

Syngene

Putting Science to Work

Analytical Development & Testing

Science
For People
**ADVANCING
INNOVATION**

Certainty at Every Stage of
Your Molecule's Journey



Who We Are

The preferred integrated analytical sciences partner for complex CMC programs where quality, speed, and scientific problem-solving matter most.

End-to-End Analytical Development Solutions Across Molecules, Modalities & Innovation Platforms.

 USFDA / PMDA / Health Canada Approved	 >95 % QUOTIF Performance	 5S JUSE Certified	 Integrated Analytical Solutions
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 Product Line Services	 End-to-End Analytical Capabilities	 Key Differentiators
• Small molecules • Large molecules (Oligonucleotide / Polymers, Peptides, and mAb) • Complex injectable	• Drug substance analytical testing • Drug product analytical testing • Oligonucleotide testing • Polymers, Peptides, and mAbs testing • Special analytics support • Characterization and Reference Standards Qualification • ICH stability services • Nitrosamines and Genotoxic impurities testing • Extractable and Leachable testing • Medical device testing	• Blanket of Health Authority approvals (USFDA, Health Canada, PMDA, CDSCO, ISO standard) • 5S JUSE work place management certification • Phase-Appropriate Quality Systems (PAQS) • Integrated teams for integrated services • World class quality system • Proven delivery performance with >95 % QUOTIF (Quality On-Time In-Full)

 New Service Lines	 Technical Breakthroughs
Reference standard global program (RSGP) Ageing stability studies for large volume parenterals NG Tube studies High-potent API lab analytical testing capabilities	Challenge Pharmacopoeial Methods • Advanced method development • Complex analytical problem solving Gen AI in Documentation • Intelligent report generation • Faster turnaround • Enhanced accuracy & compliance

 Key Takeaway	Our analytical development team is your integrated analytical development partner delivering comprehensive testing, stability services, regulatory compliant solutions, and innovation-led capabilities across small molecules, large molecules and complex injectable.
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 Global Compliance	 World-Class Quality	 Integrated Delivery	 Future-Ready Innovation
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One Partner. Multiple Modalities. Global Quality. Future-Ready Innovation.

Why Syngene Analytical Development

Scientific Solutions Partner, Not Just a Testing Service Provider

We partner with clients to solve complex scientific, analytical, and CMC challenges throughout the product lifecycle. Our experienced subject matter experts, supported by dedicated project management and governance teams, deliver customized solutions tailored to the unique needs of each molecule and program.

Scale, Speed, and Regulatory Readiness

With one of Asia's largest analytical and stability infrastructures, Syngene supports development, registration, and commercial products across global regulatory markets. Our extensive stability capabilities enable accelerated development timelines while maintaining the highest standards of scientific and regulatory compliance.

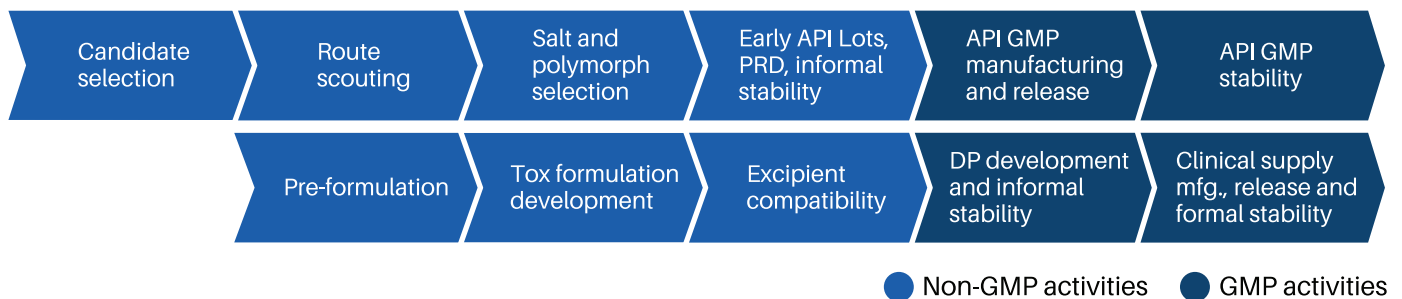
Advanced Analytical Expertise for Complex Molecules

Our specialized analytical platforms support the most challenging development programs, including:

- Nitrosamines assessment and control strategies
- Extractable & Leachable (E&L) studies
- Impurity characterization and unknown identification
- Elemental impurities (ICH Q3D)
- Large molecule and biologics characterization
- NG tube compatibility studies
- HPAPI and low OEL analytical support
- Reference standard qualification and lifecycle management

Integrated End-to-End CMC Support

Syngene offers a seamless analytical CMC ecosystem from preclinical to commercial lab support.



Quality and Compliance

Zero 483s, no critical audit observations with QUOTIF performance above 95 %.

Digital and Productivity Roadmap

Digital tools include - LIMS, EDMS, ELN, RFID, TrackWise, and LMS, along with TAT reduction, PAQS, documentation RFT, and productivity improvement priorities.



