MilliporeSigma

Antibody Drug Conjugates

Products. Services. Expertise.

Advanced ADC Solutions

The development journey of an Antibody Drug Conjugate (ADC) is complex and remarkably challenging: it requires linking a unique, tumor targeted monoclonal antibody (mAb) to a potent, cell killing cytotoxic small molecule drug. This requires expertise in small and large molecule development, manufacturing, formulation and testing. Choosing an experienced partner, with these skills and the required containment facilities can help advance your ADC to market. Whether you are seeking to build your process based on our tailored technology platforms, a service provider – or a combination of both, we can collaborate with you.

Our ADC Services – integrated from gene sequence to liquid bulk

Complex supply chains with multiple vendors can impede clinical development, lengthening timelines. We offer a seamless supply chain from gene sequence to stability testing of final drug product that minimizes development and manufacturing complexity, reducing time to market. Our team offers:

- Development and manufacturing of monoclonal antibodies, high potency payload molecules, linkers and conjugation services.
- More than 30 years of expertise in process development of more than 220 biologics and in conjugation of more than 35 different constructs.
- Passionate teams with comprehensive experience and a track record of successful execution of customer projects.

Our ADC product offering – Take advantage of our dedicated technological innovations

ADCs are challenging molecules requiring advanced manufacturing suites and dedicated equipment to characterize the molecule and demonstrate its purity, homogeneity and stability. Optimized and robust purification steps using chromatography (hydrophobic interaction or ion exchange) or tangential flow filtration (TFF) are essential to remove process related contamination as well as residuals of linkers and cytotoxic agent, and to concentrate the active pharmaceutical ingredient (API) and stabilize the final bulk substance. ADCs also require an extended containment strategy to protect operators while avoiding the bulk product and the environment from any contamination.We offer a comprehensive portfolio of products from Cell Culture Media to TFF, from buffers to stabilizers to fit your ADC manufacturing needs.

Rely on our expertise to develop the right process, the right systems and the right solutions to empower your ADC to success.

More information

Products, services and expertise for your ADC process:
EMDMillipore.com/buildyourprocess

Conjugation or Linker/Payload Contract Manufacturing services:
SigmaAldrich.com/adc

No guide will replace the need to conduct process development and optimization experiments. The unique nature of every process stream combined with application and regulatory requirements play a part in determining the optimum process solutions. Use this selection guide as a starting point for selecting and sizing the most appropriate MilliporeSigma's solutions.

Antibody drug conjugates

process flow

Provantage® End-to-End services (process development, GMP clinical supply, process tech transfer, facility design and construction) | Provantage® Lab services (qualification and validation) | SAFC® ADC and bioconjugation services (from clinical to commercial scale, contract manufacturing of linkers and payloads) | BioReliance® services (non-clinical testing and manufacturing services for biologics) | Pharma and Biopharma courses

Cell culture supplements | Media prep | Mixing

- Liquid and dry powder (customized) cell culture media
- CHOZN® cell line platform and gene editing reagents
- Cellvento™ cell culture media
- EX-CELL® Advanced™ CHO Fed-batch system
- imMEDIAte ADVANTAGE™ custom media
- CellPrime® non-animal origin supplements
- Fetal bovine serum
- LONG®R3IGF-I Cell Culture Growth Factor
- Sterilizing-grade Aervent® filters
- Mobius® single-use mixing solution
- Mobius® FlexReady solution for buffer and media preparation
- Mobius® powder delivery system
- NovaSeptum® sampling systems
- NovAseptic® mixer
- Emprove® raw materials
- PharmaGrade raw materials
- Provantage® cell line development and upstream optimization

Prefiltration

- Milligard® filters

Bioburden reduction

- Durapore® hydrophilic filters
- Millipore Express® SHC and SHR hydrophilic filters

Bioreactor

- Sterilizing-grade Aervent® filters
- Mobius® single-use bioreactors
- Mobius® commitment services
- NovaSeptum® sampling systems

Primary clarification

- Millistak+® Pod disposable depth filters, COHC or DOHC media
- Clarisolve® depth filters
- Mobius® FlexReady solution for clarification
- pDADMAC 10% solution flocculation reagent
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]

Secondary clarification

- Millistak+® Pod disposable depth filters, A_1HC, B_1HC, XOHC or FOHC media
- Mobius® FlexReady solution for clarification
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]

Bioburden reduction

- Milligard® filters
- Durapore® hydrophilic filters
- Millipore Express® hydrophilic filters

Protein A affinity chromatography

- Eshmuno® A resin
- ProSep® Ultra Plus resin
- Mobius® FlexReady solution with Smart Flexware® assemblies for chromatography
- Chromabolt® prepacked chromatography columns
- QuikScale® and IsoPak® chromatography columns
- K-Prime® chromatography systems
- Custom chromatography systems and columns
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured PAB solution for cleaning in place and storage[1]
- Chromatography column packing services
- Implementation services for Mobius® FlexReady solution

Virus inactivation

- Sodium acetate trihydrate suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, JP, USP
- Mineral acids
- Mobius® single-use mixing solution
- NovaSeptum® sampling system
- NovAseptic® mixers

