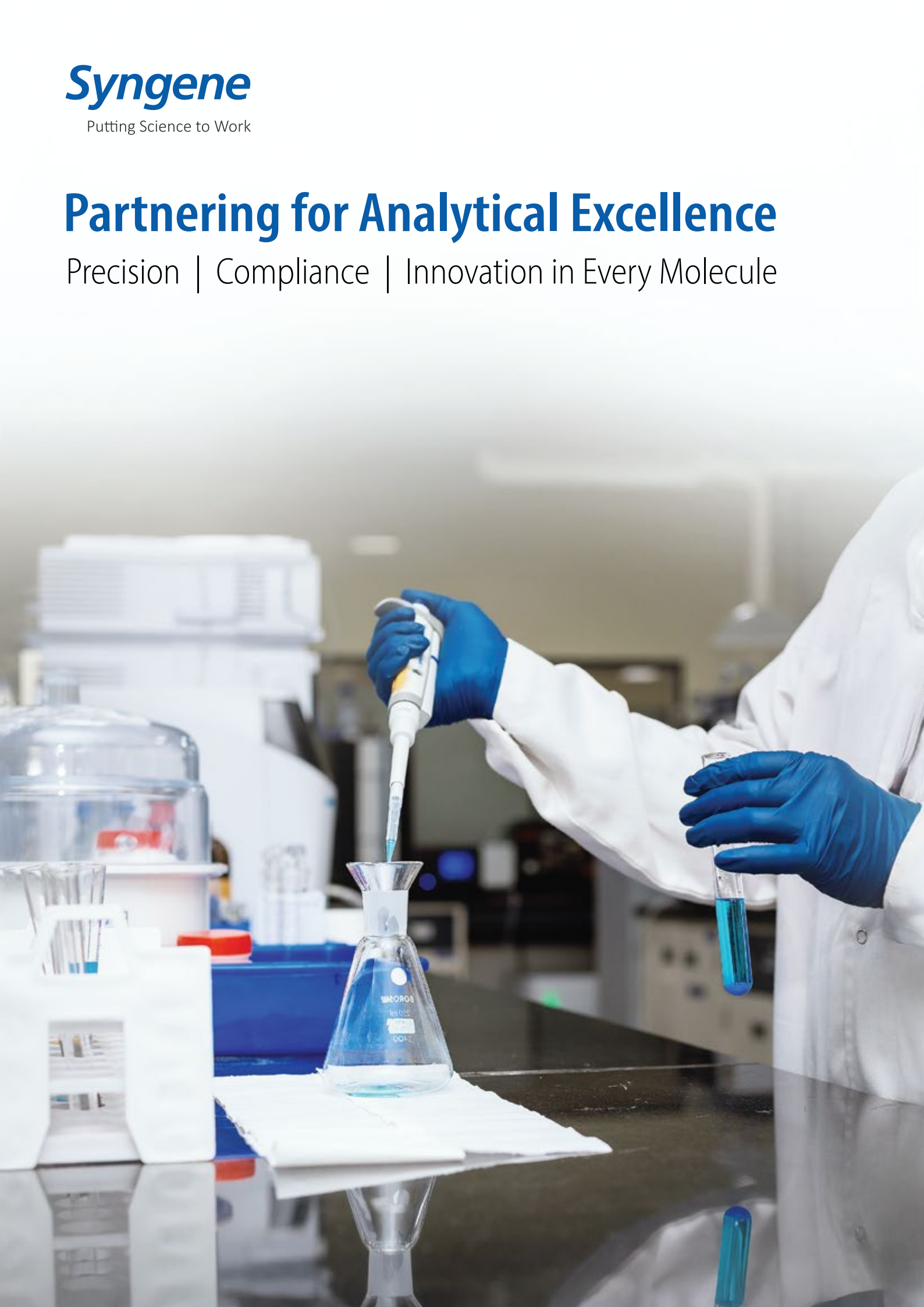
Syngene

Putting Science to Work

Partnering for Analytical Excellence

Precision | Compliance | Innovation in Every Molecule



Overview

Syngene is the go-to solution provider for pharmaceutical and biotech companies seeking precision-driven, regulatory-compliant analytical services. With over 300 scientists, Asia's largest ICH stability infrastructure, and global accreditations USFDA, PMDA, Health Canada, CDSCO, and ISO certifications such as 9001:2015, 14001:2015, 45001:2018, 27001:2013, and 13485:2016.

We deliver end-to-end analytical support across the drug development lifecycle.

Who We Are

Syngene delivers end-to-end analytical development for small molecules/large molecules & animal health—from early method development through validation, stability, and commercial QC. With 72,000+ sq. ft. of dedicated analytical and stability labs and one of Asia's largest ICH stability infrastructures, our scale, systems, and scientific depth accelerate development while safeguarding data integrity.

