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From Target to Lead

Comprehensive Discovery Services
for ADCs and Bioconjugates

One Source
One Platform
One Team

WuXi XDC: The Bioconjugation Leader

WuXi XDC is a contract research, development, and manufacturing organization (CRDMO) dedicated to providing end-to-end discovery, development, and manufacturing services for antibody drug conjugates (ADCs) and other bioconjugates. Our comprehensive, single-source technology platform greatly simplifies bioconjugate drug or diagnostic and imaging reagent development by providing lead screening and selection, preclinical activities, holistic, and integrated CMC development, and the entire production supply chain, with one company in one centralized region.



419+
GLOBAL PARTNERS



71+
SUCCESSFUL INDs



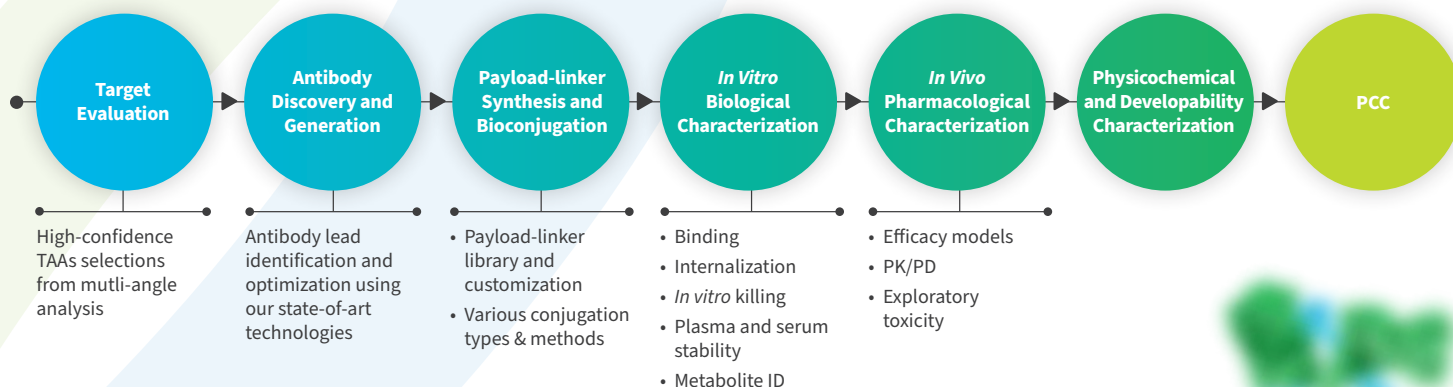
167+
INTEGRATED CMC
PROJECTS



29+
PHASE II/III
PROJECTS

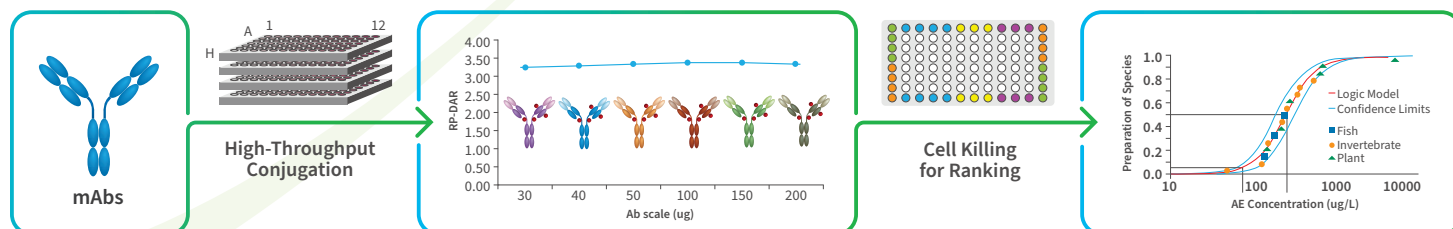
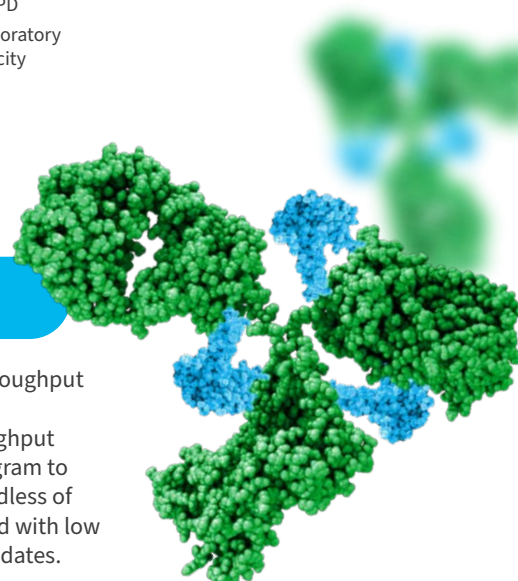
ADC Discovery Toolbox

