ChemPartner
Dedicated to LifeScience

CMC MANUFACTURING

Founded in 2003, Shanghai ChemPartner is one of the leading contract research organizations providing full service pharmaceutical drug discovery, drug development, and manufacturing capabilities to its clients around the world.

China Gateway Pharmaceutical Development, a division of ChemPartner founded in 2009, handles scale-up and manufacturing of advanced intermediates, drug substances (DS), regulatory starting materials (RSMs), and active pharmaceutical ingredients (APIs) in order to meet clients' demands.

The China Gateway facility in the Fengxian industrial park, a suburb of Shanghai, was designed by Foster Wheeler and has been fully operational for GMP manufacturing since September 2011.

Development Capabilities

- Process R&D from discovery candidate to development candidate
  - Route scouting
  - Development
  - Optimization
- Development and manufacturing
  - Advanced Intermediates
  - RSMs
  - API/DS
- GMP Kilo-Lab and Pilot Plant Manufacturing
- Custom Synthesis
- CMC CTD Support
- QA/QC Support
- Safety hazard screening / EHS management systems

Phase-Appropriate Development

- "SWAT" team for quick scale up to hundreds of grams from medchem procedures
- Efficient project transfer from MedChem to CMC
- CMC guidance for all stages of development
- Regulatory starting material (RSM) strategy
- Process robustness, DoE, QbD
- Quality managment
- CMC filing expertise in US, EU, and China
- Process optimization to drive down costs
- Cost of goods (COGS) analysis, long term manufacturing projections

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Stability Management

- Development of Stability Indicating HPLC Assay
- Stability Studies as per ICH Guidelines
  - 3 Conditions & 4 Zones

Analytical Development

- In Process Control
- Assay Method Development and Validation
- Impurity Characterization
- Release Testing
- Drug Substance
- Drug Product
- Excipient Compatibility
- Dissolution Testing

Pre-Formulation & Formulation Development

- Preclinical Formulation Development
- Early Phase Clinical Formulation
- Oral Solid Technologies

Three Levels of EHS Management Systems

- Level 1: Corporate EHS Policy and Goal
- Level 2: Standard EHS Management Procedures (SMP)
- Level 3: Standard EHS Operation Procedures (SOP)
- EMA audited 2016

Miscellaneous

- Cryogenic, High Pressure (including hydrogenation) and High Temperature manufacturing capabilities
- X-Ray Diffraction, Single Crystal-XRD (out-sourced)
- Enantiomeric Separations Capability from mg to kg
- Supercritical Fluid Chromatograph and Preparative HPLC
- Liquid Nitrogen Cooling - Cryogenic TCU Control
- 9 Processing Bays, Including Clean Room Finishing Areas (Class 100,000)
- 47 Reactors, Total 57 m^3

IP and IT Security to Protect Client Property

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