TARGETED DRUG DELIVERY THROUGH CONJUGATION

With more than 30 years of experience in bio-conjugation, SAFC is a leading expert for the conjugation of highly active molecules to monoclonal antibodies for the development and manufacture of ADCs.

ANTIBODY-DRUG CONJUGATES (ADCs)

Antibody-drug conjugation technology uses monoclonal antibodies or other biologics to deliver potent or highly active pharmaceutical ingredients (HPAPIs) to targeted cells. In conjugated form, the HPAPIs exhibits more selective cytotoxicity, thereby, sparing non-target cells from many of the toxic effects and improving the safety profile.

ADC CAPABILITIES

SAFC has the expertise needed to deliver solutions for your ADC or bioconjugate.

• Experience with >20 different ADC constructs and >100 batches
  - random cysteine or lysine conjugation technology
  - site directed conjugation via engineered mAbs or enzyme catalyzed
  - various payloads (Microtubule Inhibitors or DNA binding)
• Extensive analytical capabilities for characterization, including mass spectrometry and cell-based assays
• Release testing and stability for both Bulk Drug Substance (BDS) and Drug Product (DP)
• Personnel and suites dedicated to ADC development, manufacturing, and testing
• Collaboration with Baxter BioPharma Solutions to offer comprehensive ADC services, including formulation development, technology transfer and fill/finish
MANUFACTURING CAPABILITIES

For antibody-drug conjugates, SAFC provides development and manufacturing services of commercial-scale payloads, linkers and conjugation, respectively at the SafeBridge® certified Madison, WI (USA) and St. Louis, MO (USA) facilities. Extensive analytical testing and characterization for both APIs and biologics are available to customers. Highly experienced Quality and Regulatory support for EU, US and Japan is provided with Drug Master Files (DMFs) in over 30 countries.

PAYLOADS AND LINKERS

With over 25 years of experience working with highly-active pharmaceutical ingredients (HPAPI), SAFC can handle your complex and highly-active molecules.

- FDA inspected, premier high potency cGMP manufacturing facilities in Madison (WI), US
- SafeBridge® certified upt Cat. IV
- Highly-active pharmaceutical ingredients, APIs, linkers, payloads and secondary metabolites
- Facility features include:
  - Kilo lab manufacturing to 50 L
  - 40 Reactors from 20–4,000 L
  - Temperature range from -60 °C to 200 °C
  - Batches from grams to >400 kg
  - Warehouse with capacity for storage and inventories of raw materials and components for GMP manufacture

CLINICAL ADC MANUFACTURING

SAFC’s clinical ADC manufacturing facility was purpose-built for the handling of HPAPIs, antibodies, linkers and for performing complex conjugation processes in a cGMP suite featuring isolators and specialized handling equipment.

- SafeBridge® Cat. IV certified since May 2009
- 800 sq-ft footprint including airlocks
- ISO 8 classified clean room environment
- Unidirectional personnel flow with entry, de-gown, and exit airlocks
- Personnel airlocks separate from equipment/material airlocks

COMMERCIAL MANUFACTURING

A commercial scale manufacturing suite has been commissioned in 2015, including:

- Ability to manufacture batches up to 600 L/~3 kg under Grade C classification
- Segregated areas for HPAPI solids handling, conjugation, with aseptic bulk filling under Grade A classification

SUPPORTING SERVICES

SAFC’s comprehensive ADC solutions include analytical and process support at all stages of drug development and manufacture.

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:

- Phase-specific analytical development
- QC testing of in-process materials
- Release testing of BDS and DP
- Analytical instrumentation, including: MS, HPLC, CGE, ELISA, UV , NMR, IR

PROJECT MANAGEMENT

From evaluation to execution, SAFC’s highly skilled and dedicated project managers are responsible for coordinating multi-disciplinary teams, international site activities and timelines:

- Dedicated and transparent approach to ensure a positive customer experience
- Globally harmonized best practices
- Responsive and solution driven
- Flexible and collaborative

SAFC’s ADC Contract Manufacturing Footprint:

Contact Us

Email: conjugation@sial.com