

A SUBSIDIARY OF WUXI BIOLOGICS

WuXi XDC:

The Bioconjugation Leader

WuXi XDC, as a dedicated CRDMO providing end-to-end discovery, development, and manufacturing services for bioconjugates and antibody drug conjugates (ADCs), provides a broad range of linkers, payloads and combinations thereof, for early research and manufacturing, from milligram to kilogram scale. We design novel payload linker as part of our integrated discovery services and we maintain large-scale commercial GMP manufacturing to provide a seamless, one-stop service for all of your payload linker needs.



400+

CLIENTS ACROSS THE DISCOVERY TO CLINICAL SPECTRUM



180+

DISTINCT PAYLOAD/ LINKER PROJECTS



71+

INDS FILED FROM OUR CLIENTS USING OUR INTEGRATED SERVICE PLATFORMS



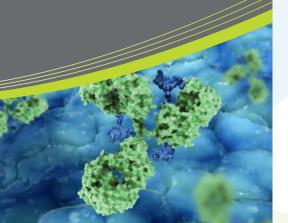
5+

DMFs AVAILABLE FOR PAYLOADS, LINKERS OR PAYLOAD-LINKERS



29+

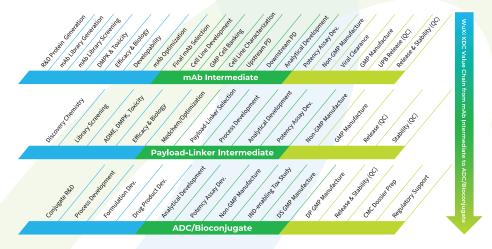
PHASE II/III PROJECTS





ADC's often come with significant development and manufacturing challenges. WuXi XDC offers extensive multi-disciplinary expertise and experience working with a wide array of bioconjugates across the entire discovery to GMP manufacturing continuum. To help overcome obstacles, our fully integrated end-to-end services also streamline timelines and eliminate the inefficiencies and risks associated with the multi-vendor drug development model.

An integrated one-stop value chain for the development of ADCs and other bioconjugates



One Stop Payload Linker Services

WuXi XDC offers comprehensive and integrated discovery, CMC development and cGMP manufacturing of the payloads, linkers and payload-linker chemical intermediates used in the production of Antibody Drug Conjugates (ADCs) and other bioconjugates.



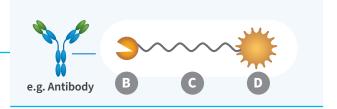


We offer extensive experience and one-stop service platforms across a wide range of chemical/biochemical modalities conjugated to antibodies or other biomolecules:



Chemical Payload-Linker Platform (e.g., Antibody Drug Conjugate/ADC)

WuXi XDC provides discovery/screening to GMP manufacturing for the chemical payloads, linkers and connectors used in bioconjugate development.





Chemical connectors for conjugation

Maleimide; NHS; Di-Br-Maleimide; Pyrimidine; DBCO; BCN; and more...



Cleavable/non-cleavable linkers

Peptide: GGFG; VC; Val-Ala; Gly-Gly-Phe-OH and more...

PEG: PEG4; PEG8; PEG16; PEG2; PEG4000 and more...

Sugar: mono-poly, di-poly, tri-poly Branched: di-payloads, multi-payloads...



D Payload

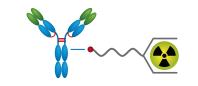
Common payloads: Auristatin derivative; Authracycline Der; Camptothecin Der; Tubulysin; Calicheamincin Der; Maytansinoid Der; Duocarmycin; PBD derivative

Custom design, process development and synthesis also available

Experts, highly trained scientists and the requisite facilities and equipment are available for R&D and manufacturing of the many new bioconjugate modalities being developed.



Chelator-Linker Platform (e.g., Radionucleotide Drug Conjugate/RDC)



Our teams provide single-source solutions for molecule modification, route design, fast synthesis and GMP production for chelator and chelator-linker (often with a radionucleotide) approaches.

Examples of various chelators offered by WuXi XDC: NOTAM; NOTA; DOTA; TETA; HBED; DTPA



Oligo Platform (e.g., Antibody Oligo Conjugate/AOC)



Through our partner WuXi STA, R&D-scale oligonucleotide synthesis and larger-scale non-GMP/GMP manufacturing along with full process and analytical development and QC. Screening of oligo-antibody conjugate combinations is also available for AOC developers.



Peptide Platform (e.g., Peptide Drug Conjugate/PDC)



Liquid/solid phase peptide synthesis, along with full analytical method development and non-GMP & GMP manufacturing is available for the CMC development and production of peptide drug conjugates.



From library generation and screening to preclinical candidate (PCC) selection, we provide tailored linker and payload selection and optimization services to advance your path to success.