From target ID and evaluation to final preclinical candidate (PCC) selection, WuXi XDC offers an unprecedented single-source ADC and bioconjugate discovery service.



High-Throughput Conjugation Screening for ADC Discovery

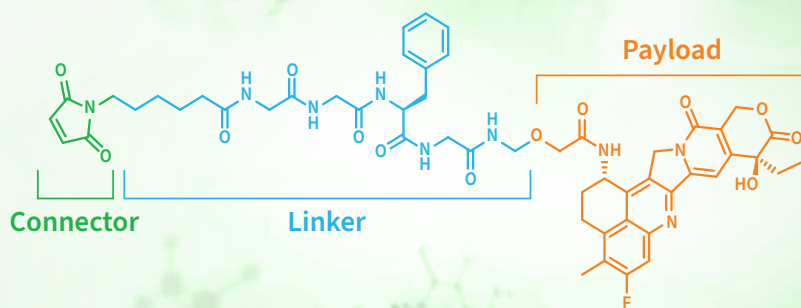
To maximize the efficiency of your drug discovery efforts, we use a state-of-the-art, high-throughput ADC conjugation platform and a highly vetted project management system to facilitate ADC candidate selection. We use a design of experiment (DOE) matrix approach with high-throughput (HTP) methodologies to generate and evaluate intermediates and conjugates from a microgram to milligram scale. In the following example, IgGs from hybridoma crude culture media, regardless of their concentrations, can be made into ADCs of the same DAR (tunable from DAR2–DAR4 and with low residual free drug) for the ensuing batch analyses and the selection of ADC preclinical candidates.



It Starts with the Intermediates

Chemical Payloads and Linkers

WuXi XDC offers comprehensive and integrated discovery, CMC development, and cGMP manufacturing of the payload and linker chemical intermediates used in the production of ADCs and other bioconjugates. The quality systems that oversee our linker and payload services satisfy the quality and cGMP standards outlined by the FDA, EMA, and NMPA, and have passed multiple inspections by global regulatory agencies.



Capabilities

Extensive linker, payload, and linker-payload library, including many ready-made intermediates

Customize or design novel or proprietary synthetic routes

Experience with a wide range of technologies

- Hydrogenation
- Fluid dynamic and flow chemistry
- Biocatalysis
- Chemocatalysis
- Low-temperature and light-sensitive reactions

Capable of handling OEB-5 highly potent materials (OEL ~10 ng/m³)

Process development, high-performance liquid chromatography, and lyophilization under GMP conditions

Analytical development and lot release and stability quality control

Antibodies and Other Biologics

We provide the full spectrum of biologics discovery services for the generation, selection, characterization, production of high affinity, novel antibodies. We offer seven integrated antibody discovery platforms for screening and lead identification of monoclonal, bispecific, and multispecific antibodies or other antibody-based approaches such as antibody fragments (eg, fragment antigen-binding, single-chain variable fragments [scFvs]) and Fc-fusion proteins.

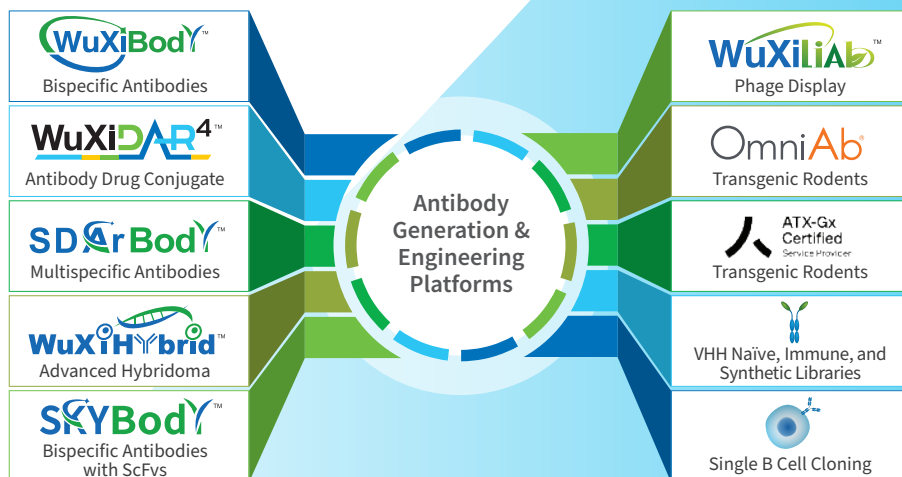
Research-Scale Antibody and Protein Generation

