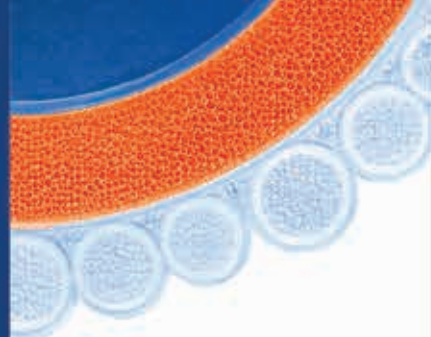


Syngene

Putting Science to Work



Science
For People
**ADVANCING
INNOVATION**

Reference Standard Qualification & Management

One Partner Across
Synthesis, Qualification,
Storage, and Traceability



Why Reference Standards are Mission-Critical

Reference standards are the benchmark for identifying and quantifying your drug substance and drug products (APIs, impurities and metabolites). If the standard is wrong, everything measured against it is wrong. We treat qualification and lifecycle management as a core discipline, not an afterthought, so your data holds up to the toughest scrutiny.

300+ Scientists	72,000+ Sq. ft. analytical & stability labs	Asia's Largest ICH and non-ICH stability infrastructure	RT to -80 °C Monitored storage range
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Accreditations: USFDA, PMDA, Health Canada, CDSCO | ISO 9001:2015, 14001:2015, 45001:2018, 27001:2013, 13485:2016

Analytical Accuracy Every identity, purity, potency, assay, and impurity level is only as reliable as the standard behind it.	Regulatory Compliance Qualified standards are mandatory for method validation, cGLP, and cGMP testing against global pharmacopeial requirements.
Risk & Delay Mitigation Proactive requalification and retest management prevent costly errors and timeline slips.	Quality & Patient Safety Reliable standards protect product integrity across the full drug lifecycle.

The Full Lifecycle, Under One Roof

We manage your reference standards from synthesis / procurement to CSU (continued suitability for use) supplies to retirement, so you never have to stitch together multiple vendors for synthesis, characterization, storage, and traceability.

- **Procurement, receipt & selection:** We synthesize / source and qualify standards with rigorous pre-assessment for reliability from day one
- **Qualification & requalification:** Validated analytical methods confirm identity, purity, and potency against global pharmacopeial requirements, aligned to ICH Q2(R2). Expired and retest standards are managed proactively
- **Characterization:** In-house impurity isolation and structural confirmation using HPLC UV / DAD / CAD / ELSD / RI, LC-MS / MS, HR-MS, GC-MS, IR, NMR, and ATR, plus solid-state analysis by pXRD, DSC, TGA, PSD, melting point, and microscopy
- **Secure storage:** Scientifically defined conditions across room temperature, 2 °C – 8 °C, -20 °C ±5 °C, and -80 °C, with 24/7 monitoring, and alarms
- **Controlled dispensing & usage:** Integrated LIMS captures every issuance and use, giving you real-time visibility and audit-ready records

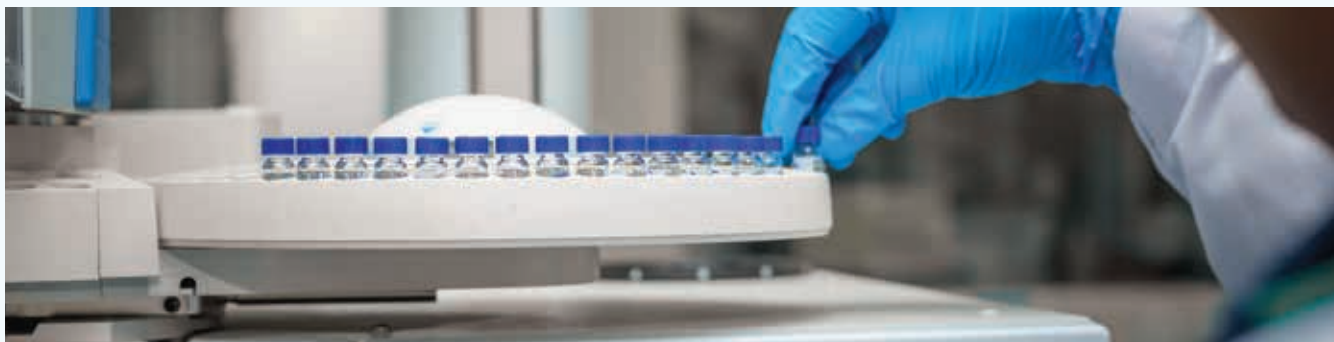
Our USP: Comprehensive Where Others are Fragmented

Most providers cover a slice of the reference standard journey. You end up coordinating a supplier for material, a lab for characterization, and a separate facility for storage, carrying the compliance risk across every hand-off. We bring the whole chain together in one integrated, LIMS-tracked service.

Capability	Typical / Fragmented Provider	Syngene
Standard synthesis & isolation	Often outsourced	In-house
Structural characterization (NMR, LC-MS / MS, HRMS, pXRD, DSC)	Partial / referred out	Full in-house fleet
Qualification & requalification (ICH Q2(R2))	Varies	Validated protocols
All standard types: PRS, CRS, in-house & working, qualitative	Limited	Complete range
Multi-condition secure storage (RT to -80 °C)	Limited range	Full range, monitored 24/7
LIMS dispensing, traceability & retest alerts	Manual / partial	Fully integrated
Global accreditations & audit support	Selective	USFDA, PMDA, Health Canada, CDSCO

Intelligent Storage & Monitoring

- Real-time, validated temperature tracking across every condition, from room temperature to -80 °C ± 20 °C for high-value standards
- Proactive trend analysis to catch drift before it becomes a deviation
- Scientifically defined conditions that keep sensitive materials stable and compliant



Why Partner with Syngene

Comprehensive Expertise

End-to-end capability across synthesis, characterization, qualification, and storage.

Advanced Infrastructure

A full spectrum of analytical technologies delivering uncompromising precision.

Global Compliance & LIMS

Robust systems for CoA tracking, retest notifications, and inventory management.

Flexible Partnership Models

Tailored solutions for pharma and biotech, built for speed and scalability.

Flexible Engagement Models

- **Dedicated R&D labs:** Ring-fenced infrastructure and teams built to your specifications for long-term programs
- **FTE:** Dedicated scientific resources from your chosen disciplines, evolving as the project advances
- **FFS:** Flexible, on-demand support with defined scope, ideal for fluctuating or ad-hoc demand
- **Risk-reward:** Milestone-based engagement across discovery, development or truly end-to-end

Ready to De-Risk Your Reference Standards?

Talk to us about an integrated qualification and management program for your molecule.

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