300+
Scientists

72,000+
sq ft lab.
Asia's Largest ICH stability Chambers

Accreditations
USFDA, PMDA, Health Canada, CDCSO
ISO STANDARD: 9001:2015, 14001:2015, 45001:2018, 27001:2013,13485: 2016

Why Syngene

- **Lifecycle-Aligned Analytics:** Risk-based method design, development, and validation aligned with ICH Q14 and Q2(R2) to ensure robust release and stability strategies
- **Regulatory-Ready Data Packages:** Submission-ready outputs mapped to global standards (FDA, EMA, PMDA & Health Canada) for seamless regulatory approvals
- **Stability at Scale:** Asia's largest ICH stability infrastructure with 24/7 monitored chambers across Zones I–IVb, plus photostability and microbiology under cGMP
- **Digital Quality & Data Integrity:** Paperless, 21 CFR Part 11-compliant systems powered by LIMS, TrackWise, and ALCOA+ principles for audit-ready operations
- **Flexible Engagement Models:** FTE and FFS options with proven vendor transitions and client-aligned QA for maximum agility

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Analytical Capabilities

Drug Substance

Assay & related substances method development/ validation

Method lifecycle: assessments, remediation, technology transfer

pH–solubility & stability profiling; pKa and partition coefficient

Intrinsic dissolution, melting point, hygroscopicity

Drug Product

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

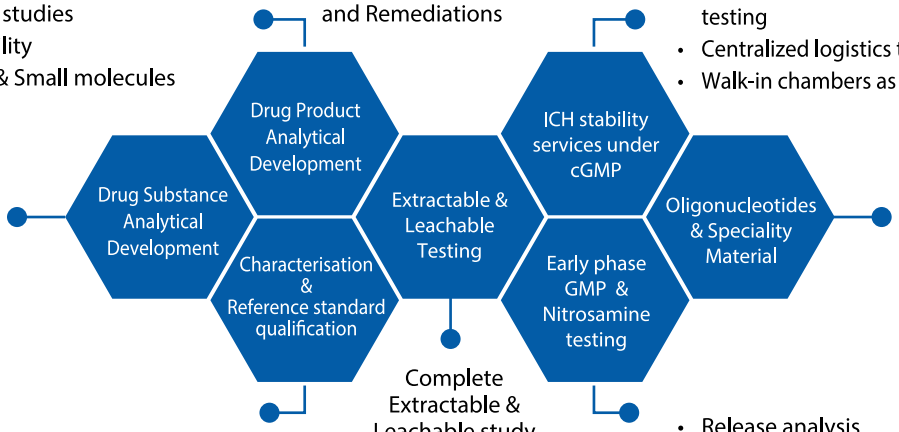
Stability & forced degradation; excipient compatibility

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 form 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

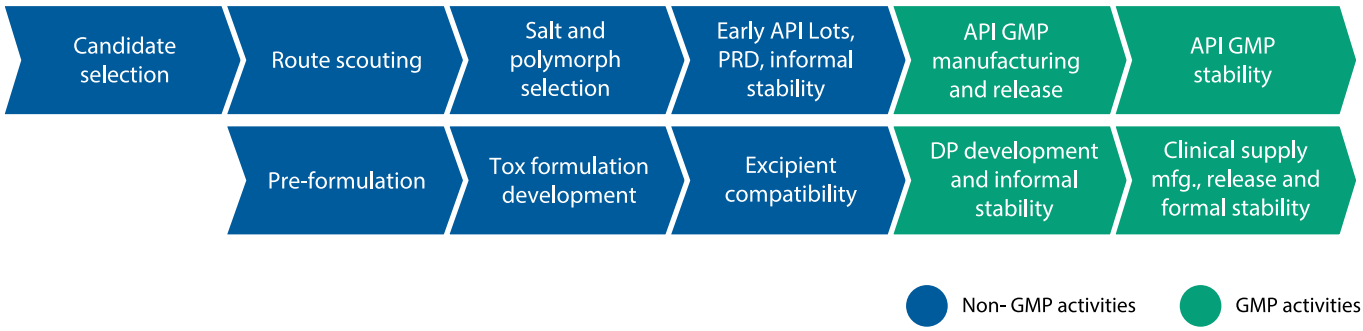
- End to End analytical capability and service for
  - Therapeutic Oligonucleotides
  - Polymer & specialty materials

Complete Extractable & Leachable study testing

- 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-HS-MS, IR, NMR, ATR
- Solid state characterization using pXRD, DSC, TGA, PSD, microscopy

- Release analysis
- Method validation- *Chromatographic, Non-chromatographic*
- Method transfer
- Clinical manufacturing support
- Reference standard qualification
- Nitrosamine and Genotoxic impurity testing

Integrated analytical support: Non-GMP and GMP activities



Characterization & Reference Standards

- Comprehensive characterization for APIs and drug products: impurity isolation & ID using HPLC, LC-MS/MS, GC-HS-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 photo-stability conditions with 24/7 online temperature/humidity monitoring; biometric access control
- Dedicated infrastructure for controlled drug substances/ drug products and semi-permeable packaging; photostability and in-house microbiology
- 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
- 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

Extractables & Leachables (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 leachables
- Leachables 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

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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 – Syngene 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±3°C), Freezer (-20±5°C), and Deep Freezer (-80±10°C) well maintained and equipped sensors with alarms

Distribution & Traceability

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

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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 Can be 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.

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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