Our industry-leading R&D-scale custom protein production group generates high-quality proteins and antibodies to meet your various bioconjugate program needs. No project is too large or small. Our team of experts can support preparation and purification of the most complex proteins or provide one to hundreds of monoclonal, bispecific, and multispecific antibodies and other recombinant proteins for your diverse needs throughout early-stage discovery research, lead candidate screening, immunizations, *in vivo* studies, biochemical assays, crystal structure analysis, and other research purposes.



Program Features

- Unique codon optimization process and high-expression platforms
- High-throughput automated expression, purification, and analytics system
- Micro-developability and more extensive developability studies



Ready-Made Payload Linkers

[Request A Quote Now](#)



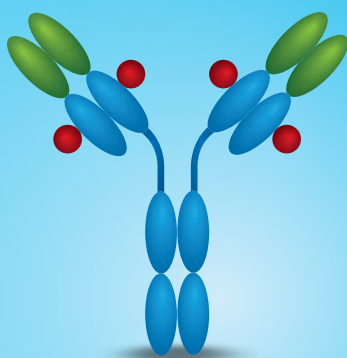
Extensive Modalities and Conjugation Experience

WuXi XDC has extensive experience making various types of bioconjugates, from ADCs to nanoparticles, that range in use from drug candidates to diagnostic and imaging reagents. As seen in the following tables our vast expertise covers a multitude of payloads, linkers, carrier types, and a diverse set of conjugation technologies.

| Payload Examples | | | Linker Examples | | |
|-------------------------------|--|--------------------|--------------------------------|--|--------------------|
| Category | Chemical Name | Chemical Structure | Release Mechanism | Chemical Name | Chemical Structure |
| Microtubule Inhibitor | Monomethyl Aurastatin E (MMAE) | | Cleavable by Cathepsin B | NHS-Glu-VC- PAB (N-hydroxysuccinimide- glutamic acid-valinecitrulline-p-aminobenzyl alcohol) | |
| DNA Topoisomerase I Inhibitor | Exatecan mesylate (DX-8951f) | | | | |
| DNA Ditch Crosslinker | Pyrrolobenzodiazepine (PBD derivatives) | | Cleavable by Reduction | SP-PEG4-DP | |
| Microtubule Inhibitor | DM1 (Mertansine (a maytansinoid derivative)) | | Cleavable by Acid (in the ADC) | PEGn and triazole-containing PABC-peptide-MC | |
| | | | Non-cleavable | SMCC | |

| Carrier Examples | | | | | | | |
|------------------|---------------------|---------------------|-------------------|---------------------|---------|------------------------------------|---------|
| Category | Monoclonal Antibody | Bispecific Antibody | Fc-fusion Protein | Recombinant Protein | Peptide | Synthetic Polymer and Nanoparticle | Micelle |
| Example | | | | | | | |

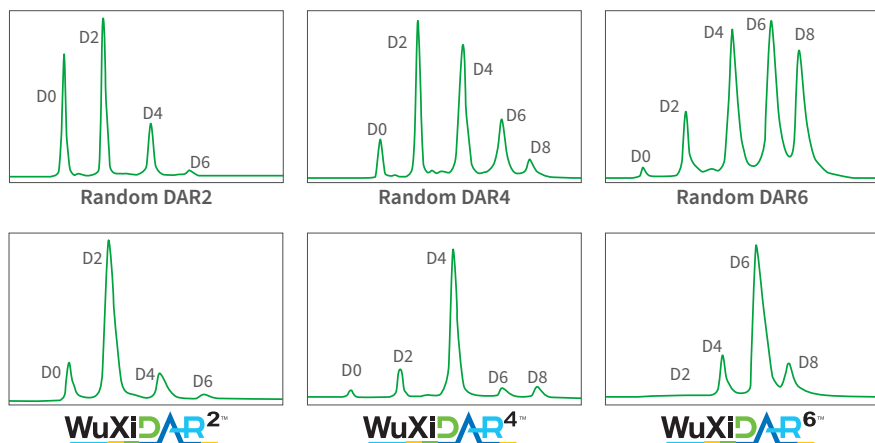
State-of-the-Art Conjugation Technology



The discovery team at WuXi XDC has extensive experience in various bioconjugation types. Over 10 conjugation technologies are applied to generate conjugates.