MedChem Based Approaches



Physicochemical Properties

(e.g., improve hydrophilicity)

- Polar group introduction
- Charged group introduction
- Hydrophilic group introduction



Serum Stability

- Hindrance proximate to cleavable site
- Two or more release steps required



Release Mechanism

- Non-cleavable
- Tumor specific enzymes cleavable
- Extracellular cleavable



MDR

- Hydrophobic group modification
- Steric hindrance around HBD
- Multi payloads



Mechanism of Action (MOA) & Structure-Activity Relationship (SAR) Methodologies

Different MOA

- DNA crosslinker
- Antimitotic agents
- TOP1 inhibitors
- Protein degraders
- · Multi payloads

Elucidated SAR

- Potency essential group
- Modifiable group
- Linkable group

High Potency Payload Linker Development

With extensive development experience for various high potency chemical entities, we accelerate your payload/payload-linker journey from R&D to commercialization. Our HP development capabilities include:

Development Capability

- Process development for >kg scale batch size
- Projects conducted via FTE (Full-Time Equivalent) or FFS (Fee-for-Service) business models

Analytical Method Development Capability

- Experience developing wide-ranging analytical methods
- Extensive capacity, equipment and facilities available
 - UHPLC/HPLC (Agilent, Waters, Thermo, SHIMADZU)
 - GC, HSGC (Agilent, SHIMADZU)
 - · LC-MS, GC-MS, IC, SFC
 - DSC, TGA, XRPD, PSD, Polarized Light Microscope
 - ICP-OES, ICP-MS, AAS, Kjeldahl Auto Analyzer
 - NMR, Q-Tof MS, FT-IR, UV-Vis, Polarimeter, Raman Spectrometer
 - KF, ROI, Potentiometric Titrator, Melting Point, DVS

Strong Enabling Technologies

- · Hydrogenation
- · Flow chemistry
- Biocatalysis
- Chemocatalysis





High Potency Payload Linker Manufacturing

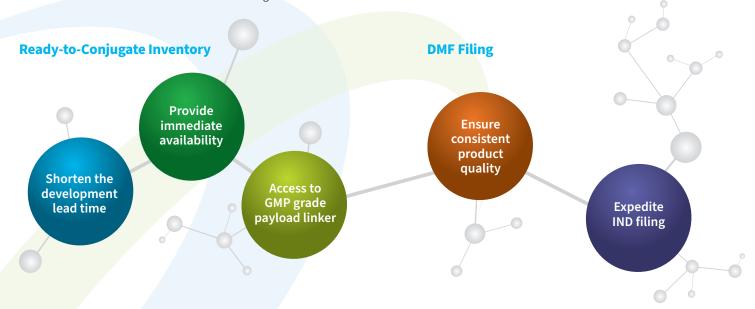
With a highly-vetted, and global regulatory agency approved, quality management system and cutting-edge equipment, we safely handle OEB-5 materials (OEL~10 ng/m³) ranging from several milligrams to tens of kilograms. Our production capabilities include 10 L - 3,000 L reactors and 10 square meter lyophilizer to handle the market's increasing commercial manufacturing needs.

Manufacturing Capabilities:

- GMP high potency (HP) lab and plant to produce chemical payloads in scales from gram to >10 kilogram scale
- All common reactions including HP hydrogenation reactions and HP cryogenic reactions
- Production of compounds with an OEL limit down to 10 ng/m³
- Isolation/purification includes prep-HPLC / lyophilization
- Analytical method development and validation for QC release and stability
- HP products testing under GMP conditions including; HP sample handling for IR, HPLC, GC, KF, DSC, XRPD, ROI, DVS, PLM, and stability chambers down to -70°C if required
- 7 days X 24 hours plant operation
- · Clinical- to commercial-scale manufacturing

Inventory & DMF-ready Payload Linker

WuXi XDC offers a growing library of common payloads and linkers for use in a variety of R&D and pharmaceutical purposes including use as chemical intermediates in the production of antibody drug conjugates (ADCs) and other bioconjugates. These ready-made small molecule entities can be manufactured as both GMP and non-GMP grade.



Making these common molecular complexes readily available (and ready-to-conjugate) – many with existing DMFs - helps expedite the time through CMC development activities and on to IND filing. Examples of these ready-made payload linkers include:

- Payloads: MMAE, MMAF, DM1, DM4, SN38, Exatecan mesylate, PNU159682, PBD etc.
- Linkers: MC-VC-PAB-PNP, Glu-VC-PAB, NHS-Glu-VC-PAB, Azido-Glu-VC-PAB, Hydrazone (acid Sensitive), Disulfide (Glutathione sensitive), SMCC, Fmoc-VA-PAB-PNP

- DMF files for common payload-linkers: vcMMAE, MCMMAF, MMAE, Exatecan Mesylate, etc.
- Commercial DMF for vcMMAE submitted August 2023

About WuXi XDC

WuXi XDC (2268.HK) is a leading global CRDMO focused on antibody drug conjugates (ADC) and the broader bioconjugate market. It provides end-to-end contract research, development and manufacturing services for bioconjugates, including ADCs. Its services cover antibody and other bioconjugate intermediates, chemical payloads and linkers, as well as bioconjugate drug substances and drug products.



