

...To cGMP!

A state-of-the-art facility acquired from Merck/MSD (Organon Biosciences) in 2012 focusing on custom development and manufacturing for Active Pharmaceutical Ingredients and Nanomedicines.

- Four Reactor Suites - Class D Air Quality
- Enclosed suites for high potency materials
- Temperature from -60° C to 200° C
- Class C Clean Room
- LAF Powder Handling Room
- EMA GMP Approved
- License for Drug Substance and Drug Product Manufacture
- 16 Reactors up to 350 liter scale
- Hastelloy and Glass Lined
- Autoclaves 20L (15 bar) and 70 L (7 bar)
- Two Dry Powder Handling Rooms
- Three Vacuum Dryers
- Operational Since 2000

Services

- Process Development
- Process Scale up
- Analytical Development
- Release and Stability Testing
- Process Optimization
- Process Validation
- Analytical Validation
- IMPD/IND Compilation

Purification Technology

- Gravity Chromatography
- Ion Exchange Chromatography
- Nanofiltration
- Purification of Peptides
- Preparative HPLC
- Ultrafiltration
- Purification of Complex Mixtures
- Enantiomer Separation

Expertise

- Steroids
- Peptides
- Heterocycles
- Carbohydrates
- Nanomaterials
- Complex APIs

Nanoformulations

- Functionalized Cyclodextrins
- Functional Lipids
- homo- and hetero-bifunctional PEG derivatives for bio conjugation

Highlights

- QbD
- Continuous Flow Technology
- Reactions with hydrogen, acetylene, carbon monoxide, liquid ammonia
- Equipment for Process Safety Research (RC1, DSC)



Services Available on an FTE and Milestone Basis

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