

PHT SHANGYU CONTRACT DEVELOPMENT & MANUFACTURING ORGANIZATION

- **Manufacturing**
 - Four Workshops Capacities >200 m³ reactor volume and 400t/year output;
 - cGMP Kilo lab and pilot workshop with reactors of 100 – 1000L
 - Flow reactors for nitration and oxidation reactions
 - High pressure hydrogenation(40bar)
 - High temperature reaction(250°C)
 - Cryogenic reaction (-70°C)
 - LAH and RedAl for reduction reactions
 - US FDA Inspections: 2012, 2015, and 2017 - No 483s
 - ISO: 9001:2015, 14001:2015 and 45001:2008
- **EHS**
 - Anaerobic/aerobic wastewater treatment(200t/day)
 - Fenton wastewater oxidation
 - Wastewater de-salination
 - Sodium sulfate processing
 - 3 sets of sludge filter presses
 - Waste gas scrubbers
 - RTO
 - Halogen-containing exhaust gas adsorption device
- **Workshop 1**
 - Built in 2005 for APIs and advanced intermediates
 - GMP approved in 2006
 - Total reaction volume 11.0 m³
 - 10 glass-lined reactors
 - 1*200L; 5*500L and 4*2000L
 - 3 Centrifuges
 - 1 Tray vacuum dryer
 - 2 Double cone dryer (2000L)
 - Temperature range: -15~140°C
- **Workshop 2**
 - Built in 2011 for making cGMP products
 - Total reaction volume 16.6 m³
 - 16*(100 - 3,000L) reactors, 14 Glass-lined, 2 Stainless steel
 - 2 Centrifuges
 - 1 Tray vacuum dryers
 - 1 Rake dryer
 - 1 Double cone dryer
 - 1 Nutsche dryer
 - Temperature range: -15~250°C
- **Workshop 3**
 - Kilo lab
 - 50-100L Glass reactor
 - Capacity: 1-20kg
 - Production under GMP for early clinical stages
 - Flow-reactor for process development and kg-sample prep
 - Temperature Range: -10~120°C
- **Workshop 4**
 - 174 m³
 - Total Reactors: 40
 - Ranging from 2000L to 8000L
 - Glass-lined reactors: 24
 - Stainless steel reactors: 13
 - High pressure hydrogenation reactor (40 bar):1
 - Cryogenic reactors:2
 - 7 *1250mm centrifuges
 - 1*1000mm centrifuge
 - 1*2000L rake dryer
 - 1*2000L Nutsche dryer
 - 1*2000L glass-lined double cone
 - 1*3000L glass-lined double cone
 - 4 *2000-3000L: stainless steel double cone
- **Reactions**
 - Aldol reactions
 - Alkylations
 - Buchwald-Hartwig Amination
 - Bromination
 - Chlorination
 - Chloro Sulfonation
 - Diels-Alder Reaction
 - Friedel-Crafts Acylation
 - Friedel-Crafts Alkylation
 - Heck Reaction
 - Mannich Reaction
 - Michael reaction
 - Nitration
 - Reductive amination
 - Suzuki reaction
 - Vilsmeier-Haack reaction
 - Williamson reaction
 - Wittig reaction
- **Chiral Resolutions**
- **Chiral Catalysis**
- **Metal-Organic Reactions**
 - Boronic acids
 - Cyro reactions down to -70°C
 - Grignard reaction
 - Lithium-Halogen exchange
 - Lithiation
- **Homogenous Catalysis**
 - Asymmetric hydrogenations (up to 40 bar)
 - Heck reaction
 - Suzuki reaction
- **Reductions and Oxidations**
 - Alkene reductions
 - Chiral reductions
 - Heterogenous Hydrogenation up to 40 bar
 - Homogenous Hydrogenation up to 40 bar
 - Reductions with Lithium Aluminiumhydride
 - Reductive amination
 - Reduction of nitro groups
 - Oxidation with O₂
 - Oxidation with KMnO₄
- **Application of Special Chemicals**
 - Lithium Aluminiumhydride
 - Sodium Hydride
 - Butyl Lithium
 - Dimethyl sulfate
 - Oxidation with KMnO₄
- **Workshop 4 Continued**
 - 1*Commercial flow chemistry
 - 1*Pilot flow chemistry
 - 1*vaporization film separation equipment for solvent recovery
 - 2*Acetonitrile and methanol distillation column
 - 1 Class D clean room