

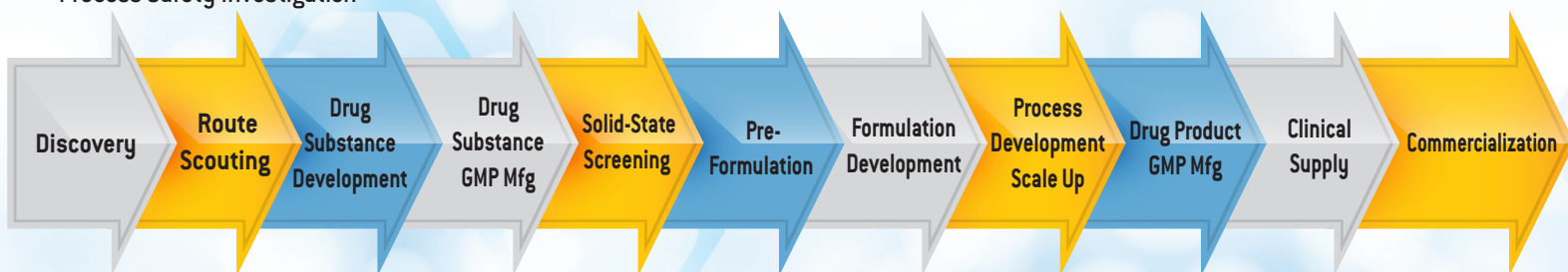
API

Services

- Discovery
- Medicinal Chemistry
- Parallel Chemistry
- Computational Chemistry
- Route Scouting
- Process Research and Development
- Metabolites, Stable Label, and Impurity Synthesis
- Process Safety Investigation
- Process Scale Up
- Analytical Method Development and Validation
- ICH Stability Studies
- Solid Form Screening and Selection
- Crystallization Process Optimization
- GMP Production

Technology

- Flow Chemistry
- Chiral Resolution Technologies
- Catalyst Screening
- Salt Screening
- Polymorph Screening
- Synthesis of Linkers and Labels
- Chromatographic Purification
- Ion Exchange Chromatography
- Ultra- and Nanofiltration
- Short Path Distillation
- Peptide Development and Manufacture
- Single Crystal X-ray Diffraction
- High Throughput and High Resolution X-ray Diffraction



Drug Products

Services

- Powder Flow and Compaction Analysis
- Preformulation
- Formulation Development
- Process Development and Scale Up
- Analytical Method Development and Validation
- ICH Stability Studies
- cGMP Manufacture
- Packaging and Labeling
- Clinical Logistics

Technology

- Real Time Dissolution Profiling
- Nanosuspensions
- Amorphous Solid Dispersions
- Lipid Based Formulations
- Oral Solid Dosage
- Liquid Filled Capsules
- Coated Multi Particles

Enzymatic Technology

- Enzyme supply from a library of over 20,000 strains
- Enzyme Engineering (Random / Semi-rational Design)
- Route Design, Enzyme Screening, Process Optimization, Scale up
- Commercialization in FDA Inspected Plant(s)

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Biosynthesis

- Fermentation
- Asymmetric reduction
- Hydroxylation
- Hydration
- Resolution

Organic Synthesis

- Asymmetric synthesis
- Azide chemistry
- Heterocyclic chemistry
- Cryogenic reaction
- Oxidation
- Sugar chemistry

Process Technology

- Modeling
- Process simulation
- Process optimization
- Process control
- Separation technology
- Reactor design

Chromatography Technology

- SMB separation
- Chiral separation
- Large Scale Chromatography



Select Manufacturing Capabilities

- Benzene (Large Scale)
- Biocatalysis
- Bromination
- Chiral Synthesis
- Chlorination
- Chromatography
- Cryogenic (-80°C)
- **Cyanation**
- Distillation
- Energetic Chemistry
- Enzymatic Screening and Engineering
- **Flow Reactor (-100° to 300°C, 300 Bar)**
- Fluorination
- Grignard Reaction
- High Pressure
- High Temp (200°C)
- **Hydrogenations (300 Bar)**
- Natural Product Extraction
- Organometallics
- Oxidation (H₂O₂ & MnO₂)
- Ozonolysis
- Phosgenation
- Silane Chemistry
- Sodium Metal
- Sulfur Chemistry

Pilot & Commercial Facilities

- US, European and Asian assets
- Custom Contract and Toll Manufacturing
- FDA inspected facilities and DMF filing
- Stainless steel, glass lined and Hastelloy™ reactors up to 14,000 L
- Cryogenic synthesis (-80°C)
- High temperature (to 200°C)
- **Hydrogenation (up to 300 bar)**
- Process Safety Studies — Reaction Calorimeters, DSC, Adiabatic Calorimeter
- Stability testing — according to ICH guidelines

HPAPI Capability

- Europe – to 10 ng/m³
- Asia – to 100 ng/m³
- Current batch size 10 g to 2 Kg
- Batch size 10 g to 20 Kg
- New unit (2020) Batch size
- Reactors up to 1,000 L
- 5 to 30 Kg

Fermentation Development & Engineering, Scale Up, and Manufacture

- **CHO and E. coli based**
- Preparation of cell bank
- Strain improvement
- Pilot Facilities to 1,000 L
- Commercial Scale 15,000 to 255,000 L

Enzymatic Technology

Route Design

- Mutual and deep understandings among organic/process chemists

Enzyme Screening

- Access to rich microbial resources
- Enzyme/microbial screening
- Collaborative partners

Enzyme Engineering

- Random/semi-rational design
- Collaborative partners

Process Optimization

- Deep understandings of enzymes
- Process development
- Manufacturing partners

Precious Metal Catalysts

- Refining
- Fabrication
- Recovery

Particle Engineering

Spray Drying

- FDA Inspected
- Up to PSD-3 Closed Cycle

- Stability Studies
- Formulation Capability

Micronization

- FDA Inspected
- Fluidized Jet Mills
- Spiral Jet Mills
- Fine Impact Mills
- Cutting Mills

Global Sourcing and Services

China, India, Europe, and USA

- Fully integrated offices for 30+ years
- Manufacturing sites audited

Contractual Sourcing — the first company in the Life Science and Specialty Fine Chemical Industries to have offered chemical sourcing and procurement (1988/1992)

- Detailed metrics and reporting
- Fixed or variable fee

Tail End Sourcing — using our experienced teams and successful techniques

- Current Supplier Strategy
- New Supplier Strategy
- Validated/Current Information

Logistics & Warehousing

Logistics Expertise Import and Export

- Over 40 years experience

Warehousing Service

- GMP warehousing — NJ, MA, IN, NV & CA

APIs & Excipients

- Di-Pac® Tablet Excipient
- Egg Yolk Phospholipid
- Granulated Sugars NF
- Guar Gum NF
- Colloidal Silica

- Cytarabine USP
- Heparin Sodium USP
- Heparin Lithium and Salts
- Tranexamic Acid USP
- Vitamin D Analogs

