REGIS CUSTOM PHARMA

Expediting APIs from Preclinical to Commercial

REGIS® TECHNOLOGIES, INC.
CUSTOM PHARMA CDMO | CHROMATOGRAPHY PRODUCTS

A Comprehensive Portfolio of Drug Substance Services

REGIS Technologies, Inc. partners with pharmaceutical and biotechnology companies to help accelerate drug candidates to market. Our combined expertise in **Process Chemistry, Manufacturing**, **Solid State Chemistry**, **Analytical Services** and **High Potency API** allows us to seamlessly scale your API from initial process development to validation and commercial manufacturing.

- Privately-held **US-Based Company**, established in 1956
- A **Small Molecule CDMO** for preclinical to commercial products
- A **Single-Site Manufacturing Facility**, with direct access to our technical teams at all times
- We offer an innovative line of **Chromatography Columns** and **Specialty Reagents**

CGMP MANUFACTURING
CGMP Scale up, Clinical Supply, Commercial API

QUALITY ASSURANCE
Proven Systems for Global Compliance

HPAPI MANUFACTURING
Initial Process Development to Commercial Manufacturing

PROCESS DEVELOPMENT
IND Enabling Through Late-Stage Development, In-house Thermal Hazard Evaluation

SOLID STATE CHEMISTRY
Salt, Co-Crystal and Polymorph Screening During All Phases of Development

STRUCTURE ELUCIDATION & IMPURITY SERVICES
Identification, Characterization, Isolation, Synthesis and Qualification

QUALITY CONTROL
Reliable Evaluation and Production Support for Product Integrity

ANALYTICAL DEVELOPMENT
Process Support, IPCs, Release Methods, Development and Validation

Rely on **REGIS'** decades of organic synthesis expertise to solve your chemistry challenges and expedite your next drug to market, *fast*.

FACILITY

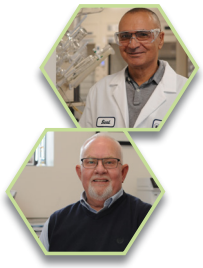
100,000 sq ft. CGMP Facility

- **20,000 sq ft. Production Area**
- **6,500 sq ft. Analytical Development/QC**
- **6,200 sq ft. Single Pass HEPA Filtered Air**
- **9 CGMP Reactor Suites**
  - Cryogenic Suite
  - Single Pass HEPA Filtered Air
  - 63 - 2000 L Glass-lined Reactors
  - Typical Output 1–150 kg/Batch
  - Self Contained Filter Dryers
  - Containment for OEL > 1 ug/m_3

- **4 CGMP Kilo Suite**
  - 5L-50 L Jacketed Glass Reactors
  - Typical Output 100 g - 1 Kg
  - Single Pass HEPA Filtered Air
- **CGMP Separations**
  - Large Scale Gravity Columns for Kilo Scale Operations
- Biotage® Isolera Flash 150, 400 mL
- **Potent Compound Suite**
  - Containment for OEL - 0.05 1 ug/m_3
  - Reactors up to 22 L
  - Single Pass HEPA Filtered Air
- **Drying/Finishing Suites**
  - Shelf Dryers
  - Lyophilizers
  - Single Pass HEPA Filtered Air
- **Production Operations Seven Days a Week**

Synthesis

- **Process Chemistry**
  - Route Scouting Development and Optimization
  - Critical Process Parameters
  - Fate and Purge
  - Identification & Synthesis of Process Impurities and Reference Standards
  - Solid Isolation



SERVICES AND EQUIPMENT

Pharmaceutical Services

- **Analytical Method Development**
  - GC & ICP-MS Method Development
  - Validation & Transfer
  - Analytical Instrumentation
    - HPLC, UV/VIS, ELSD, RI, CAD, UV, UPLC
    - NMR: 400/600 MHz
    - ICP-MS, GC/MS
    - XPRD, DSC, TGA
    - LC/MS, UPLC-MS
    - Polarimeter
    - Particle Size Analyzer
    - Microscopy: Polarized & Thermal

- **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 & Cocrystal Screens
  - Crystallization Development

GLOBAL QUALITY STANDARDS

Regulatory

- **FDA Facility Registration #1416120**
- **>10 Years of Clean Compliance (no 483s)**
- **100 NCEs brought into Clinical Trials**
- **> 10 CGMP programs commercialized**

Global Quality Standards

- **ICH Q7 Good Manufacturing Practices**
- **Title 21 210/211 for APIs**
- **EU Directive 2003/94/EC**
- **WHO Guidelines**

To learn how REGIS can help advance your next drug candidate to market
Contact a REGIS Custom Pharma Expert for more information at customsales@registech.com.

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