

SAFC®

Pharma & Biopharma Raw
Material Solutions

MERCK

Complex Small Molecule Manufacturing

Sheboygan Facility Overview

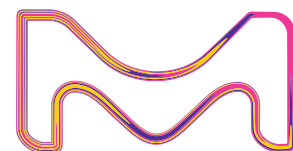


At our site in Sheboygan Falls, Wisconsin (USA), we offer a uniquely flexible environment for supply of customer-specific chemical products, including multi-step and air sensitive organic and organometallic syntheses. This ISO 9001:2008 certified site has been built to meet customer needs from development to commercial-scale production. With a well trained staff of over 350 people, including dedicated development and project management teams, our customers can be assured that their projects will receive the individualized attention required to meet challenging time-lines and unique supply chain and quality needs.

Chemistry specialties

At our Sheboygan site we offer a wide range of chemistry expertise to support customer synthesis needs including:

- Multi-step and air sensitive syntheses
- Continuous flow chemistry
- Phosgenations
- Hydrogenations
- Cryogenic and high temperature reactions
- High purity organics and organometallics
- Non-GMP manufacturing



Development services

The site provides a full range of development services to support customer projects:

- Process design flexibility with rapid scale up abilities
- Over 40 Process Development Scientists and Chemists
- Design of Experiment (DOE)
- On site hazard evaluation in support of internal manufacturing
 - Differential Scanning Calorimetry (DSC)
 - Reaction Calorimeter (RC-1)
 - Accelerating Rate Calorimeter (ARC)

Manufacturing

Our Sheboygan site is equipped to support customer projects from development to commercial scale batches:

- Lab scale glassware synthesis and distillation up to 50-L
- Variety of process vessels ranging from 200L to 16000L, -110 °C to 260 °C
- Production scale flow reactor
- Expertise in distillation at small and large scale
- Three stainless steel autoclaves up to 400 L with pressure up to 450 psi and a temperature range of 5 °C to 200 °C
- 24/7 work schedule for all large scale manufacturing
- Packaging customization

Analytical services

Complete analytical support for all operations from raw material quality to final product release. Capabilities include:

- Analytical method development, qualification and Validation for support of non-GMP manufacturing

Extensive analysis capabilities

- Multinuclear NMR
- Optical spectroscopy: FT-IR, Polarimetry, UV-Vis and Fluorescence
- Chromatography: GC, GC-MS, HPLC, LCMS, GPC, Ion Chromatography
- Trace element analyses: Flame-AA, ICP-MS, ICP-OES
- Compositional analyses: CHN, ROI, KF titration and other wet chemical titration and gas evolution analyses

Project management

Our Sheboygan project management group is part of an integrated worldwide project management team. Our project managers serve as the single point of contact for customers and are responsible for all project communications and milestones related to:

- Development, manufacturing, procurement, analytical, and regulatory/compliance
- Summary reports
- Project tracking via Gantt chart
- Business development support



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