

**cGMP
& Process
Chemistry**

Process Chemistry And cGMP API Manufacturing



The SCYNEXIS process chemistry team is capable of solving the most complex chemical development issues in a fast and efficient manner. A distinguishing feature of our team is the equal balance between experienced process and analytical chemists. The team is focused upon developing safe, scalable processes and has an excellent track record of providing innovative solutions to drug development companies across the globe.

The selection of a Process Chemistry outsourcing partner is one of the most critical decisions in your drug development program. At SCYNEXIS, you gain the skill level, experience and infrastructure of a big company with the responsiveness and agility of a focused chemical development team. Our facilities are registered with both the FDA and DEA.

Process Chemistry Core Capabilities

Custom Syntheses

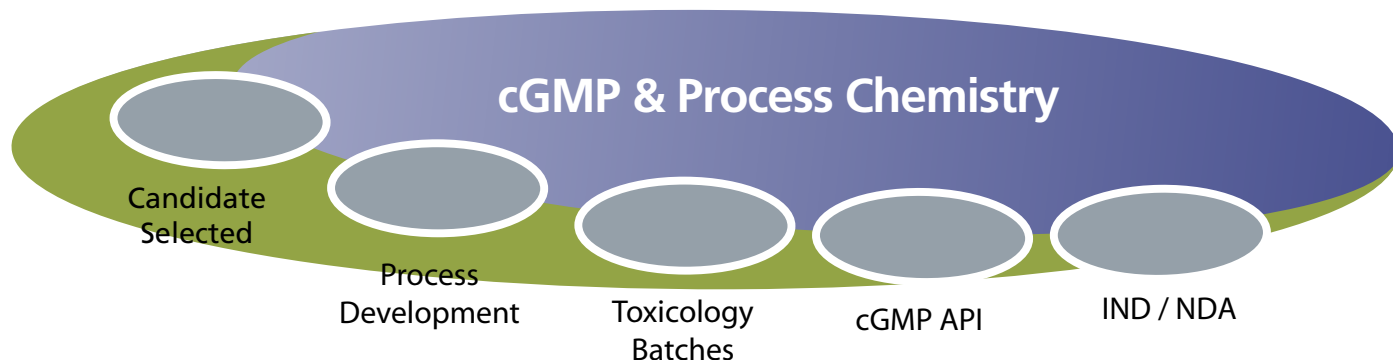
- Intermediates
- Reference Standards
- Preclinical Toxicology Batches
- Degradants & Impurities
- Metabolites
- Controlled Substances

Chemical Development

- Scale-up of MedChem
- Route Identification
- Route Development
- Process Optimization
- Novel Route Design
- Intellectual Property Protection

cGMP API Production

- Early Clinical Supplies
- Small Scale Phase 3 Supplies
- Small Scale Commercial
- Orphan Drugs
- Quality Assurance Auditing
- FDA-Inspected cGMP Facility



Customer-focused Process Research:

Chemical process development is as much art as it is science and at SCYNEXIS our artistry begins with our creative chemists. At SCYNEXIS, you will find our chemical expertise is second to none. The process chemistry team provides practical solutions for complex chemical problems based upon extensive industry experience. Our average chemical development scientist has worked in the pharmaceutical or CRO business for more than 15 years. More than half of the SCYNEXIS chemical development team members hold Ph.D. degrees and our facilities are best-in-class.

Our project managers will ensure their teams meet the most demanding timelines using the flexibility of multiple resourcing models including: Time & Materials, Fixed Bid Contracts and Full-Time Equivalent (FTE) programs with dedicated resources. Our team has outstanding analytical support including in-house NMRs (GMP-compliant), multiple LC-MS systems, GC-MS, and more than 30 HPLC systems. The team consists of dedicated experts to assist in all method development, validation and impurity identification activities to accelerate your chemical development programs.

Chemical Process Development Expertise Areas:

Our team has particular expertise in the following areas of chemical development:

Selected Chemical Process Development Expertise Areas

- Nucleosides
- Chiral Resolutions
- Asymmetric Syntheses
- Natural Products
- Carbohydrates
- Heterocyclic Chemistry
- Hydrogenation
- Pressurized Reactions
- Stable-labeled Compounds

cGMP Manufacturing Suites & non-GMP Kilo Facilities:

- FDA-inspected (PAI 2009)
- 3 separate GMP Suites
- Controlled access, dedicated air handling
- QVF Glass Fixed GMP Reactors: 25 L to 200 L
- Glass-lined Stainless Steel GMP Reactor: 200L
- Huber heaters/chillers including low temperature (-80°C)
- Versatile non-GMP facilities
- Non-GMP Reactors: 20 L to 200 L QVF glass fixed reactors
- 6" Biotage chromatography systems



Selected Achievements:

- Reduced cost of goods (COGS) by more than 88% for a client that originally placed the initial phase of the project with an Asian CRO, saving the client more than \$72,000 per kilogram of API
- Performed full technical transfer of a Phase 3 nucleoside campaign in six weeks from client contact to batch release
- Rapidly scaled-up a lab-scale process from milligrams to multi-kilograms of GMP material while removing costly chromatography and lyophilization.
- Reduced 16-step synthesis to six steps with an innovative chemical development approach
- Developed Intellectual Property (IP) for client to produce enantiomerically pure compound by simple recrystallization



From Concept To Clinic With Speed And Innovation™

SCYNEXIS, Incorporated • PO Box 12878 • Research Triangle Park • North Carolina • 27709-2878 • USA • +1.919.544.8600

WWW.SCYNEXIS.COM

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