

A close-up photograph of a female scientist in a white lab coat, wearing safety glasses and a light blue surgical mask. She is holding a test tube with a green liquid inside. In the background, another scientist is visible, also in a lab coat and mask, looking at a test tube. The background is blurred, showing laboratory equipment and shelves.

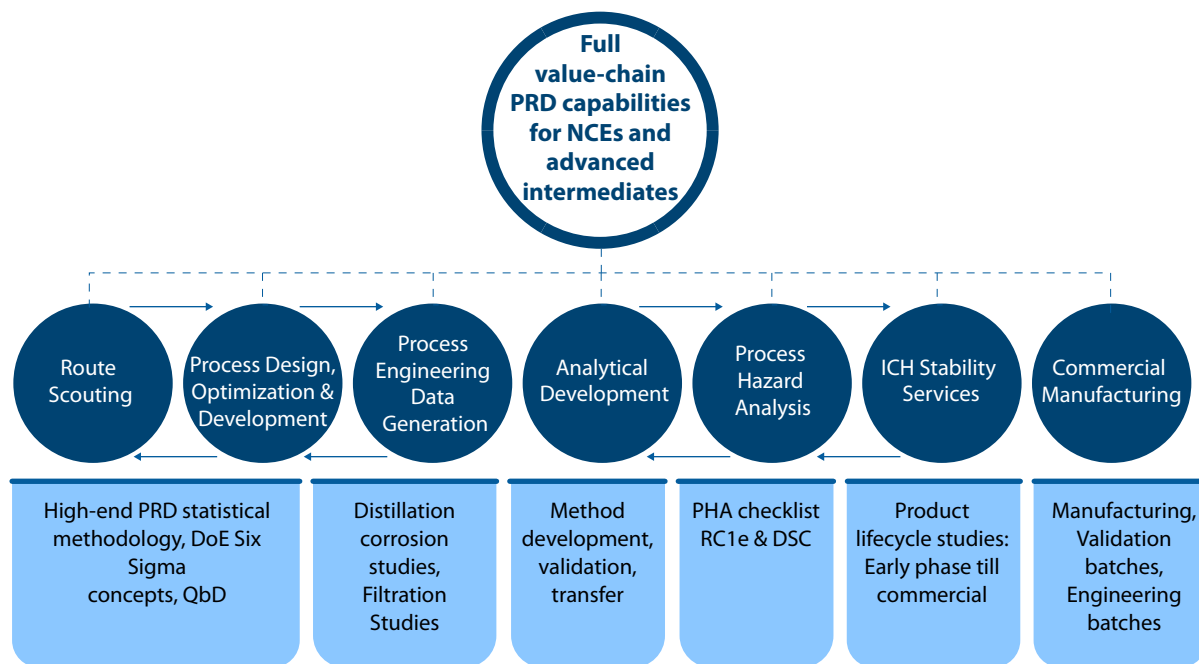
Syngene

Putting Science to Work

Chemical Development

Innovate | Integrate | Customize | Accelerate

Chemical Development



Highlights

- 125+ fume hoods in multiple suites
- Automated lab scale jacketed reactors (-70- to 180 °C)
- OEL- micro gram 0.1 $\mu\text{g}/\text{m}^3$ - 8h
- Flow Chemistry
- Dedicated process engineering and safety lab
- HPAPI development from lab to Manufacturing scale
- Therapeutic and Diagnostic Oligonucleotide- from Lab to Manufacturing scale
- Performance and Speciality Materials - synthetic organic chemistry, polymer chemistry and scale-up activities
- Integrated analytical services- analytical method development, validation, transfer and reference standard qualification
- Regulatory Support

Oligonucleotides

Salient Features

Therapeutic oligonucleotides

- Process development and cGMP supplies
- Antisense oligos (ASOs), siRNA, Anti-miRNA
- Process R&D laboratory and cGMP manufacturing plant
- Equipped with ÄKTA oligopilot 100 and ÄKTA oligopilot 400 synthesizers
- Platform technology based on solid phase synthesis
- Tox to clinical supply- 100 mg to 135 mg per batch
- Base, backbone and sugar modifications
- Natural and modified DNA/RNA oligos
- Conjugated oligos (lipid & GalNAc), Aptamers, Morpholino oligos & Fluorescent oligos