Drug Substance



Assay & related substances method development / validation



Method lifecycle: assessments, remediation, technology transfer



pH-solubility & stability profiling; pKa and partition coefficient



Intrinsic dissolution, characterization, polymorphic studies

Drug Product



Assay, related substances, and dissolution method development (Types I, II, IV)



Stability & forced degradation; excipient compatibility



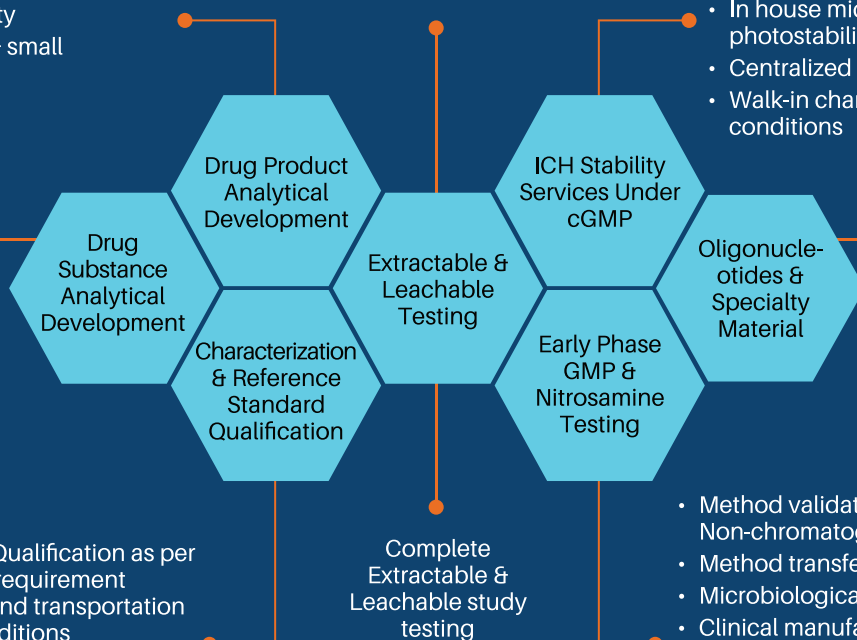
Analytical support for polymers, peptides, and small molecules

- Assay, RS, dissolution method development
- Stability studies
- Forced degradation studies
- Excipient compatibility
- Polymers, Peptides, & small molecules

- Life Cycle Management of analytical methods assessments and remediations

- Small molecules, Generics, Animal Healthcare, FMCG, Consumer Health
- Experience to handle any phase from FIH, NDA / ANDA and commercial
- In house microbiology testing, photostability testing
- Centralized logistics team
- Walk-in chambers as per ICH stability conditions

- Assay, RS method development
- pH-solubility and stability profile
- pKa determination, partition coefficient
- Intrinsic dissolution
- Melting point
- Hygroscopicity



- Reference Standard Qualification as per USP / pH Eur / Client requirement storage, portioning, and transportation under controlled conditions
- Isolation and characterization of impurities using HPLC UV / DAD / CAD, LC-MS / MS, GC-MS, IR, NMR, ATR
- Solid state characterization using pXRD, DSC, TGA, PSD, microscopy

Complete Extractable & Leachable study testing

- End-to-End analytical capability and service for
 - Therapeutic Oligonucleotides
 - Polymer & specialty materials
- Method validation - Chromatographic, Non-chromatographic
- Method transfer
- Microbiological and sterility testing
- Clinical manufacturing support
- Reference Standard Qualification
- Nitrosamine and Genotoxic impurity testing
- GMP QC lab for full release testing (Raw Materials, Excipients, Packaging Material, In Process, Cleaning Samples, Drug Substance and Drug Product)

Reference Standards and Drug Substance Characterization

- Comprehensive characterization for APIs: impurity isolation & ID using HPLC, LC-MS / MS, GC-MS, IR, NMR, ATR
- Solid-state analytics: pXRD, DSC, TGA, particle size distribution, microscopy
- Reference & working standards qualification and lifecycle governance
- Instrumentation depth: large HPLC / UPLC fleet with UV / DAD / ELSD / RI / CAD, Ion Chromatograph, LC-MS / MS, GC-MS, HRMS (Orbitrap), ICP-MS / OES, NMR (300 / 400 MHz)

ICH Stability Services (cGMP)

- Zones I – IVb refrigerated and photostability conditions with 24/7 online temperature / humidity monitoring; biometric access control
- Dedicated infrastructure for controlled drug substances / drug products and semipermeable packaging; photostability and in-house microbiology
- Stability studies support for all regions including PMDA (Japan)
- Capability in handling ageing studies for large volume parenterals
- Centralized logistics and regulatory support from IND to commercialization
- Backed by one of Asia's largest ICH stability centers for small and large molecules



Specialized Analytical Services

Nitrosamines & Genotoxic Impurities (GTIs)

- Methods for nitrosamines and NDSRIs; *in-silico* potency category prediction and enhanced Ames testing
- Integrated safety assessment team
- Programs aligned to ICH M7 principles and USP <1469>, with current frameworks for establishing acceptable intakes (AIs) for NDSRIs per FDA, Health Canada, and EMA / EDQM updates

Extractable & Leachable (E&L)

Our Study Involves the Below Steps:

- Material Selection – Identify potential extractables from packaging, components, and delivery systems
- Risk Assessment – Evaluate toxicological impact and define study scope
- Extractables Studies – Simulate worst-case conditions to identify potential leachable
- Leachable Studies – Monitor actual product-contact scenarios during stability and shelf life
- Regulatory Submission & Control – Align with PQRI, FDA, EMA, ICH, and USP guidelines for compliance

Key Capabilities for Oligonucleotide Analysis



Intact Mass Determination, Sequence Creation, & Editing

Build oligonucleotide sequences using predefined or custom building blocks.



