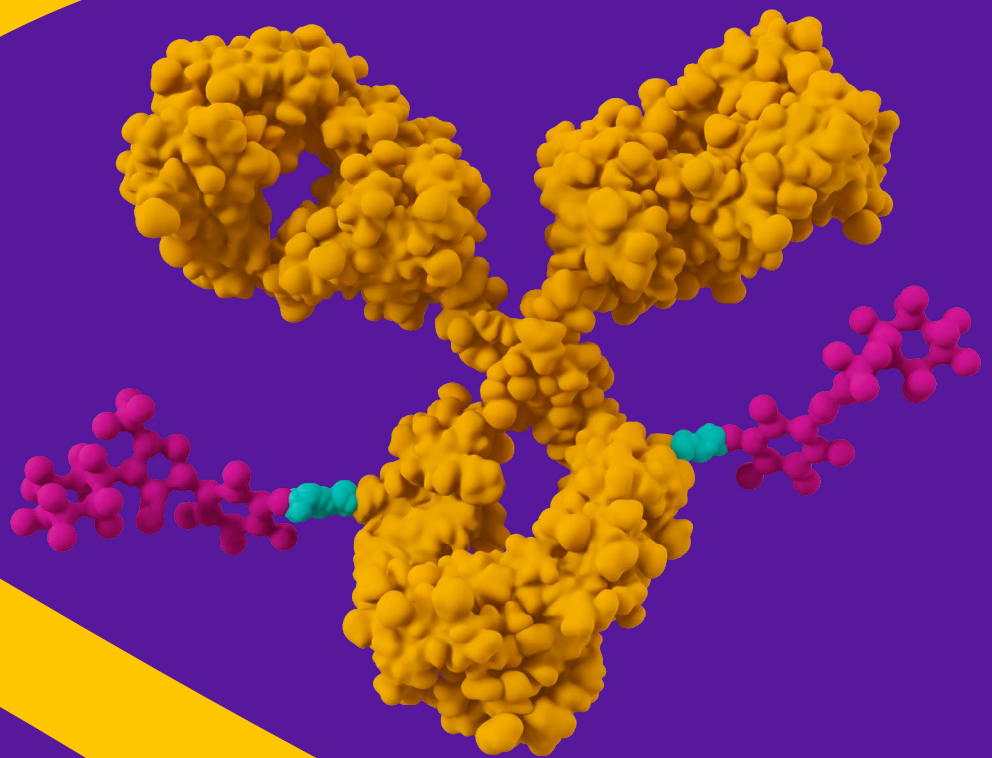


Antibody DRUG CONJUGATES

Products. Services. Expertise.



Millipore®
CTDMO Services

Millipore®

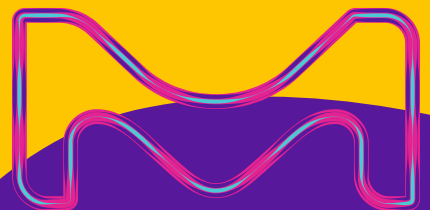
Preparation, Separation,
Filtration & Monitoring Products

SAFC®

Pharma & Biopharma Raw
Material Solutions

BioReliance®

Pharma & Biopharma
Contract Testing Services



MilliporeSigma is the U.S. and
Canada Life Science business of
Merck KGaA, Darmstadt, Germany.

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 270 biologics and in conjugation of more than 85 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

