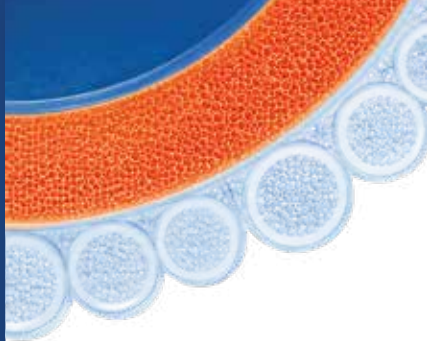


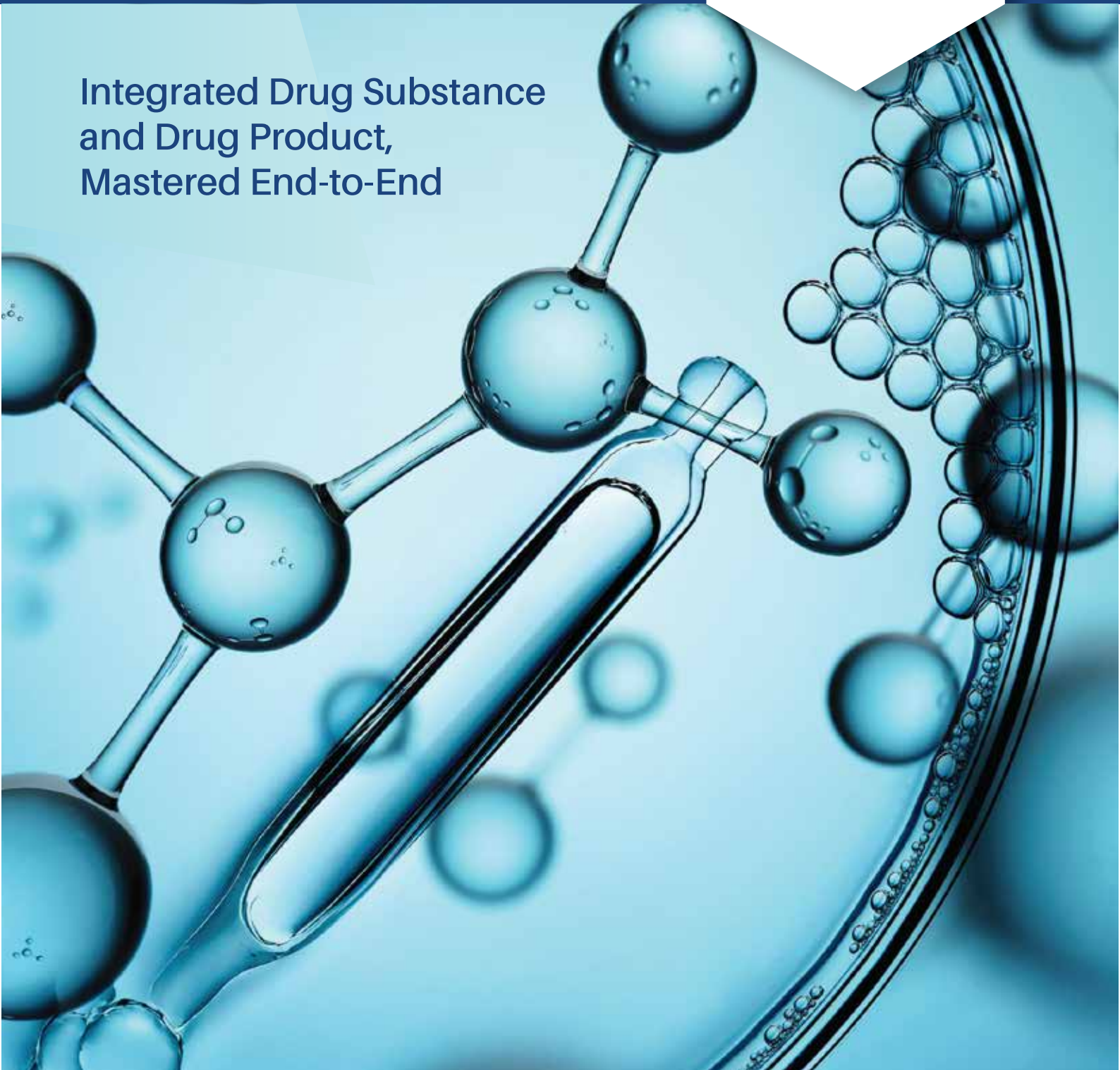
The Syngene logo is rendered in a white, italicized sans-serif font against a dark blue background.