Component Detection & Identification

Detect and identify oligonucleotide components using high-resolution accurate mass (HRAM) data.

Perform terminal truncation searching (3' or 5') to identify impurities like shortmers and longmers.



MS2 Fragmentation & Spectral Matching

Predict MS2 spectra using kinetic models and match them with experimental data.

Visualize fragment coverage maps to confirm sequence integrity and modifications.



Impurity & Degradation Product Analysis

Confidently identify and quantify impurities and degradation products using ddMS2 workflows.

Analyze stress-induced degradation (e.g., heat, oxidation) and compare purification methods.



Quantitative Analysis

Perform relative quantitation of oligonucleotide impurities across samples.



Modification Detection

Identify and quantify Post-Translational Modifications (PTMs) and chemical modifications like phosphorothioate linkages.

Reference Substance Management Capabilities

Lifecycle Management

End-to-end tracking from qualification to expiry, including requalification and retirement of reference substances.

Digital Inventory Control

Integrated systems (e.g., LIMS) for real-time tracking, stock management, and audit-ready documentation.

Qualification & Characterization

Reference standards are qualified using validated analytical methods to ensure identity, purity, and potency. ICH Q2(R2) guideline is considered as the primary reference for recommendations and definitions on partial validation characteristics for analytical procedures (i.e. analytical performance characteristics).

Secure Storage & Handling

Controlled environmental conditions (temperature, humidity) with monitoring and alarm systems to maintain integrity. Temperature Controlled Qualified equipment and Chambers ($5^{\circ}\text{C} \pm 3^{\circ}\text{C}$), Freezer ($-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$), and Deep Freezer ($-80^{\circ}\text{C} \pm 10^{\circ}\text{C}$) well maintained and equipped sensors with alarms.

Distribution & Traceability

GMP-compliant labelling, aliquoting, and distribution with full traceability across internal and client projects.

Regulatory Compliance

Aligned with global regulatory standards (ICH, USFDA, EMA), supporting audits and regulatory submissions.

Cross-functional Collaboration

Seamless coordination between Analytical Development, QC, QA, and regulatory groups for consistent reference standard usage.

Medical Device Testing Capabilities

Key Testing of Medical Devices

Key testing categories include functional testing, performance testing, safety testing, usability testing, E&L, and environmental testing. Other comprehensive testing include drop test, seal integrity test, packing integrity test, temperature & humidity exposure testing, Injection mechanism test, retention test (for auto injectors), plunger movement, needle bond strength and penetration test.

Universal Testing Machine for tensile strength (pulling), compressive strength (pushing), flexural strength, bending, shear, hardness, torsion testing and physicochemical, microbiological, and biocompatibility testing for medical devices, including polymers, coatings, and combination products.

Quality, Digital Systems, & Compliance

- 24/7 QC operations, robust SOPs, document control, incident management, and analyst qualification written as robust SOPs, document control, QMS with high standards of integrity and transparency
- 21 CFR Part 11 compliant instrument software / e-records / e-signatures; risk-based computerized system controls
- ALCOA+ data-integrity framework



What's New: Trends Shaping Analytical Development

- **ICH Q14/Q2(R2):** Lifecycle, risk-based method development / validation; enhanced approaches, multivariate analytics, and RT-release enablers
- **Nitrosamines (inclusive NDSRIs):** Updated AI frameworks and categorization approaches driving deeper risk assessment and control strategies
- **E&L maturity:** Risk-based PQRI-aligned strategies expanding to parenteral / ophthalmic, devices, and single-use systems
- **Oligo analytics surge:** Beyond IP-RP / IEX to HILIC and SEC for MS-friendly workflows and aggregation monitoring
- **Digital QA & Data Integrity:** Heightened ALCOA++/Part 11 expectations; paperless, audit-trail-centric operations as inspection-readiness differentiators

Partner with a Leader in Analytical Development

Syngene brings together deep scientific acumen, cutting-edge instrumentation, and a robust quality framework to deliver comprehensive analytical development solutions. From early-phase method development to late-phase validation and regulatory support, our capabilities are designed to ensure precision, reliability, and compliance at every stage. Whether it's impurity profiling, stability studies, or characterization of complex molecules, we help clients navigate analytical challenges with confidence.

With a commitment to data integrity, global standards, and continuous innovation, Syngene is the trusted partner for Pharmaceutical, Agro Chemical, Animal Health, and Biotech companies seeking excellence in analytical science.

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