SAFC®

Pharma & Biopharma Raw Material Solutions

MilliporeSigma

ADC's, bio-conjugation, and bio-organics

St. Louis Facility Overview

Our St. Louis (USA) manufacturing site has more than 30 years of experience in bio-conjugation, APIs, excipients and adjuvants manufacturing. Extensive analytical capabilities and dedicated compliance resources, along with innovative manufacturing capabilities help our customers around the globe to accelerate their drug development programs.

Bio-conjugates

(Potent bio-conjugates (ADC), non-potent bio-conjugates)

Antibody-drug conjugation technology uses monoclonal antibodies or other biologics to deliver highly potent 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.

Bio-conjugates also use traditional APIs and possible new novel drugs to provide a similar therapeutic effect.

ADC Capabilities

We have the expertise needed to deliver solutions for your bioconjugation, whether it be potent (ADCs) or non-potent for clinical and commercial supplies.

- >45 constructs and >400 development batches and >115 cGMP batches, with extensive chromatography experience
  - random cysteine or lysine conjugation technology
  - site directed conjugation via engineered mAbs or enzyme catalyzed
  - various payloads (Microtubule Inhibitors or DNA binding)
- Analytical capabilities for characterization, including mass spectrometry and cell-bases 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

Potent-Bioconjugates (ADCs)			
QTY	Equipment	Capacity	Temp Range
1	Clinical ADC Suite	10-100 L	2 to 37 °C
1	Commercial ADC suite	600 L max reactor	2 to 37 °C
2	Mobius® FlexReady TFF systems	up to 200 L	
4	Mobius® Single Use Mixing System	50 L to 100 L	
	WFI supply system		
1	AKTA™ Ready Chromatography System		
	Bulk Fill Room (Grade C)		
	Isolator (Grade A) with VHP for bottle filling		
	GE 6610 Autoclave		
2	Biosafety Cabinet		

Non-Potent-Bioconjugates			
QTY	Equipment	Capacity	Temp Range
2	Jacketed Reactors	2,5000 L	2 to 37 °C
2	Portable Equipment	up to 1,000 L	
2	Mobius® FlexReady TFF systems	up to 200 L	
4	Mobius® Single Use Mixing System	50 to 100 L	
	WFI supply system		
	AKTA™ Ready Chromatography System		
	Biosafety Cabinet		

Complex API Lab and Equipment

This facility is focused on the synthesis and purification of bio-organic materials such as polyamino acids, liposomes, polynucleotides, and lipids.

Bio-organics			
QTY	Equipment	Capacity	Temp Range
6	Glass lined reactors	50 L - 3000 Gallons	-9 C to 120 °C
2	Filter Dryer	0.6 m^2 to 2 m^2	-9 C to 120 °C
3	Walk in Hoods	50 L reactors	Plant operating temperature 17 °C
	Chromatography		
	Hastelloy Centrifuge	Capacity is 120 kg	Ambient
	Lyophilization	200 L	-50 to +30 °C

Process and Analytical Development

Our supporting services include developing robust analytical methodology platforms supporting all cGMP manufacturing areas:

- State-of-the-art analytical methods for characterization of bio-conjugates and complex APIs
- Bio-analytical methods for product functional characterization – binding, enzyme and cell based assays

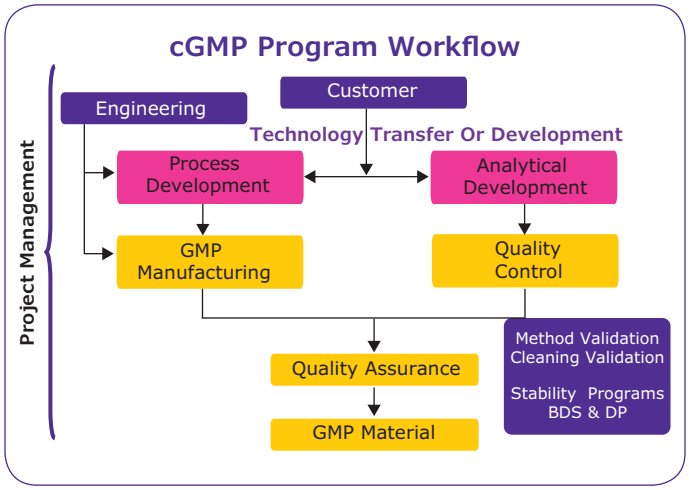
Quality Management and Compliance

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

- ICH Q7 is our Quality System and the Global standard for the manufacturing, testing, packaging, and release of APIs
- ISO 9000 cGMP compliant operations
- 21 CFR 210/211 is in place for contract Drug Product testing for our customers
- FDA registered site with commercial API production since 1999

Project Management

From evaluation to execution, our dedicated project managers are coordinating multi-disciplinary teams, international site activities and timelines throughout the lifecycle of your program.



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