REGIS® CUSTOM PHARMA

CGMP Custom Manufacturing

Expedite Your Drug to Market

Expertise & Experience

Regis has successfully brought multiple products through validation and onto the market. Put our expertise in synthesis and pharmaceutical services to work to speed your drug to market. We will advance your active pharmaceutical ingredient (API) from initial pre-clinical development to scale-up and clinical trials, through validation and commercial manufacturing.

Regulatory Compliance

The U.S. Food & Drug Administration (FDA) routinely inspects our CGMP facility. Our last three FDA audits have earned perfect results with zero objectionable findings (i.e. Form 483 observations). Regis uses internal and customer audits, consultation, and training to continuously prepare to meet the FDA's and Regis' own standard of excellence.

"Excellent work on a cost competitive basis. Strong technical capabilities and excellent communication. Would not hesitate to return or recommend to colleagues."

–Chris Bemben, Lumos Pharma

People

Customers consider us for our technical expertise and outstanding history of FDA compliance, but they choose us for the engaging people found in every department from purchasing to process development. Our team has a wealth of experience and education, and we look forward to introducing you to each person who will contribute to your project.

Reachable & Responsive

We value your input as much as your business. We are family-owned and operated, and our small size allows us to be accessible, responsive, and to act quickly. Our team of experienced Chemists, Project Managers, and support staff values each client and is dedicated to helping their work move forward.

Project Management

Your dedicated Project Manager will take the time to get to know you and what you feel would make the project successful, including timelines, quantity, and quality. In constant communication with our analytical, production, and quality groups, your Project Manager ensures everyone is working to best meet your needs and keeps you informed and included. All Project Managers have chemistry backgrounds and industry experience.

CGMP MANUFACTURING

Initial Process Development to Commercial Manufacturing

PROCESS RESEARCH & DEVELOPMENT

Process Design to Validation

HPAPI MANUFACTURING

Dedicated Potent Compound Suite

STRUCTURE ELUCIDATION

Isolation, Characterization, Scale-up, and Qualifcation

SOLID STATE CHEMISTRY

Polymorph, Salt, Cocrystal screens and form selection

ANALYTICAL METHOD DEVELOPMENT

Standalone and complementary analytical support services

SEPARATION SERVICES

Fast & Efficient CGMP gravity, HPLC, and SFC separations

QUALITY CONTROL

Reliable evaluation and production support for product integrity

QUALITY ASSURANCE

A comprehensive CGMP compliance program

Learn more about our services and take a virtual facility tour at registech.com.

Regis Custom Pharma At a Glance

CGMP Facility

FDA inspected • 36,000 square feet of production space
Individual Reactor Suites from 25 to 500 gallons • Flow Reactors
Single Pass HEPA Filtered Air, NMR, UPLC, ICP- MS, GC/MS, XRPD, DSC, TGA, & LC/MS/MS Instruments

Synthesis

Process Research
Route Development • Critical Process Parameters
Identification & Synthesis of Process Impurities

Production & API Manufacturing
R&D Suites • Potent Compound Suite • Kilogram Suites
Nine Production Suites • Cryogenic Suite • Lyophilization

Pharmaceutical Services

Analytical Method Development
HPLC, GC & ICP-MS Method Development, Validation & Transfer

Quality Control
API Release • Reference Standard Qualification • Structure Elucidation

Stability Services
Forced Degradation Studies • ICH-compliant Stability Studies

Solid State Chemistry Services
Polymorph Studies • Salt and Cocrystal Screens
Crystallization Development

Quality Assurance

Customer & Agency Audits • GMP Release

Contact us for more information. We look forward to advancing your work.

ABOUT REGIS TECHNOLOGIES, INC.

Regis Technologies, Inc. is a privately held company that partners with pharmaceutical and biotechnology companies to help expedite drugs to market. We offer unrivaled expertise in synthesis, analytical and separation services to scale your active pharmaceutical ingredients (API) from initial process development to validation and commercial manufacturing. For more information, please visit www.registech.com.

t 847.967.6000
f 847.967.5876

www.registech.com

sales@registech.com

8210 Austin Avenue
Morton Grove, IL 60053