Putting Science to Work

Peptides & Oligonucleotides

A microscopic image showing a cross-section of a cell or tissue, with a prominent orange layer and several blue, circular structures below it.

Science
For People
**ADVANCING
INNOVATION**

A composite image featuring a blue-tinted molecular structure on the left and a petri dish containing a grid of small, circular samples on the right. A glass test tube is positioned diagonally across the center, overlapping both elements.

Integrated Drug Substance
and Drug Product,
Mastered End-to-End

One Integrated Partner for Peptides & Oligonucleotides

Complex modalities demand more than synthesis capacity. They demand continuity across chemistry, analytics, process development, drug substance, and drug product.

At Syngene, we bring these together in a single team and quality system – so your program moves faster, transfers cleaner, and reaches the clinic with less risk.

32+ yrs

Integrated
Discovery to GMP

6000+

Peptides Delivered

USFDA • EMA • PMDA

Approved Facilities

5 Sites

Global Delivery Network



For peptide and oligonucleotide programs, risk rarely lives in the synthesis step alone. It emerges at the interfaces - between synthesis and analytics, between drug substance and formulation, between development and GMP. Every hand-off to a new vendor adds a queue, a re-qualification, and a knowledge gap.

At Syngene, we remove those interfaces. Discovery, process development, analytics, GMP drug substance and sterile drug product run inside one organisation, one team, and one quality system – giving you a single point of accountability from first residue to filled vial.

What this Means for You



Move Faster

One CRDMO across every step means fewer queues and cleaner single-site tech transfer into GMP.



Transfer Cleaner

Scientific knowledge stays with the molecule as it scales, so less is lost and re-learned between stages.



De-risk CMC

Analytics and impurity understanding are built in from day one, strengthening specs, stability, and filings.

The Value We Build Around

Your Challenge	How We Deliver
Sequential DS and DP Planning	Drug substance and drug product executed under one roof, aligned early to cut late-stage rework.
Fragmented Vendor Accountability	One integrated team across chemistry, analytics, GMP, and fill-finish, with a single point of contact and quality system.
Late-stage Analytical Surprises	Method development and impurity profiling run from the first batch, so quality is defined before scale-up.
Tech-transfer Knowledge Loss	Single-site scale-up preserves process understanding from discovery through clinical supply.
Scale Uncertainty	Clear capacity pathways for both modalities so supply grows with your program milestones.



Peptides

Peptides: Complexity, Mastered, and Scaled

From difficult linear sequences to stapled, bicyclic and heavily modified macrocycles, we turn peptide complexity into a faster, lower-risk path to the clinic. A deep discovery engine feeds directly into process development, GMP Manufacturing, and sterile fill-finish – so the same team that solves the chemistry also delivers your clinical material.



6000+

Peptides
Delivered

~300

Unnatural
Amino Acids

up to 85-mer

Linear, Up To
98 % purity

6

Parallel
Synthesizers

What We Make

Capability	Scope
Formats	Linear, cyclic (head-to-tail, disulfide, stapled, bicyclic, lactam), branched, and conjugated peptides.
Modifications	N-methylation, phospho/sulfo, lipidation, PEGylation, peptoids and depsipeptides; natural, all-D and ~300 unnatural residues.
Conjugates	DOTA, AAZTA, PEG, biotin, fluorescent labels, and peptide-PROTAC constructs.
Libraries	Linear (> 150 peptides, >90 %), cyclic (up to 40, >95 %), plus stapled, and bicyclic libraries.
Technologies	SPPS, LPPS, and hybrid (fragment) synthesis with advanced orthogonal protection strategies.

Complexity We Handle Routinely

High hydrophobicity and aggregation, long and difficult sequences, multiple disulfide bridges, heavy N-methylation, stapled, bicyclic, and lactam macrocycles – backed by ~300 in-house unnatural amino acids, all-D residues, a full resin, and coupling-reagent suite, and QC by SOR, and chiral SFC.