Diagnostic Oligonucleotides

- Primers and Probes
- Desalted as well as HPLC purified
- Highly sensitive and structured molecular beacons
- Wide variety of fluorophores - FAM, HEX, JOE II, Cy3, Cy5

Enzymatic synthesis

- Synthetic dsRNA Analogues
- Poly (I:C)

Oligonucleotide analytical services

- Combination of orthogonal analytical techniques
- Analytical method development/method validation
- Identification, purity impurity analysis, and sequence confirmation
- Product characterization/reference material qualification



High Potent API

Capabilities

- Integrated solutions from Discovery, Process R&D, Optimization, Scale-up & Clinical supplies to Commercialization
- OEL determination toxicity studies
- cGMP manufacturing
- Facilities designed to handle cytotoxic, cytostatic and high potent compounds with OEL values in the range of $>100 \mu\text{g}/\text{m}^3$ to $0.1 \mu\text{g}/\text{m}^3$
- Isolators for full spectrum of unit operations from Sampling, Dispensing and Weighing, Reactor charging, Filtration, Drying, Milling & Sieving to Packing
- Broad range of Reactors (Stainless steel, Glass lined, Hastelloy)

Highlights

- Highly experienced process chemists, analytical chemists, process engineers, manufacturing and QC team
- cGMP facility for lab-scale to commercial-scale manufacturing including registration and validation batches for regulated market
- Integrated with a separate cGMP facility to manufacture non potent compounds.
- Provision to add reactor & matching downstream equipment to enhance capacity/capability
- PAI inspection for the API registration and validation batches



Performance and Specialty Materials

Capabilities

- Synthesis and Purification of Monomers/Polymers
- Functionalization chemistry
- Material Characterization
- Process Development & Process Engineering
- GMP and Non-GMP manufacturing capabilities

Monomers

Acrylates; Schiff bases; Ionic liquids; Radical compounds; Macrocycles; Heterocycles, End functionalization of polymers; Light and air sensitive compounds

Polymers

Supramolecular Polymer; Conducting Polymers; Polymer Self Assembly; Self-healing Polymers; Hydrogels; Silicones; Random/Block/star/comb copolymers

Materials

Inorganic Materials; Additives; Catalysts; Biomaterials; Nanomaterials-Nanofibers, CarbonNanoTube (CNT)

Highlights

- Excellent track record of continuous supply of polymers & specialty materials (250-500 kg/batch), Nano materials (1-2 kg) and additives (10-100 kg scale)
- cGMP compliant facilities inspected by USFDA and audited by global customers and QPs from Europe
- Innovation on specialty materials and polymers from lab scale to commercial manufacturing level



ICH Stability Studies

One of Asia's largest Stability and Analytical facility spread across 72,000 sq. ft.

Capabilities

- End-to-end offerings including
 - License application
 - Centralized logistics team to handle all inbound and outbound shipments fast clearance being In Sez
 - Statistical analysis
- Studies at different phases – FIH, NDA/ ANDA and Commercial
- Multiple walk-in and reach-in chambers covering all climatic zones as per ICH Q1 A(R2), Q1B, Q1C and Q1 F guidelines
- Dedicated centres customised to client requirements

Highlights

- Diverse experience in handling Generic, Animal Health, CPG, Nutrition and OTC products
- Comprehensive analytical solutions including method development, validation and in-house microbiology testing
- Backup chambers available as part of business continuity plan
- Biometric access control system for individual chambers apart from overall facility with access control
- Separate infrastructure for handling steroids, hormones, narcotics and other special categories
- USFDA, PMDA, Russian Regulatory Agency approved facility
- Electronic data management systems as per 21CFR, Part 11 compliance





For more information, contact bdc@syngeneintl.com

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