

Chemical Services for Pharmaceutical Development

Ricerca Biosciences is a leading USA-based independent contract development organization. We provide the full spectrum of services needed to support the commercial development and launch of innovative new pharmaceuticals. Our extensive client base ranges from the established research-based multinational drug companies to emerging biopharmaceutical companies focused on the discovery and development of small-molecule drugs. Our project approach is tailored to meet the specific technical and timing needs of our clients' development programs.

Our specific capabilities include:

Synthetic Chemistry

- *De novo* synthesis
- Chiral synthesis
- Analogs
- Metabolite & degradant identification
- Radiolabeled synthesis (^3H , ^{14}C , ^{32}P , ^{35}S)
- Analytical reference standards

Analytical Chemistry

- Full FDA GLP & cGMP compliance
- Comprehensive problem solving
- Expertise in HPLC, GC, GC-MS, thermal, microscopy, XRD, ICP, FTIR, UV/Vis, NMR, LC-MS, LC-MS/MS, dissolution testing, and an extensive suite of classical chemical and physical tests
- Microbial laboratory for endotoxin and microbial limits testing
- Methods development and validation
- Polymorph evaluation
- Salt screening and selection
- Stability studies

Process Chemistry

- Route discovery and definition
- Process improvement & optimization
- Robustness & process limits testing

Process development/Engineering

- Process scale-up & demonstration
- Engineering data acquisition
- Technology transfer to commercial scale

Custom Manufacturing

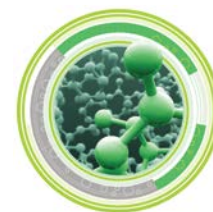
- Preparation of active pharmaceutical ingredients (APIs) under cGMP controls
- Multi-gram to multi-ton amounts

Core chemistry services

- Analytical chemistry
- Process chemistry
- Engineering & API manufacturing
- Radiochemistry

Related services

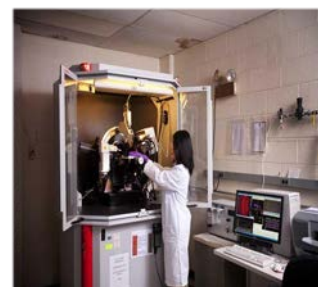
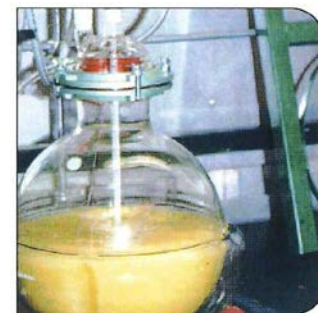
- Analytical method development and validation
- Impurity metabolite synthesis
- Stable labeled bioanalytical standard synthesis
- Kilo labs
- In-process analytical support
- Plant facility
- Dissolution testing
- Microbiology
- DMPK
- Degradant & impurity identification
- Toxicology & pharmacology
- Regulatory support



Chemical Services for Pharmaceutical Development

Major equipment

- Modern, well-equipped organic chemistry laboratories
- Analytical laboratories incorporating a broad range of qualified analytical instruments
- Five chemical preparations laboratories
 - Reactor capacities from 40 to 3,000 liters
 - GLS & SS materials of construction
 - Standard temperature range: -55 to +165 °C
 - Standard pressure range: full vacuum to 450 psig
 - Isolation/finishing rooms for drying, milling, blending and packaging operations
 - Complete support equipment
 - Operated in compliance with US FDA & ICHQ7 cGMP regulations



Ricerca Biosciences: Your research partner of choice

Ricerca Biosciences, a contract drug development organization, provides science-based services to the pharmaceutical, biotech, and specialty chemical industries for the development and commercialization of new innovative products. Ricerca's 260,000 ft² complex is located on a 43-acre site in Concord, Ohio. The facility is equipped with a full complement of well-maintained instrumentation and processing equipment operated in rigorous regulatory compliance to the highest quality standards.