- Lysine (random)
- Interchain cysteine (random)
- Interchain cysteine (site-specific): WuXiDAR4
- Interchain cysteine (site-specific): ThioBridge
- Cysteine (site-specific): THIOMAB
- mTransglutaminase
- Sortase A (SMACTM, iLDC)
- Farnesyltransferase (ConjuAll)
- GlycoConnect (glycosyl transferase)
- Affinity peptide-mediated conjugation
- And more

The most clinically validated conjugation sites, including those used by many blockbuster ADCs, are interchain cysteines. Using these sites as a foundation, WuXi XDC developed the novel WuXiDARx conjugation platform. WuXiDARx provides a highly flexible drug-to-antibody ratio (DAR), demonstrated homogeneity, compatibility with native IgG1 and many commonly used linker-payloads, and a simplified CMC process. This technology is valuable not only at the discovery stage to streamline ADC engineering and identify the optimal DAR when screening antibody and linker-payload combinations, but also at the CMC stage to accelerate CMC development and reduce development risks and eventual large-scale manufacturing costs.

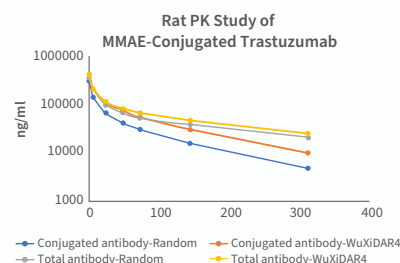


WuXiDARx offers the following advantages:

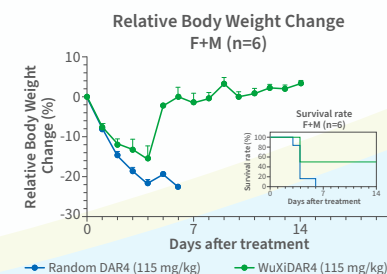
- Flexible DAR approaches: DAR2, DAR4, and DAR6
- High homogeneity of a single conjugated species: $\geq 65\%$ without column purification; $\geq 95\%$ with column purification
- Compatibility with native IgG1: no protein engineering modifications required
- Compatibility with common linker-payloads: no connector modifications needed
- Cost-effective bioconjugation process

WuXiDAR⁴

WuXiDAR4 is our most advanced WuXiDARx platform. ADCs produced from WuXiDAR4 demonstrated comparable cytotoxicity to ADCs produced by conventional stochastic conjugation methods, but demonstrate better PK profiles and tolerability. **So far, seven ADC molecules, generated via the WuXiDAR4 platform, have entered clinical trials.**



In WuXiDAR4-generated ADCs, the majority species are DAR4, leading to an overall better PK profile.



Comprehensive Bioconjugate Analytical Panel

At WuXi XDC, we leverage in-house expertise and state-of-the-art analytical equipment to characterize the distinct intermediates and bioconjugates. Listed in the following tables are critical methods in the characterization, and stability evaluation of bioconjugates and ADCs.

| Basic ADC package | | Analytical Capacity | |
|--|--|----------------------|---|
| <ul style="list-style-type: none"> • Concentration: UV280nm or BCA • Purity: SEC-HPLC • DAR: HIC-HPLC or LC-MS • Free drug: RP-HPLC, SEC-HPLC or LC-MS • Endotoxin: LAL (dynamic turbidity or Endosafe[®] nexgen-PTS[™]) | | Purity test | <ul style="list-style-type: none"> • SEC-HPLC • AEX-HPLC • HIC-HPLC • NR/R CE-SDS |
| | | Impurity test | <ul style="list-style-type: none"> • Free drug • Endotoxin |
| | | Identity | <ul style="list-style-type: none"> • LC-MS (intact, reduced, and native) • SDS-PAGE • Peptide mapping • icIEF • SEC-MALS |
| Mini stability package <ul style="list-style-type: none"> • Freeze and thaw: 1, 3, and 5 cycles • Thermo stress: 40°C for 1 week and 2 weeks UV280nm, SEC-HPLC, and DAR determination (HIC-HPLC or LC-MS) | | Potency | <ul style="list-style-type: none"> • Binding assays (ELISA, SPR, FACS) • Cytotoxicity • Functional assays |

