

ADC Express™ Services

Conjugation Services for the Best Candidate Selection

Speeding your path to the clinic with ADC Express™ Services

As an industry leading Contract Testing, Development, and Manufacturing Organization (CTDMO) in the antibody-drug conjugate (ADC) space, we are offering a rapid approach for developing your ADC constructs. Identification of an ADC candidate for preclinical development requires bioconjugation expertise and oftentimes multiple ADCs to compare the impact of varied components on biological efficacy. For developers requiring conjugation capabilities or ADC library generation, we leverage our extensive bioconjugation experience to efficiently turn antibodies, linkers, and payloads into ADCs. For candidates later entering the clinic, our ADC Express™ Service facilitates transition to development and GMP manufacturing.

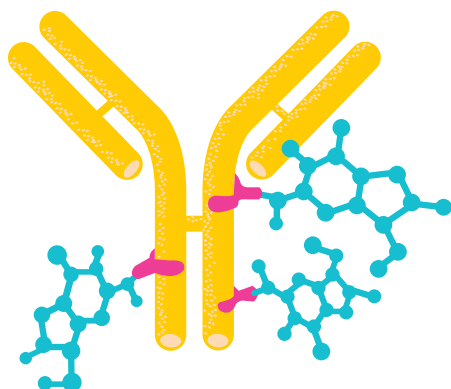
Why choose ADC Express™ Services?

Speed to selection:

- Experience in constructing ADC libraries to allow head-to-head comparison of components
- Production of multiple constructs facilitates target ADC identification
- Ready stock of sourced, research-grade linker-payloads: vcMMAE, mcMMAF, SMCC-DM1, SPDB-DM1, SMCC-DM4, SPDB-DM4, Exatecan-maleimide

Speed to clinic:

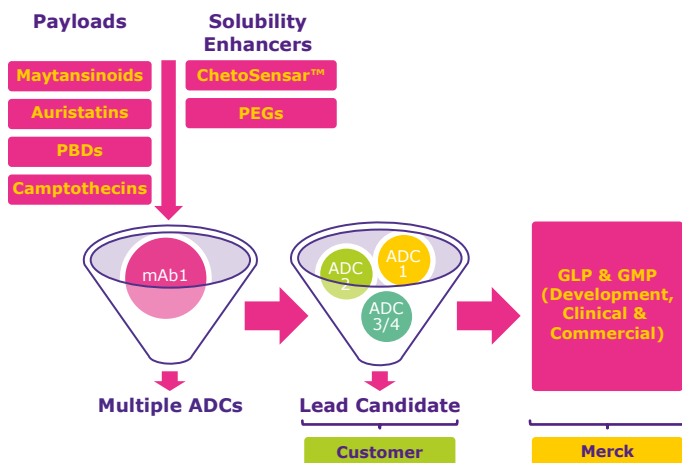
- Rely on our expertise to scale-up your target molecule
- Benefit from an established partner offering comprehensive services for GLP and GMP production
- Supply chain consolidation gives you comprehensive ADC services within one organization



ADC Express™ Services Features

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

How do ADC Express™ Services work?



We offer a library of popular linker-payloads to rapidly produce multiple ADC constructs from a single mAb. Payloads include but are not limited to

- Maytansines
- Auristatins
- Pyrrolobenzodiazepine (PBD) dimers
- Camptothecin (CPT)

ChetoSensar™ technology or PEGs can be discussed for enhanced solubility. Now available for immediate use: MMAE, DM1, DM4, exatecan, and MAYCore™ drug linkers with ChetoSensar™ technology already incorporated.

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
- Linker, payload, conjugation development, and manufacturing services
- Technology transfer, analytical method development, and validation
- Stability studies for bulk drug substance and drug product

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.

For additional information please visit [SigmaAldrich.com/services/contract-manufacturing/adc-bioconjugation](https://www.sigmaaldrich.com/services/contract-manufacturing/adc-bioconjugation)

To place an order or receive technical assistance, please visit [SigmaAldrich.com/services/contact-sa-fc](https://www.sigmaaldrich.com/services/contact-sa-fc)

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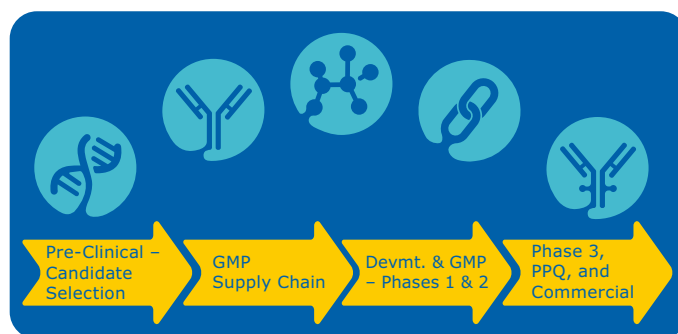
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ADC Conjugation and Manufacturing

With +35 years of industry-leading experience in conjugation, we have the expertise needed to develop and deliver your bioconjugate or ADC. Our purpose-built manufacturing facilities are designed for the handling of HPAPIs, antibodies, linkers, and for performing complex bioconjugation processes. Our new site expansion gives you access to one of the world's largest single nanogram OEL containment Facilities.

- Safebridge® Cat. IV certified facility in 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)
- 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
- Experience with +85 constructs, +600 development batches, +50 INDs, and +215 GMP batches (+25 batches for commercial use)
- Random cysteine or lysine conjugation technology
- Site-directed conjugation via engineered mAbs or enzyme-catalyzed
- Alternate scaffolds & non-potent bioconjugates

Integrated services from gene to BDS and from pre-clinical to commercial



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