SAFC®

Pharma & Biopharma Raw Material Solutions

MERCK

High potency and complex API's

Madison Facility Overview

With more than 25 years of experience in handling highly active materials, we can support development and manufacturing of your complex small molecule from pre-clinical to commercial scale. Our Safebridge® certified manufacturing sites in Madison (WI) are engineered to handle highly-active pharmaceutical ingerdients, APIs, linkers, cytotoxic materials, payloads, and secondary metabolites.

Manufacturing Capabilities

Madison has a variety of manufacturing spaces and equipment to provide the necessary flexibilty for multi-step synthesis of complex and highly potent APIs (HPAPIs). All pilot and production scale plants and equipment are rated to handled Safebridge® Cat IV materials and were designed with HPAPI handling in mind, and most of the kilo labs are Safebridge® Cat IV capable as well. Equipment overview:

QTY	Equipment	Capacity	Temp Range
7	Kilo Labs: Safebridge Cat IV capable	g to kg scale	-75 to +190 °C
3	Kilo Labs: Safebridge Cat III capable	g to kg scale	-75 to +190 °C
2	Safebridge ® Cat IV drying/ packaging suites	g to kg scale	-10 to +100 °C
2	Process Scale up Labs	g to kg scale	-75 to +190 °C
1	Hydrogenation Suite	2-100 L	-40 to +110 °C
11	Glass Lined Reactors	120 -4000 L	-30 to +180 °C
2	Glass Lined work up vessels	4000-8000 L	-30 to 80 °C
5	Hastelloy Reactors	200 - 2000 L	-80 to +180 °C
7	Nutsche filter dryers	up to ~400 kg/ batch	-30 to +70 °C
	Column Chromatography	up to 40 kg silica	
	Vacuum oven dryers	~4 kg	up to +100 °C
2	Lyophilizer, trays	~600 g/lot	-80 to +40 °C
	Varying filtration equipment		

The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

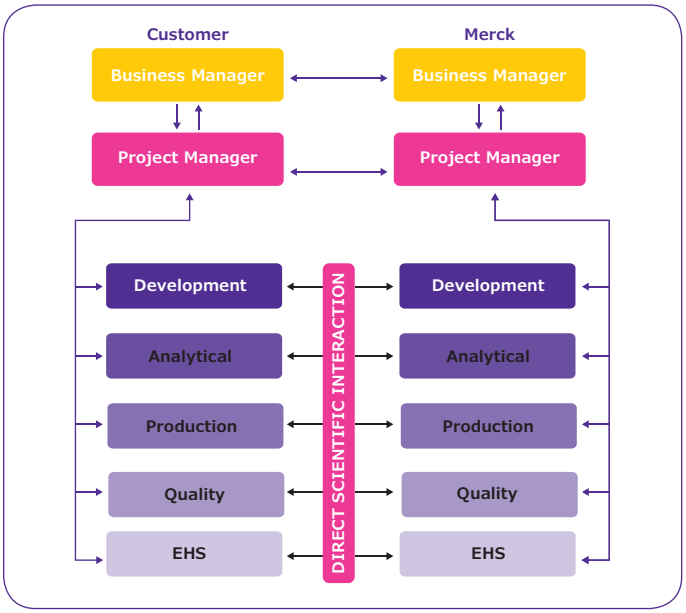
Containment and Safety

Purpose built, the fully validated GMP sites are certified by Safebridge® and designed to follow the most stringent criteria for highly active compound manufacturing and engineered for containment and isolation of potent compounds.

- Differential room pressure designed for containment (with monitoring and verification)
- Airlocks/vestibules surrounding manufacturing/lab spaces
- HEPA filtered single pass air
- Filtration/capture of contaminants, with safe-change filters

Project Management

From evaluation to execution, our dedicated project managers are coordinating multi-disciplinary teams, international site activities and timelines. They consolidate and facilitate direct communication by technical leads.



Process Development

- 2 Sites in Madison/6 labs/19 hoods
- Process scale-up labs in Madison and Verona
- 4 Segregated potent compound capable labs
- Phase appropriate development to support pre-clinical through commercial activities
- Specialization in complex chemistry, purification and isolation

Analytical Development and Quality Control

Our supporting services include developing robust analytical methodology platforms.

- Raw material, intermediate and final product testing methods
- Impurity identification and characterization
- Analytical method development, qualification, and validation
- Stability testing (ICH guidelines)
- Broad range of instrumentation including XPRD, Particle Size, and ICP-MS
- Troubleshooting activities

Quality Management and Compliance

Our offer includes extensive regulatory expertise in quality, compliance and regulatory.

- ICH Q7 cGMP facility
- ISO 13485 Certified
- Active DMFs filed in over 35 countries
- Ability to support customer development activities:
  - Preparation of regulatory filings (CMC sections)
  - Vendor audits
  - Control documentation and testing

Starting Materials and Key Intermediates

We use uses an established supply chain to advance molecules from clinical to commercial. We work closely with our internal sites to complement the supply of critical or custom starting materials, intermediates, and GMP reagents.

Bio- and Antibody-Drug Conjugates (ADCs)

We are a leading expert in bioconjugation services. Madison's expertise in the production of linker and payload technology combined with our clinical and commercial ADC facilities in St. Louis (MO) enable us to offer a comprehensive solution for your supply chain, including our BioReliance® End-to-End services, offering process development and cGMP production of monoclonal antibodies for clinical supplies.

To place an order or receive technical assistance in Europe, please call Customer Service:
France: 0825 045 645
Germany: 069 86798021
Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
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For other countries across Europe, please call: +44 (0) 115 943 0840
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