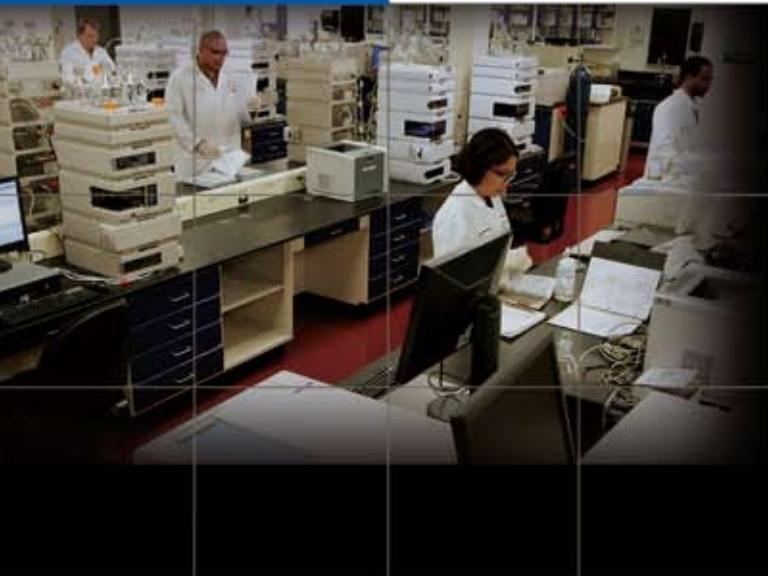




Regis Technologies cGMP Custom Manufacturing



Expedite Your Drugs to Market

► From Small-Scale Synthesis to Commercial Manufacturing

Put Regis' long-standing expertise in synthesis, chiral separations and pharmaceutical services to work to speed your drug to market. We will advance your active pharmaceutical ingredients (API's) from initial pre-clinical development to scale-up and clinical trials, through validation and commercial manufacturing.

Manufacturing Services	Pre-Clinical	Phase I	Phase II	Phase III	Commercial
GMP Synthesis					
Non-GMP Synthesis					
Process Development					
Process Scale-Up					
Critical Parameter Evaluation					
Analytical Method Development					
Analytical Validation					
Structure Elucidation					
Ref. Std. Characterization					
Analytical Release					
Stability Services					
Quality Assurance					
Supplier Qualification & Audits					
Cleaning Validation					
Process Validation					
Project Management					
Regulatory Support					
Preparative SFC Separation					

"We aim to exceed our customers' expectations. That's why more than 90% of our customers return to Regis for more synthesis and separations services."

*Dr. Louis Glunz III,
Founder, Regis
Technologies, Inc.*

► Combining Synthesis and Separation

Expedite your compound's timelines by combining custom synthesis and preparative separations. Small-scale non-GMP syntheses and larger-scale GMP syntheses are efficiently separated using supercritical fluid chromatography (SFC) and commercially available stationary phases. Partner with a separations expert that is a leader in chiral stationary phase technology. Regis offers free screening of your chiral and achiral compounds.



Quality Assurance



Process Research



Business Development



Production

**The Right Services
For Your
Project's Success**



Analytical Method Development



Project Management



Separation Services



Quality Control

► It's Good Science

Synthesis Expertise

Completing complex syntheses for over 50 years, our strength lies in solving complex chemistry problems and developing scalable chemical processes to produce syntheses suitable for commercial manufacturing. Regis' team will take you from initial development through commercialization.

Pharmaceutical Services

In-house expert Analytical Method Development services including: HPLC (chiral and achiral), LC/MS and GC methods, stability indicating methods and method validations. In-house Quality Control services including: API release, Reference Standard Characterization, Structure Elucidation and ICH compliant stability.

Preparative Separations

Separate your chiral and achiral products efficiently using SFC. Milligrams to kilograms, separations are conducted on a GMP and non-GMP basis. Regis has been a leader in chiral stationary phase technology for over 25 years.

► It's Good Business

Quality Compliant

Partner with a Quality Systems driven organization with over 16 years of GMP experience. Regis is regularly inspected by the FDA, other regulatory agencies and has successful PAI experience.

Effective Project Management

Rapid project execution reduces your project timelines. Projects are managed efficiently by effective communicators with chemistry expertise.

Affordable and Flexible

Make the most of your budget by working with a trusted, affordable U.S. service provider that adapts to meet your evolving needs.

IP Protection

Regis Technologies is committed to the full and complete protection of your intellectual property.



Regis Technologies At A Glance

► Facility

All services conducted at our 51,000-square-foot U.S. facility located minutes from Chicago O'Hare Airport

► Synthesis

Process Research

Production and API Manufacturing

Reaction calorimeter

R&D development suites

Kilogram suites

Eight production suites 25-500 gallons

Lyophilization

Cryogenic suite

WFE distillation

Large-scale, low-pressure chromatography

► Separation Services

GMP and non-GMP separations from milligrams to kilograms

Free screening

► Pharmaceutical Services

Analytical Method Development

HPLC and GC method development

Method validation

Stability indicating method development

Quality Control

API Release, Reference Standard Characterization, Structure Elucidation

HPLC, LC/MS

GC, GC/MS

NMR, FTIR

Particle Size

LOD, KF

DSC, CV

Stability Services

Force degradation studies

ICH-compliant stability studies

► Quality Assurance

Customer and Agency Audits

Vendor Qualification

SOP Training

CAPA

Validation

GMP Release

► Chromatography

Pirkle-type columns

Polysaccharide-based chiral columns

Bulk stationary phases

GC derivitization reagents

For more information,
contact Mr. Sean F. Bradley,
Director of Business Development

Email: sbradley@registech.com

Phone: 847.583.7631

*We look forward to
meeting your needs.*

About Regis Technologies, Inc.

Regis Technologies, Inc. is a privately held company that provides cGMP and non-GMP synthesis and separations services to the pharmaceutical, biotechnology, and other industries worldwide. Regis partners with these organizations to provide synthesis services including: analytical method development, synthesis development, scale up, SFC preparative separations, validation and stability services toward the manufacture of complex custom synthetic products. Regis provides innovative chromatography products and services, especially those with a chiral emphasis.

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