



Small Molecule Process Development and Manufacturing Services

Process Research and Development

- Route scouting/design and evaluation
- Phase appropriate process development and optimization
- Process safety and engineering
- Specialty technologies: biocatalysis and flow chemistry

Material Science

- Polymorph and salt screening
- Solid state characterization and pre-formulation services
- Crystallization process development

nonGMP/cGMP Manufacturing (API, RSM and Intermediate)

- Capacity: 430 reactors globally ranging 20 to 12,500 L, -80 to 150°C range
- Hydrogenation, cryogenic, carbon monoxide, use of headspace oxygen
- High potency capability for cGMP manufacture
- Milling

Quality Control, Quality Assurance and Regulatory Affairs

- Method development and validation
- Impurity profiling and forced degradation studies, mutagenic impurity quantitation
- Non-GMP and cGMP release and ICH stability studies to support filing
- Global regulatory submission

Regulatory Approved

FDA, EMA, MHRA, PMDA, NMPA

Facilities

US • UK • China

Pharmaron is a premier R&D and commercial service provider for the pharmaceutical, biotech and life science industries that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical, clinical development and commercialization.



Laboratory
Services



Chemistry,
Manufacturing
& Control



Clinical
Development



Biologics
& CGT

Pharmaron's End-to-end CMC Platform



API Process Development, Analytical
Development & Process Safety



Material Science



API Manufacturing



Preformulation & Preclinical



Product Formulation &
Analytical Development



Drug Product Manufacturing



Regulatory Support &
Consultation

Manufacturing Facilities

China

Beijing

- API cGMP kilo labs
- High potency cGMP lab
- Reactor size: Up to 300 L
- Product Development & GMP Manufacture (Oral Solids)
- Batch size: Up to 80 kg

Shaoxing

- Clinical and Commercial API Manufacturing
- Reactor size: Up to 12,500L

Tianjin

- API cGMP manufacturing plant
- Reactor size: Up to 8,000 L

Ningbo

- API cGMP pilot plant
- Reactor size: Up to 500 L
- Product Development & GMP Manufacture (Oral Solids)
- Batch size: Up to 140 kg

United States

Coventry, RI

- Clinical and Commercial API Manufacturing
- Reactor size: Up to 7,600 L

United Kingdom

Hoddesdon

- API cGMP pilot plant
- Reactor size: Up to 1,000 L
- Product Development & GMP Manufacture (Oral Solids)
- Batch size: Up to 15 kg

Cramlington

- API Commercial Manufacturing
- Reactor size: Up to 10,000 L