Aggregate removal

- Millistak+® Pod disposable depth filters, A_1HC or XOHC media
- Durapore® hydrophilic filters
- Millipore Express® hydrophilic filters

Bioburden reduction

- Milligard® filters
- Durapore® hydrophilic filters
- Millipore Express® hydrophilic filters

Diafiltration

- Pellicon® 3 cassettes with Ultracel® 30 kD membrane
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]

Cation-exchange chromatography

- Eshmuno® CPX resin
- Fractogel® EMD SO_3, EMD SE Hicap, and EMD COO- resins
- Chromabolt® prepacked chromatography columns
- Mobius® FlexReady solution with SmartFlexware® assemblies for chromatography
- QuikScale® and IsoPak® chromatography columns
- K-Prime® chromatography systems
- Custom chromatography systems and columns
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]
- Chromatography column packing services
- Implementation services for Mobius® FlexReady solution

Bioburden reduction

- Milligard® filters
- Durapore® hydrophilic filters
- Millipore Express® hydrophilic filters

Anion-exchange chromatography

- Eshmuno® Q resin
- Fractogel® EMD TMAE Hicap resins
- Chromabolt® prepacked chromatography columns
- Mobius® FlexReady solution with Smart Flexware® assemblies for chromatography
- QuikScale® and IsoPak® chromatography columns
- K-Prime® chromatography systems
- Custom chromatography systems and columns
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]
- Chromatography column packing services
- Implementation services for Mobius® FlexReady solution

Viral clearance

- Viresolve® Pro solutions
- Mobius® FlexReady solution for virus filtration
- Virus safety services and support

Lynx® connectors

Ultrafiltration/Diafiltration

- Pellicon® 3 cassettes with Ultracel® 30kD membranes
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]
- TFF cleaning validation services
- Implementation services for Mobius® FlexReady solution

Sterile filtration

- Hydrophilic single layer Durapore® filters
- Hydrophilic multilayer Durapore® filters
- Millipore Express® SHC hydrophilic filters
- Mobius® 2D and 3D assemblies and storage systems
- NovaSeptum® sampling systems
- Custom filtration skids
- Integritest® 4 series automated filter integrity test instrument

ANTIBODY MODIFICATION

Conjugation with linker molecule

- Sterilizing-grade Aervent® filters
- Mobius® single-use mixing solution
- NovaSeptum® sampling systems
- NovAseptic® mixer
- Emprove® raw materials

Removal of residual linker UF/DF

- Pellicon® 3 cassettes with Ultracel® 30kD membranes
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]
- TFF cleaning validation services
- Implementation services for Mobius® FlexReady solution

TOXIC CONTAINMENT

Conjugation with cytotoxic molecule

- Sterilizing-grade Aervent® filters
- Mobius® single-use mixing solution
- NovaSeptum® sampling systems
- NovAseptic® mixer
- Emprove® raw materials
- Bifunctional PEGs

Aggregate removal by chromatography (optional)

- Eshmuno® CPX and HCX resins
- Fractogel® EMD SO_3, EMD SE Hicap
- Chromabolt® prepacked chromatography columns
- Mobius® FlexReady solution with SmartFlexware® assemblies for chromatography
- QuikScale® and IsoPak® chromatography columns
- K-Prime® chromatography systems
- Custom chromatography systems and columns
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]
- Chromatography column packing services
- Implementation services for Mobius® FlexReady solution

Removal of residual cytotoxic | Final formulation by UF/DF

- Pellicon® 3 cassettes with Ultracel® 30kD membranes
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- Millipore Express® PHF filters
- Emprove® buffers, salts and stabilizers
- PharmaGrade buffers
- GMP manufactured solutions for cleaning in place and storage[1]
- TFF cleaning validation services
- Implementation services for Mobius® FlexReady solution

Sterile filtration

- Hydrophilic single layer Durapore® filters
- Hydrophilic multilayer Durapore® filters
- Millipore Express® SHC hydrophilic filters
- Mobius® 2D and 3D assemblies and storage systems
- NovaSeptum® sampling systems
- Custom filtration skids
- Integritest® 4 series automated filter integrity test instrument

Final fill

- Mobius® single-use fill finish assemblies
- Mobius® 2D and 3D assemblies and storage systems
- Particle shedding validation services

[1] Based on IPEC – PQG GMP guide for pharmaceutical excipients 2006

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.

The holder of the manufacturing authorization shall ensure that the excipients are suitable for use in medicinal products by ascertaining the appropriate good manufacturing practice.

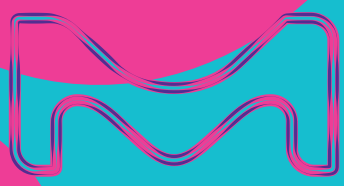
This is particularly true if the material in a certain application is regarded as high risk excipient, for example in parenteral dosage forms.

To place an order or receive technical assistance

In the U.S. and Canada,
call toll-free **1-800-645-5476**

For other countries across Europe and the world, please visit:
EMDMillipore.com/offices

For Technical Service, please visit:
EMDMillipore.com/techservice



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