From Discovery to Commercial Scale

Stage	Scale & Capability
Discovery	1 μ mol – 30 mmol; mg – g scale; singletons, libraries and SAR at ~6-8 peptides/FTE/week; 1-week cycle for a 15-mer.
Development	1 g – 100 g/batch (non-GMP); SPPS, LPPS and hybrid routes for long or difficult sequences; parallel method development.
cGMP manufacturing	10 g – 200 g/batch; ~2 kg/year; 5 L jacketed SPPS reactor plus 0.5 - 5 L reactors; 1 kg+ batch capability in existing GMP infrastructure.
Sterile Drug Product	Dedicated 4,000 sq.ft. fill-finish suite; 500 – 25,000 vials/batch; solutions and lyophilised products; potent handling to OEL $\geq$ 1 μ g/m ³ .

Strategic New Expansion

Purpose-built peptide capacity is being added within Syngene's proven GMP systems – so you scale from clinical batches to commercial supply with the same team, the same quality, and no new tech transfer.

**Up To
1000 L**
Reactor Scale

1000 mm
Purification
Column

**Up To
30 kg**
Per Batch

**Up To 500
kg/yr**
Commercial
Capacity

What this Means for You:

A clear, low-risk pathway to commercial volumes – qualified quality inherited from day one, and continuity of knowledge as your molecule grows.

Oligonucleotides

Oligonucleotides: From Sequence Design to GMP

Whether your program is an antisense oligonucleotide, a modified siRNA, an aptamer, or a conjugated construct, we advance nucleic acid therapeutics through integrated synthesis, analytics, and manufacturing. Chemistry, impurity understanding, scale-up, and GMP execution sit together, so complex sequences reach CMC-ready material without vendor hand-offs.



ASO · siRNA

Aptamers, CpG,
PMO, PNA

Up To 60-mer

Natural DNA / RNA

4 backbones

PO · PS · PS2 · PN

>50 Kg/yr

Planned
GMP Capacity

What We Make

Capability	Scope
Molecule Types	ASO, siRNA, miRNA, CpG, aptamers, PMO, PNA; modified and unmodified DNA / RNA up to 60-mer.
Backbone Modifications	Phosphodiester (PO), phosphorothioate (PS), phosphorodithioate (PS2), and phosphoryl guanidine (PN).
Sugar Modifications	2'-OMe, 2'-MOE, 2'-Fluoro, and locked nucleic acids (LNA).
Conjugation	GalNAc, lipid, peptide and drug conjugation; thiol-maleimide, click chemistry, and antibody-oligonucleotide conjugation (AOC).
Purification & Analytics	IP-RP, IEX and SEC; automated prep purification, desalting for high-purity duplex, and single-strand delivery.

From Discovery to Commercial Scale

Stage	Scale & Capability
Discovery	50 nmol – 200 μ mol; μ g – mg scale Wide range of oligonucleotide synthesis support in discovery scale.
Development	0.25 – 4 mmol; 0.2 – to multi gram scale, process development, scale-up / scale-down, and process transfer to cGMP plant. Dedicated analytical facility with structural analysis, physicochemical characterization, impurity profiling, and bioburden analysis.
cGMP Manufacturing	~2.5 kg/year; non-GMP and cGMP for clinical and commercial supply 200 g hundred gram scale; 2.5 kg/year, seamless tech transfer from development to manufacturing via compliant integrated quality system.

Strategic New Expansion

Oligonucleotide capacity is scaling in stages within Syngene's GMP infrastructure – so you can plan clinical and commercial supply against a clear, growing pathway rather than a hard ceiling.

Phase	Capacity & Purpose
Next Expansion	20 – 30 kg/year; added synthesizer and downstream capacity for clinical and commercial phases.
Full Expansion	>50 kg/year; further synthesizer, downstream, and infrastructure for large-scale clinical and commercial manufacturing.

What this Means for You:

Dedicated GMP-compliant QC laboratories, state-of-the-art synthesis and downstream processing, cleaning and process validation, and process characterization with DoE – the same team carries your sequence from process development through cGMP release.



Integrated Drug Substance + Drug Product

One Site, from API to Filled Vial

The biggest timeline risk in a complex program is the gap between drug substance and drug product.

At Syngene, we close it. Drug substance, analytical development, formulation, and sterile fill-finish run on a single site, under one accountable team – no external hand-offs, faster tech transfer, and a shared understanding of the molecule from the first batch.

Drug Substance and Drug Product, on One Site

By keeping drug substance and drug product under one team and one quality system, we remove the tech-transfer delays that typically sit between DS and DP – shortening the route to first-in-human supply.

