BIODURO-SUNDIA
保 诺 - 桑 迪 亚

# Drug Substance Development & Manufacturing

## Kilo-lab Manufacturing for IND-enabling Studies

### BioDuro-Sundia Advantages

- Strong track record: >100 clients and >1,000 INDs filed
- Extensive experience manufacturing APIs, and RSMs:
- Separate facilities for non-GMP and GMP production
- Comprehensive design development and characterization of process
- Producing a scalable synthesis: from lab-kilo to pilot-scale
- Extensive experience in flow chemistry and continuous manufacturing
- Broad preparative HPLC capabilities for problematic chemistry or time sensitive projects
- Full Analytical Department run under GMP to support R&D and Manufacturing

**Manufacturing**

GMP and non-GMP
Lab, Kilo and Pilot Scale
Discovery, Preclinical, Clinical, and Commercial

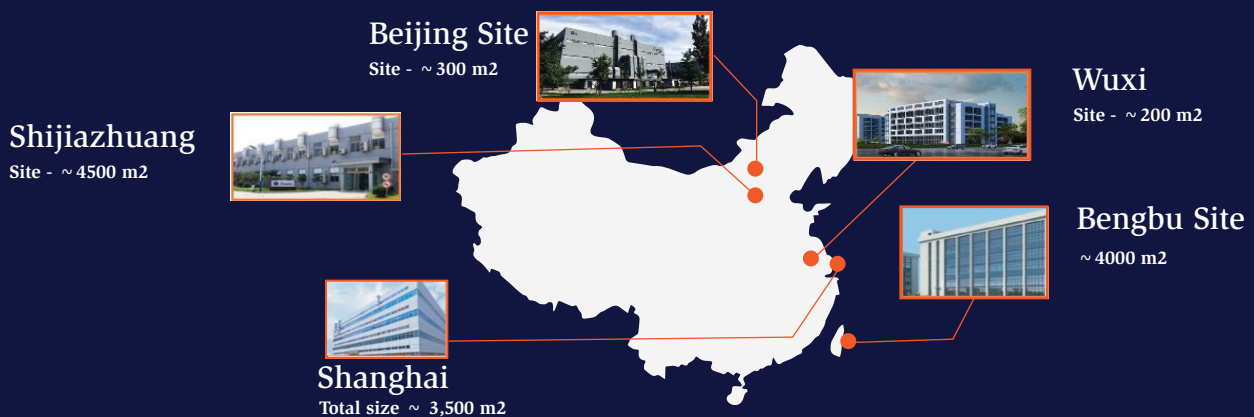
**Process Development**

Route POC/Feasibility Design and Development
Process Optimization
Scale-up Demonstration

**Specialty Services**

Reference Standard & Impurity Marker Isolation Synthesis & Purification
Analytical Validation
Flow Chemistry

### Process Department Overview – 5 Sites; 12,500 m2 capacity




In pursuit of your success.

www.bioduro-sundia.com

# Kilo/Scale-up Labs: Across All Sites

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## Versatile Equipment To Support a Variety of Chemistries

## Composition of Reactors

### ISO Kilo-lab reactors (45 x 50L to 100L)

- Glass and glass-jacketed reactors

### GMP reactors (12 x 50L to 200L)

- Glass-jacketed (3 x 200 L)
- Glass-jacketed reactor (4 x 100L)
- Glass-jacketed reactor (4 x 50 L)
- Explosion-proof glass-jacketed reactor (1 x 80 L, low temperature etc.)

## Operational Details

### Support

- GMP compliant manufacturing and Analytical team w/audit history
- Continuous production w/ dedicated team working in shifts
- On-site QA for batch control, release and hosting audits

### Auxiliary

- Separated humidity and temperature Controlled warehouses
- Clean Room for crystallization, isolation, drying, or packaging/repack
- Purified water system meeting pharmacopoeia requirement
- Lyophilization capability (2kg/day)
- Jet milling/micronization (D90=10µm)

# Flow Equipment

## R&D to Process Demonstration

### Types for Flow Reactors

- Micro-channel mixer
- Plug Flow Reactor (PFR)
- Continue Stirring Tank Reactor (CSTR)

### Advantages for Flow Chemistry

- Better mass and heat transfer
- Better selectivity/impurity control
- Superior inherent safety (smaller active reaction volume)
- Greener chemistries possible (photo)
- Less waste (greater tolerance for neat reactions)
- Ideal for reactions with extreme conditions: High temperature; high pressure; photochemical or reactions requiring short residence time