

# Small Molecule API & Drug Product Services

# **API Development and cGMP Manufacturing**

- Process development, engineering and safety evaluation
- Analytical development and validation
- Non-GMP and cGMP API manufacturing
- Reactor size: 20 to 12,500 L

## **Regulatory Approved** FDA, EMA, MHRA, PMDA, NMPA

**Facilities** US • UK • China

## **Material Science**

- Salt and polymorph screening
- Developability assessment
- Crystallization process development
- API characterization
- Hazardous materials handling

#### **Product Development**

- Clinical oral solid dose supplies (OEB1-4)
- Solubility enhancement ٠
- Formulation development
- Excipient compatibility •
- Process development and scale-up ٠
- cGMP clinical manufacturing, packaging & labelling

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.





Chemistry

& Control





Laboratory Services

Clinical Manufacturing Development & CGT



# Pharmaron's End-to-end CMC Platform

# **Manufacturing Facilities**



API Process Development, Analytical Development & Process Safety

**Material Science** 

#### API Manufacturing

Preformulation & Preclinical



Product Formulation & Analytical Development



**Drug Product Manufacturing** 

# Re

Regulatory Support & Consultation

# China

#### Beijing

- cGMP kilo labs
- High potency cGMP lab
- Reactor size: Up to 300 L
- Batch size: Up to 80 kg

#### Shaoxing

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

#### Tianjin

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

#### Ningbo

- cGMP pilot plant
- Reactor size: Up to 500 L
- Batch size: Up to 140 kg

#### **United States**

OCH<sub>3</sub>

#### Coventry, RI

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

#### United Kingdom

#### Hoddesdon

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

# Cramlington

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