

## High-Potent API Manufacturing Experts SAFC Pharma™ – Madison

Through its site in Madison, Wisconsin (USA), SAFC Pharma is the industry leader in high-potent API manufacturing. This flagship Safebridge® certified manufacturing site features the highest level of quality and containment engineering to handle cytotoxics and category IV potent compounds. With more than 15 years experience in this complex technology and highly trained personnel, SAFC's Madison facility is at the leading edge to support development and manufacturing of high-potent APIs from pre-clinical to commercial-scale quantities.



### Manufacturing

SAFC Pharma-Madison provides the best environment and highest safety criteria for high-potent API development and manufacturing. Our numerous kilo labs and manufacturing suites provide increased flexibility for multi-step synthesis of high-potent APIs.

- Eight process development labs
- Eight kilo labs featuring:
  - Barrier isolators
  - Powder weighing hoods
  - Closed system glassware
  - Local exhaust ventilation
  - Chromatography systems
  - Class 100,000 (ISO 8) single pass HVAC
  - Dedicated glassware and equipment
- Two pilot plants (200 L and 800 L) featuring:
  - Barrier isolators
  - Alpha beta valves for reactor charging
  - Chromatography systems including Biotage medium pressure chromatography (up to 40 kg cartridges)
  - Nutsche filter/dryer/isolators (category IV substance handling)
  - Class 100,000 (ISO 8) single pass HVAC
  - Dedicated suites for each project
  - Process equipment includes up to 800 L glass lined reactors, 200 L Hastelloy® reactor and distillation capabilities
  - Cleaning In Place (CIP) containment cleaning systems
- Two category IV potent drying/packaging rooms

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### SAFC Pharma™ – Madison



#### Containment and Safety

Purpose built, the fully validated cGMP site was certified by Safebridge® in 2003, and is one of the flagship facilities in the industry designed to follow the most stringent criteria for high-potent compounds manufacturing.

- Engineering controls are used as the primary means for containment and isolation of potent compounds
- Room pressure differentials designed for containment (with monitoring and verification)
- Airlocks/vestibules around manufacturing/lab spaces
- Single pass air
- Filtration/capture of contaminants, with safe-change filters



#### Analytical Services

SAFC Pharma's analytical teams are known for developing robust analytical methodology platforms. Analytical capabilities include:

- Raw material, intermediate and final product testing methods
- Impurity identification and characterization
- Analytical methods development, qualification and validation



- Stability testing (ICH)
- Instrumentation:
  - NMR (H1, C13, F19 & P31)
  - FT-IR
  - LCMS and GCMS
  - UV-Vis
  - HPLC
  - TGA
  - Polarimetry
  - DSC
  - X-Ray Diffraction
  - KF
  - Ion Chromatography
  - GC

#### Quality Management and Regulatory Affairs

- Extensive regulatory expertise
- ICH Q7A cGMP facility
- Active DMFs filed in over 30 countries
- Ability to support customer development activities:
  - Preparation of regulatory filings (CMC sections)
  - Vendor audits
  - Control documentation and testing
  - Scientific and technical writing
- Last FDA inspection (2006) resulted in no 483 form issued



SAFC Pharma–Madison has been specially designed to develop and manufacture high-potent APIs from pre-clinical to commercial-scale quantities.