Sterile Fill-Finish for Peptide and Oligonucleotide APIs

Parameter	Detail
Suite	Facility 1: Dedicated 4,000 sq. ft. campaign-based fill-finish facility (one product at a time) Facility 2: Large scale high speed commercial manufacturing fill-finish facility
Batch Size	Facility 1: Manufacturing capacity – 1 L to 300 L Vials Capacity: 2 ml to 30 ml; Prefilled syringes: 0.1 to 10 ml ready solutions and lyophilised products Facility 2: Manufacturing capacity – 150 L to 1300 L Vials Capacity: 2 ml – 100 ml Filling speed: Max. 520 vials/min for 2 ml vial
Formulation Platforms	Conventional solution and lyophilised, plus nanotech (nanoparticles, nano-emulsions, liposomes), in-situ depot
Potent Handling	OEL $\geq 1 \mu\text{g}/\text{m}^3$ (non-cytotoxic); storage chambers at 2 °C – 8 °C and -20 °C



Why It De-risks Your Program



No Hand-off Gaps

DS and DP knowledge stay in one team, so nothing is lost in transfer between sites or vendors.



Aligned Analytics

Methods and release strategies are shared across substance and product from the start.



Faster to Clinic

Single-site accountability shortens the route to first-in-human supply.

Analytics & CMC Readiness

Data that De-risks Every Decision

Scientific decisions are only as strong as the analytics behind them. Our integrated analytical platform supports both peptides and oligonucleotides under one roof – defining quality, understanding impurities, and building the stability and release data that make CMC decisions earlier and filings smoother.

Analytical Capabilities

Area	Representative capability
Method Development & Validation	IP-RP, IEX, SEC, bioburden, and endotoxin methods for non-GMP and cGMP release
Identity & Sequence Confirmation	LC-MS and LC-HRMS; ESI accurate-mass MS / MS for sequence confirmation and variant detection
Impurity Analysis	Profiling, structural identification, and process-impurity tracking
Characterisation	Product and reference-material qualification, counter-ion, and peptide-content analysis
Stability & Stress Testing	Forced degradation and ICH long-term stability with stability-indicating methods

Instrumentation

HPLC and HPLC-SEC (Agilent 1260 / 1290 Bio), UPLC-IP RP (Waters Acquity), LC-HRMS (Thermo Orbitrap), ICP-OES / ICP-MS (Varian), Karl Fischer (Metrohm), UV (PerkinElmer), GC-MS (Agilent), and NMR (Bruker) standard and specialised analysis for routine release or one-off characterization, all in-house.

Outcome:

Robust specifications, clean CoAs and audit-ready documentation that de-risk IND / IMPD filing and smooth scale-up – analytically defined material, ready for downstream studies.

The Syngene Edge

Integrated science, scalable execution, and CMC confidence – for peptide and oligonucleotide programs that cannot afford avoidable delays.

01 Integrated CRDMO Model

One partner connecting discovery, development, analytics, GMP drug substance, sterile drug product, and clinical supply.

02 Dual-Modality Depth

Peptides and oligonucleotides supported through shared chemistry, analytics, and development infrastructure.

03 DS + DP Connectivity

Drug substance, analytics, formulation, and fill-finish aligned early on one site to reduce late-stage friction.

04 Analytical Confidence

Characterization, impurity profiling, release, and stability designed to strengthen CMC decisions.

05 Scalable Pathways

Clear capacity pathways for both modalities, from early material to commercial supply.



Company At A Glance

6000+
Scientists

400+
Active Customers

3 Mn sq. ft.
R&D and Manufacturing

32+ yrs
Scientific Expertise

Quality, Regulatory Strength, & Sustainability

01 Quality & Compliance

USFDA, EMA, and PMDA approved facilities; rigorous QMS across GMP, ISO, and OECD GLP.

02 Regulatory & IP

Support for IND, CTA and NDA filings with CMC; IP fully assignable to clients.

03 Sustainability (ESG)

92 % of power from renewable sources, 95 % of hazardous and non-hazardous waste recycled, and 63 % of total water use from recycled sources; zero waste to landfill across all facilities.

Accelerate Your Next Peptide or Oligonucleotide Program

Engage us early to align molecule complexity, analytical needs, scale-up expectations, and DS + DP requirements, and build the right development path from the start.

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