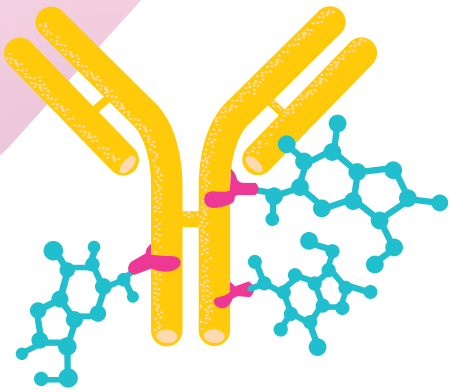
SAFC®

Pharma & Biopharma Raw Material Solutions

MilliporeSigma

ADC Express™

Pre-clinical Conjugation Services for the Best Candidate Selection



Speeding your path to the clinic — with ADC Express™

As an industry leading contract manufacturing organization (CMO) in the Antibody-Drug Conjugate (ADC) space, we are offering a rapid approach for developing your ADC constructs. By using our extensive bioconjugation expertise we can reduce your time to produce development grade constructs for target molecule identification. To efficiently turn your and our antibody, linker and payload into an ADC we will leverage our established platform technology.

Why choose ADC Express™?

Speed to selection:

- Rapid production of multiple ADC constructs for screening
- Our platform technology with key analytics

Speed to clinic:

- Our expertise for reliable scale up of your target molecule
- Benefit from a reliable partner offering comprehensive services for GLP and GMP production
- Supply chain consolidation gives you comprehensive ADC services within one organization

ADC Express™ Features

- Mini-prep scale: 10–20 mg ADC construct ± column purification
- Medium-prep scale: up to 100 mg ADC ± column purification
- Certificate of testing with key quality attributes
  - ADC concentration
  - Payload density/DAR (drug antibody ratio)
  - Monomer/aggregate content
  - Endotoxin

For more information, please visit
EMDMillipore.com

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

Comprehensive Solutions for Your ADC

We offer comprehensive supply chain reliability from discovery to commercialization of your ADC. This includes coordinated and collaborative services for the development, manufacturing, and testing of bulk drug substance and drug product. We offer a full range of services needed for ADCs:

- Biopharmaceutical process development services and clinical supplies for monoclonal antibodies
- Conjugation
- Linkers and cytotoxic agents
- Process development
- Technology transfer
- Analytical method development and validation
- Stability studies for bulk drug substance and drug product

Conjugation Technology

We have the expertise needed to develop and deliver your bioconjugate or ADC, with over 35 years of industry-leading experience in conjugation. This experience allows us to utilize a broad range of conjugation experience:

- Random cysteine or lysine conjugation technology
- Site directed conjugation via engineered mAbs or enzyme catalyzed
- Various payloads (Microtubule Inhibitors or DNA binding) and linkers
- Alternate scaffolds
- Non-potent bioconjugates
- Conjugation process and analytical chemistry platforms

Payloads and Linkers

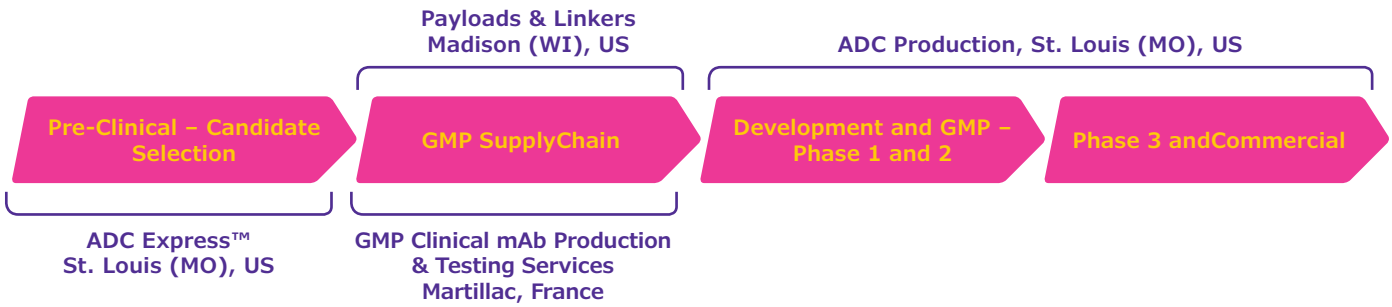
With over 30 years of experience working with highly-active and complex molecules, we handle your payload demands. Our dedicated facilities at Madison and Verona (WI), US, are Safebridge® certified up to Cat. IV and FDA inspected. We have partnered with a number of leading companies in developing conjugation products. We have developed our own proprietary linkers, and have also synthesized many client specific linkers that have proven to be consistent and scalable.

Manufacturing Capabilities

Our purpose built manufacturing facilities are designed for the handling of HPAPIs, antibodies, linkers and for performing complex bioconjugation processes. Whether it be potent (ADCs) or non-potent, our suites feature isolators and specialized handling equipment for clinical and commercial supplies.

- Safebridge® Cat. IV certified facility at St. Louis (MO), US with Grade C classified clean room environment
- Personnel and suites dedicated to ADC development, manufacturing, and testing
- 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)
- Experience with >55 constructs, >600 development batches and >115 cGMP batches
- Commercial scale manufacturing suite:
  - Ability to manufacture batches up to 600 L/3 kg under Grade C classification either with multi-use or single-use equipment
  - Segregated areas for potent solids handling, conjugation,and aseptic bulk filling

ADC Contract Manufacturing Footprint



We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

To place an order or receive technical assistance

For additional information, please visit **EMDMillipore.com**

To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

MilliporeSigma
290 Concord Road
Billerica, MA 01821 USA

© 2019 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved. MilliporeSigma, the vibrant M, SAFC and ADC Express are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

Lit. No. MS_FL4728EN Ver 1.0 2019 - 24972 09/2019