In Vitro and In Vivo Characterization

Beyond our extensive analytical capabilities, we have years of experience and expertise conducting a wide variety of biological assays for the characterization of highly potent ADCs and other bioconjugates, including the ability to screen leads within multiple oncology efficacy models.

Oncology Efficacy Models

Syngeneic

CDX

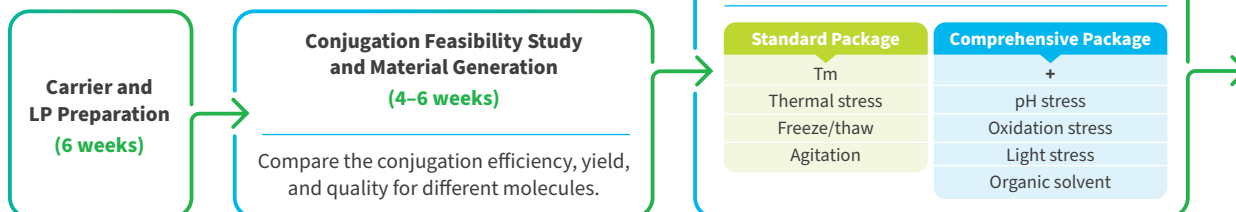
IVIS platform

PBMC and reconstitution

KI model

Flexible Developability Study Packages for Your Bioconjugates

Gram-scale conjugation identifies potential challenges and risks during development.

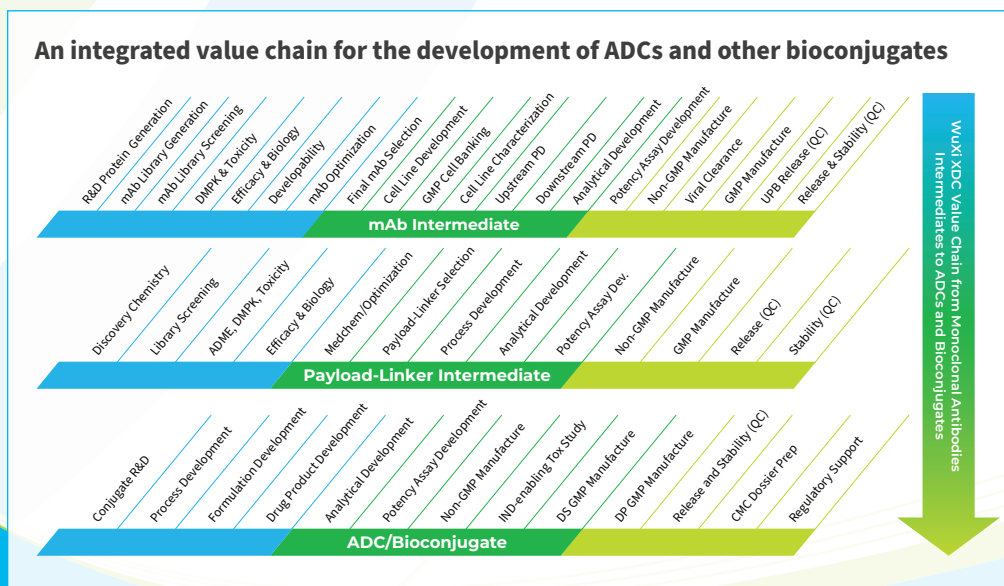


Your Single Source from Target ID to Lead Candidate Selection

WuXi XDC offers integrated discovery services, from target evolution to preclinical candidate determination. Our extensive R&D capabilities allow us to generate, engineer, evaluate, and optimize ADC and bioconjugate lead candidates, including troubleshooting and overcoming the challenges associated with the development of these complex bioconjugated moieties. A complete ADC discovery toolbox and world-class expertise in both platform and novel conjugation technologies are available, as is the ability to handle highly potent and toxic payloads.

Integrated Value Chain

ADCs 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.



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.

Your Single-Source for Bioconjugation Development and cGMP Manufacturing
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