Millipore®
CTDMO Services

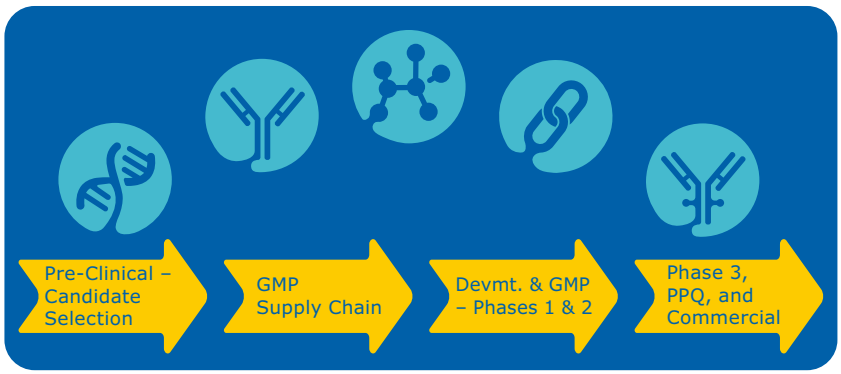
MERCK

Comprehensive ADC and Bioconjugation Solutions

We offer end-to-end services to bring your ADCs and bioconjugates into the clinic and to commercialization. This is accomplished through collaborative services integrated with a reliable supply chain for the development, manufacturing, and testing of bulk drug substance (BDS) and drug product (DP).

- Cell line development and cGMP supplies of monoclonal antibodies
- Linker, payload, conjugation development, and manufacturing services
- Technology transfer, analytical method development, and validation
- Release testing and stability studies for bulk drug substance (BDS) and drug product (DP)
- Regulatory support for seamless scale-up (IND, PPQ, BLA/NDA)
- Innovative technologies to advance your drug discovery and development

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



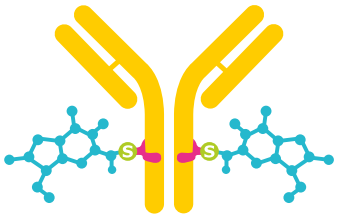
ADC and Bioconjugation Development and Manufacturing

With over 15 years of industry-leading experience in conjugation and purpose-built manufacturing facilities, we have the expertise needed to develop and manufacture your bioconjugate or ADC.

This includes +100 constructs, +1000 development batches, +60 INDs and +240 GMP batches (+25 for commercial use).

- FDA/EMA inspected and Safebridge® Cat. IV certified facility in St. Louis (MO), US, with Grade C classified clean room environment
- Extensive analytical capabilities for characterization, including mass spectrometry and cell-based assays
- Ability to manufacture batches up to 600 L (~3 kg) under Grade C classification either with multi-use or single-use equipment
- Pilot Scale Manufacturing area under Grade D classification
- Segregated areas for potent and non-potent handling

Vast bioconjugation experience with diverse components: novel antibody formats, solubilizers, linkers, and both cytotoxic and non-traditional payload classes



Antibody

- Humanized IgG
- Site specific engineering
- Bispecific mAbs
- fAb

Solubilizer

- ChetoSensar™ Technology
- PEGs
- Polymers

Linker

Cleavable
- Enzymatic (protease)
- Acid Labile (hydrazone)

Non-Cleavable
- PEG/Cyclohexyl Hindered Disulfide

Payload

Cytotoxic
- Maytansines
- Auristatins
- Camptothecins
- PBDs
- Tubulysins
- Calicheamicin
- SN-38

Non-traditional
- Oligos
- Metal chelators
- Antibiotics
- Polymers
- Biomolecules
- Dyes

Integrated Supply and Technology Solutions

ChetoSensar™ Technology

Novel solubilization technology for hydrophobic ADCs.

- Increased ADC solubility, important for reaching high DAR
- Wider therapeutic index and higher drug efficacy
- Improved bioconjugation efficiency
- ChetoSensar™ and ready-to-conjugate drug linkers available as samples or within ADC Express™ Services (ChetoSensar™-MMAE, -DM1, -DM4, -exatecan, -MAYCore™)

Monodisperse Activated PEGs for ADC Conjugation

With decades of PEG synthesis expertise, our technical teams tailor our approach to meet your unique needs, everything from monodisperse to polydisperse, linear to branched, and all varieties of functionalization.

ADCore Payload Intermediates

We have developed advanced precursors to synthesize common payloads faster and with less risk.

- Includes MAYCore™, DOLCore™, and PBDCore™ advanced intermediates
- Enables rapid synthesis of maytansine, dolastatin-10, and PBD payloads
- Suitable for up to phase I clinical studies with process, validation to support path to commercial approval
- Free samples available

Integrated Services

ADC Express™ Services

Preclinical conjugation services for lead candidate selection.

- 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

GMP mAb supplies

Our multi-disciplinary team has more than three decades of experience with hundreds of biologics – providing technology, equipment, and expert counsel you can trust.

- GMP Clinical manufacturing from 50 L to 2,000 L scale
- Commercial manufacturing at 200 L and 2,000 L scale
- MAbs, Fabs, bispecific, recombinant proteins, Fc-fusion, and other similar formats

Payload and Linker Services

With +35 years of experience, we are proficient in the handling of APIs, highly potent APIs (HPAPIs), linkers, and diverse payloads.

- FDA-inspected, premier high potency GMP manufacturing facilities in Madison and Verona (WI), US
- Safebridge®-certified up to Cat. IV
- One of the world's largest single-digit nanogram OEL containment facilities
- DM1 – Mertansine, MMAE and Exatecan off-the-shelf GMP quality payload without royalty payments

For additional information, please visit:
www.sigmaaldrich.com/services/contract-manufacturing/adc-bioconjugation

To place an order or receive technical assistance, contact us at:
www.sigmaaldrich.com/adc-api-ctdmo-contact

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