

Pharmaceutical Development

Olon USA is a leading USA-based drug development organization (CDO). We are a wholly-owned subsidiary of Olon SpA, a world-wide API contract manufacturing organization (CMO) Together we provide the full spectrum of services needed to support the development and commercial production 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 customized to meet the specific and unique technical and timing needs of each client development program.

Our specific capabilities include:

Synthetic Chemistry

- De novo synthesis
- Chiral synthesis
- Analogs
- Metabolite & degradant synthesis
- Reference standards

Analytical Chemistry

- Full FDA GLP/cGMP compliance
- Comprehensive problem-solving
- Expertise in HPLC, GC, GC-MS LC-MS, LC-MS/MS, thermal, microscopy, XRD, ICP-AES, ICP-MS, FTIR, UV/Vis, NMR, , LC, dissolution testing, and an extensive suite of classical chemical and physical tests
- Metabolite & degradant ID
- Method development and validation
- Polymorph evaluation
- Salt screening and selection
- Stability studies
- Commercial drug substance and drug product release

Process Chemistry

- Route discovery & definition
- Process development
- Process optimization
- Robustness & process limits testing
- Impurities purge & fate studies
- Critical process parameter assessments

Process Development & Engineering

- Process scale-up & demonstration
- Process validation
- Technology transfer

Manufacturing

- API production for clinical and commercial use
- Multi-gram to hundreds of kilogram (process-dependent)

Core Chemistry Services

- Analytical chemistry
- Process chemistry
- Engineering & API Manufacturing



Pharmaceutical Development continued

Olon USA Chemical Development Facilities

- Well-equipped organic chemistry laboratories
- Analytical laboratories housing a broad range of qualified analytical instrumentation
- Chemical preparations laboratories
 - Reactor capacities to 100 liters
 - Seven Kilo labs (Three cGMP)
- Multipurpose batch processing plant
 - Reactor capacities from 40 to 2,000 liters
 - GLS & SS materials of construction standard temperature range: -55°C to +165°C
 - Standard pressure range: FV to 450 psig
 - Isolation/finishing rooms for drying, milling, blending and packaging operations
 - Complete support equipment
 - Operated in compliance with US FDA and ICH Q7 cGMP guidelines

Olon USA: Your development partner of choice

Olon USA, a contract drug development organization, offers scientific and technical expertise in API development, scale-up, and production. Olon USA's well-maintained facility, located in a 160,000-square-foot building complex on a 25-acre site in Concord, Ohio, is equipped with state-of-the-art analytical instrumentation, cGMP chemical preparation laboratories and a pilot plant for production of clinical and commercial APIs.