

BRINGING
YOUR
SCIENCE
TO LIFE

Bioconjugation and Antibody Drug Conjugates



Your Partner for Conjugation Projects





• Pioneers in the highly potent landscape for decades, we successfully managed numerous drug-linker projects. Since our first ADC project in 2005, many customers, ranging from small biotech to large pharmaceutical companies, expressed a growing interest in our ADC and bioconjugation abilities. We can manage projects from drug-linker to final drug product.

CARBOGEN AMCIS offers tailored programs based on your needs and budget. You will benefit from our dedicated team of experienced chemists, biochemists and biologists, who can advise you on the best linker and conjugation strategy. For all other projects conducted by CARBOGEN AMCIS, safety and quality are central in the ADC area.



CARBOGEN AMCIS specializes in ADC strategies, providing expertise in every aspect.
Watch our video.



Why choose us?



Drug-linker

cGMP process development and manufacture of Warheads & Linkers (OEL < 0.01 $\mu \mathrm{g/m^3}$)



Conjugation

cGMP Conjugation of mAb to Small



Analytical

Outstanding analytical capabilities



Clean Room

Clean Room fully qualified for cGMP manufacturing dedicated to bio-conjugation



Purification

State of art purification technologies



Dedicated Team

A multi-disciplinary and extensively experienced team



Fill & Finish

Fill-&-Finish capabilities

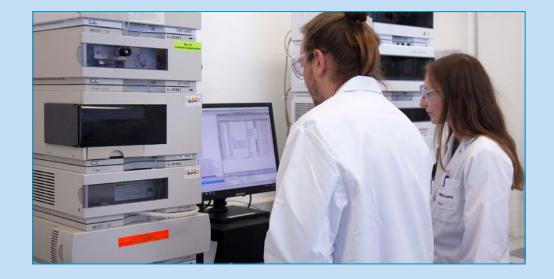


Support

Regulatory and CMC support









Your Partner for Conjugation Projects







We advise our customers on the best conjugation strategy to successfully manage projects from drug-linker synthesis to final drug product manufacture."

Luca – Manager ADC

Conjugation & Purification Capabilities

- • Chemical & enzymatic conjugation of monoclonal antibodies and biologics
- •• ÄKTA-Pure 25 chromatography system
- •• ÄKTA Ready Skid for large scale aseptic
- PALL SU-TFF automated system for aseptic diafiltration
- •• Handling of up to OEL 10 ng/m³ 3 8h-TWA
- •• cGMP compliant bioburden controlled environment Grade D and C qualified areas
- •• Single use liquid handling systems

Analytical & Bioanalytical Capabilities

- •• Comprehensive In-Process Analysis using advanced techniques such as Microvolume UV, (U)HPLC, Endotoxin Testing, pH, and Conductivity measurements.
- Full Release Testing for Drug Substance and Drug Product, including ELISA, icIEF, CE-SDS, UV, and (U)HPLC methods (RP, SEC, HIC, IEX) with DAD and CAD detection.
- •• Qualified External Partners for specialized assays such as High-Resolution Mass Spectrometry, SPR, Cell-Based Assays, Bioburden and Endotoxin Testing, and extensive Characterization Studies.
- •• Reference Standard Qualification and Storage under GMP conditions.
- •• ICH-Compliant Stability Studies to support product lifecycle management.
- Harmonized Analytical Equipment across Drug Substance and Fill & Finish sites ensuring seamless method transfer and analytical consistency.



Sterile Fill & Finish Capabilities

In addition to our process research and manufacturing services for the fast supply of highly potent APIs, we offer formulation services for highly potent drug products and cGMP sterile production of parenteral drugs, including cytostatics and cytotoxics.

- •• Pre-clinical batches (for technical, stability or toxicology studies)
- •• Clinical batches (for phases I, II and III)
- • Commercial supply
- •• Liquid and freeze-dried forms
- •• Annex 1 & GMP-compliant facility (ANSM)

New Strategic Partnership

The fully integrated ADC development and manufacturing offering combines Celonic's advanced biologics capabilities with CARBOGEN AMCIS's expertise in payload synthesis, conjugation, and sterile fill-finish, creating a seamless, end-to-end platform for ADC innovators.

- •• Cell line development and antibody production at scale (Celonic)
- Payload and linker synthesis and at scale manufacturing (CARBOGEN AMCIS)
- •• ADC conjugation and sterile fill-finish (CARBOGEN AMCIS)
- •• Regulatory support and CMC documentation for IND, IMPD, and BLA filings





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