

# Pharmaceutical Development and Manufacturing

Pharmaron's pharmaceutical development and manufacturing services include process research & development, manufacture route selection and development, scale-up and manufacture of intermediates and API, analytical development as well as preformulation and formulation.

## State-of-the-Art Laboratories and Pilot Plant

Our 80,000 ft<sup>2</sup> purpose-built laboratories include process research & development labs, kilo labs, cGMP kilo labs, pre-formulation, formulation and analytical labs. Our non-GMP pilot plant has 8 modular reaction suites, equipped with 30 reactors ranging from 100 L to 3,000 L. The cryogenic system is a 1,000 L reactor with -80°C capability and the high temperature system can reach up to 300°C.

### ▲ **Process Discovery and Development**

- Early stage process discovery, development and pilot production
- Manufacture route development
  - Route discovery, selection and development
  - Process understanding and definition
  - Reference standard preparation
  - Genotoxic impurity management strategy

### ▲ **Analytical / QC**

- Analytical method development and validation
- Compound characterization
- Impurity identification and quantitation
- cGMP release of API and drug product
- Formulation analysis
- ICH stability study of API and drug product
- Reference standard qualification

### ▲ **Pilot Production and Manufacturing**

- cGMP kilo production
- Non-GMP pilot production and manufacturing

### ▲ **Pre-Formulation and Formulation**

- Crystalline material for DMPK study
- Salt and polymorph screen of drug candidate
- API physical property characterization and evaluation
- Solid state engineering
- Formulation in early stage drug development

### ▲ **Special Expertise in Kilo Scale**

- Nucleoside phosphorus amidites
- Carbohydrate and oligosaccharide
- Heterocyclic boron compounds
- Enantiomeric pure compounds via asymmetric synthesis or chiral resolution
- Deuterium compounds

#### **Contact Us**

For more information on how Pharmaron can assist with your preclinical drug development programs in a cost-effective and quality manner, please contact us.