

Biologic APIs and Conjugation SAFC Pharma™ – St. Louis

SAFC Pharma's St. Louis, Missouri (USA) campus is a key center of manufacturing excellence in cGMP biologics, with over 25 years experience in plant- and animal-based therapeutic protein extraction and purification, bio-conjugation, excipients and adjuvants manufacturing. In addition, SAFC St Louis works in close alignment with SAFC's Madison (Wisconsin) high-potency APIs (HPAPI) manufacturing operations to lead the industry in its ability to handle high-potency conjugation projects.

Completely segregated manufacturing operations support customer requirements for large-scale programs, with capabilities to extract biomass at up to 6,500 kg/week, then purify material in chromatography columns up to 1.5 meters in diameter in a clean room environment. Extensive analytical capabilities and dedicated compliance resources, along with extensive manufacturing capabilities help SAFC customers around the globe to accelerate their biologic drug development programs.



Potent and Non-Potent Conjugation

To support exciting new cancer drugs, SAFC Pharma is one of the few companies to offer the crucial combination of small-molecule chemistry, biologics capabilities and high-containment engineering to bring HPAPI conjugated materials to commercialization.

Non-potent conjugates, primarily used for targeted drug delivery applications, are also available.

The new cGMP HPAPI conjugation facility features:

- 800 sq. ft. floor space
- ISO 8 (Class 100,000) room classification
- Walker™ dual-sided six glove isolator
- 10-100 L reactor size
- Batch size capability over 100 g

Animal-sourced APIs Manufacturing

Purpose-built, completely segregated facilities have been specifically designed to support animal protein extraction and purification at commercial scale, to meet growing customer demand for animal-sourced therapeutic proteins.

Manufacturing for sample projects includes:

- Thrombin (wound care)
- Hyaluronidase (eye care)
- Porcine/bovine sourced Trypsin
- A wide variety of excipients (such as Keyhole Limpet Hemocyanin)

SAFC® Pipeline Partners

Facility Focus

Biologic APIs and Conjugation Experts

SAFC Pharma™ – St. Louis



Plant-sourced APIs

The St. Louis cGMP facility was specifically designed to handle the increasing demand for key intermediates, excipients, adjuvants and APIs made from plant-derived materials. SAFC Pharma's dedicated upstream plant biomass extraction and clarification facility is equipped to process up to 6,500 kg of plant biomass/week. Facility features:



- Separate cGMP plant extraction and downstream purification
- Purification ISO 7 and ISO 8 classified suites
- Unidirectional process flows
- Equipment wash room
- Fixed, stainless steel jacketed biopharm grade tanks to 3,200 L
- Disposable technology availability
- Delta V control system, central Clean In Place (CIP) skid chromatography and TFF skids



Analytical Services

Complete analytical support, from development of specifications, risk assessment, implementation of process controls and validated cleaning procedures. In addition, our analytical capabilities offer:

- Solid state chemistry and analytical services for every API developed and manufactured at SAFC (services available in Europe and the US)
- Phase-specific analytical development
- Characterization, certification and control of all incoming raw materials
- QC testing of in-process materials
- Release testing upon request
- Analytical instrumentation, including:
 - CMS
 - HPLC
 - GC
 - NMR
 - UV
 - IR

Quality Management

- Dedicated Quality Assurance (QA) team
- Highly experienced personnel
- ISO 9000 cGMP and ICH Q7A compliant operations
- Numerous successful client audits
- Rigorous compliance program in place

Project Management

SAFC's project managers lead multi-functional teams and serve as the single point of contact for customers, to help facilitate the timely communication of important technical information and production timelines.



St. Louis is the heart of SAFC Pharm's expertise in biologics APIs and conjugation technologies from pre-clinical to commercialization.