Syngene's engineering team ensures seamless scale-up to commercial manufacturing through detailed studies and simulation tools, supporting commercial viability of complex processes.

In-depth studies covering corrosion, mixing, distillation, filtration, and drying

Process simulation using Dynochem and DesignExpert

Flow chemistry platforms including Vapourtec and H-Cube for continuous manufacturing

Demonstrated success in kilogram-scale production using metal carbanion chemistry

Manufacturing Infrastructure and Certifications

Syngene's manufacturing facilities in Bangalore and Mangalore support kilo to commercial-scale production with global regulatory approvals.

Bangalore (B-SEZ) & Mangalore (M-SEZ)

Mfg. Facility	Bangalore (B-SEZ)				Mangalore (M-SEZ)
	S1 Kilo Lab (non-GMP)	U-2 Kilo Lab (non-GMP)	HPAPI GMP (OEB-4 & 5) USFDA, PMDA	S14 Semi-commercial GMP USFDA, PMDA	Mangalore Including high potent Intermediate Block Commercial GMP USFDA (OEB-4)
Range	10-20 L	10-50 L	60 L to 630 L	60 L to 8,000 L	1000 L to 12,500 L
Total Capacity	120 L	90 L	2,010 L	63,600 L	71,000 L
Largest reactor	20 L	50 L	630 L	8,000 L	12,500 L
# Reactors	3	4	5	32	12
Total number of reactors (Manufacturing Volumes)					**56 reactors (~135,000 L) & expanding**

SEZ = Special Economic Zone

- Combined reactor volume: ~135,000 liters across 56 reactors
- Reactor range: 10 L to 12,500 L across GMP and non-GMP blocks
- Certifications: USFDA, PMDA, EMA, ANVISA, GLP, AAALAC, CAP, Russian Ministry of Health
- 15+ regulatory audits and 160+ client audits completed in last 3 years

Development & Manufacturing for Specialized Modalities

Syngene offers advanced capabilities in cryogenic chemistry, peptide synthesis, oligonucleotide manufacturing, and ADC development.

- Cryogenic reactions down to –110°C for sensitive intermediates
- Peptide synthesis: Over1,000 peptides delivered, up to 65-mer
- Oligonucleotide expertise for therapeutic, diagnostic, and homopolymer oligos
- End-to-end ADC services: linker-payload synthesis, DAR analysis, stability, PK, and tox studies

Seamless Technology Transfer for Manufacturing Success

Syngene ensures seamless technology transfer from PRD and ARD at BSEZ to manufacturing at MSEZ through structured workflows and cross-functional collaboration.

Process familiarization, engineering and safety studies, scale-down simulations

Comprehensive documentation and analytical method transfer

Governed by risk assessments, change controls, and safety reviews

Active involvement from technical services, QC, and EHSS teams

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Green Chemistry and Sustainability

Syngene integrates green chemistry principles to reduce environmental impact and improve process efficiency.

- Extensive analytical capabilities: LC-MS, GC-MS, NMR, SFC, Prep HPLC
- Services include method development, impurity profiling, and ICH stability studies
- Process safety tools: calorimetry (DSC, ARC), gas quantification, powder safety assessments
- CCPS-based safety protocols implemented across all laboratories

Success in Scaling and Commercialization

Syngene's success stories demonstrate its ability to deliver complex programs with speed, quality, and regulatory compliance.

- **Case Study 1:** Syngene partnered with a global pharmaceutical company to support development from early-stage research to commercial launch. Delivered multiple batches ranging from 5 kg to 24 kg, supporting clinical trials and regulatory submissions.
- **Case Study 2:** In collaboration with a Japanese pharmaceutical company, Syngene scaled up production from 100 grams to over 1,000 kilograms. The PMDA-approved Bangalore facility enabled successful execution of clinical and commercial campaigns.

Partner with a Leader in Drug Substance Manufacturing

Syngene combines deep scientific expertise, advanced infrastructure, and a proven track record of regulatory compliance to deliver reliable chemical development solutions. From low-temperature cryogenic reactions to high-potency API manufacturing, our capabilities are designed to help clients overcome complex challenges with confidence. With a commitment to quality, safety, and innovation, we accelerate the development and delivery of tomorrow's medicines—making Syngene a trusted partner for pharmaceutical and biotech companies worldwide.

Contact us to learn how our integrated development and manufacturing capabilities can advance your program.

Scan the QR code to learn how our capabilities can advance your program

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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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