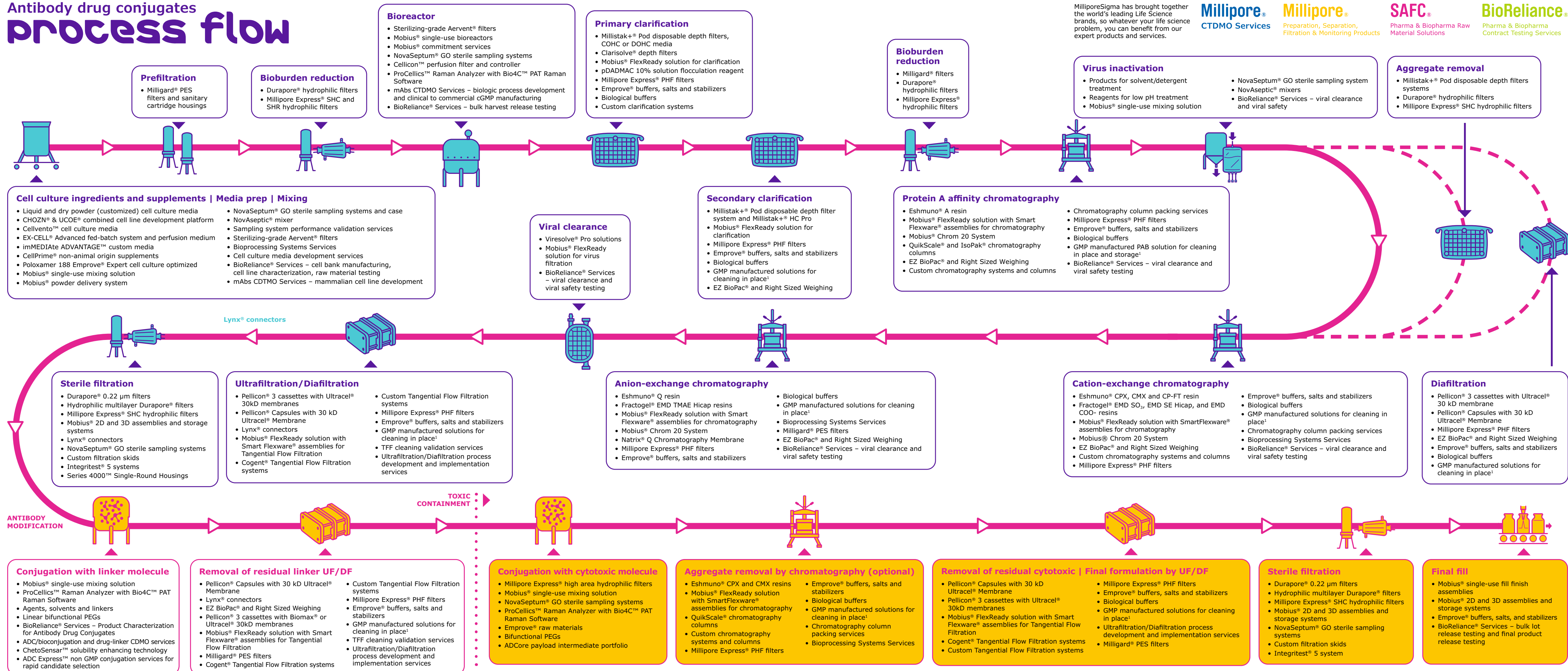
ADCs are challenging molecules requiring advanced manufacturing suites and dedicated equipment to characterize the molecule and demonstrate its purity, homogeneity and stability. Optimized and robust purification steps using chromatography (hydrophobic interaction or ion exchange) or tangential flow 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.

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



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.

Millipore®

The Millipore portfolio of MilliporeSigma offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring, as well as clinical and commercial biomanufacturing CTDMO services – all of which are deeply rooted in quality, reliability and time-tested processes. Our proven products, expert services and regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

SAFC®

The SAFC portfolio of MilliporeSigma offers customized and ready-to-use raw material solutions, backed by deep regulatory expertise. Our high-quality products and services are supported by an experienced and responsive team of raw material and regulatory experts who are committed to understand your requirements and provide tailored solutions that meet your exact needs.

BioReliance®

The BioReliance portfolio of MilliporeSigma encompasses biopharmaceutical characterization, and biosafety testing services. Our experienced teams and operational expertise make us the partner who supports you all the way and always has your vital goal in mind.

**Click. Explore.
Learn more.**

WEB PAGE ADC MANUFACTURING
Sigma-Aldrich.com/adc-manufacturing

PROCESSING APPLICATION GUIDE

Identify the relevant products for your process:
MilliporeSigma.com/BAG

