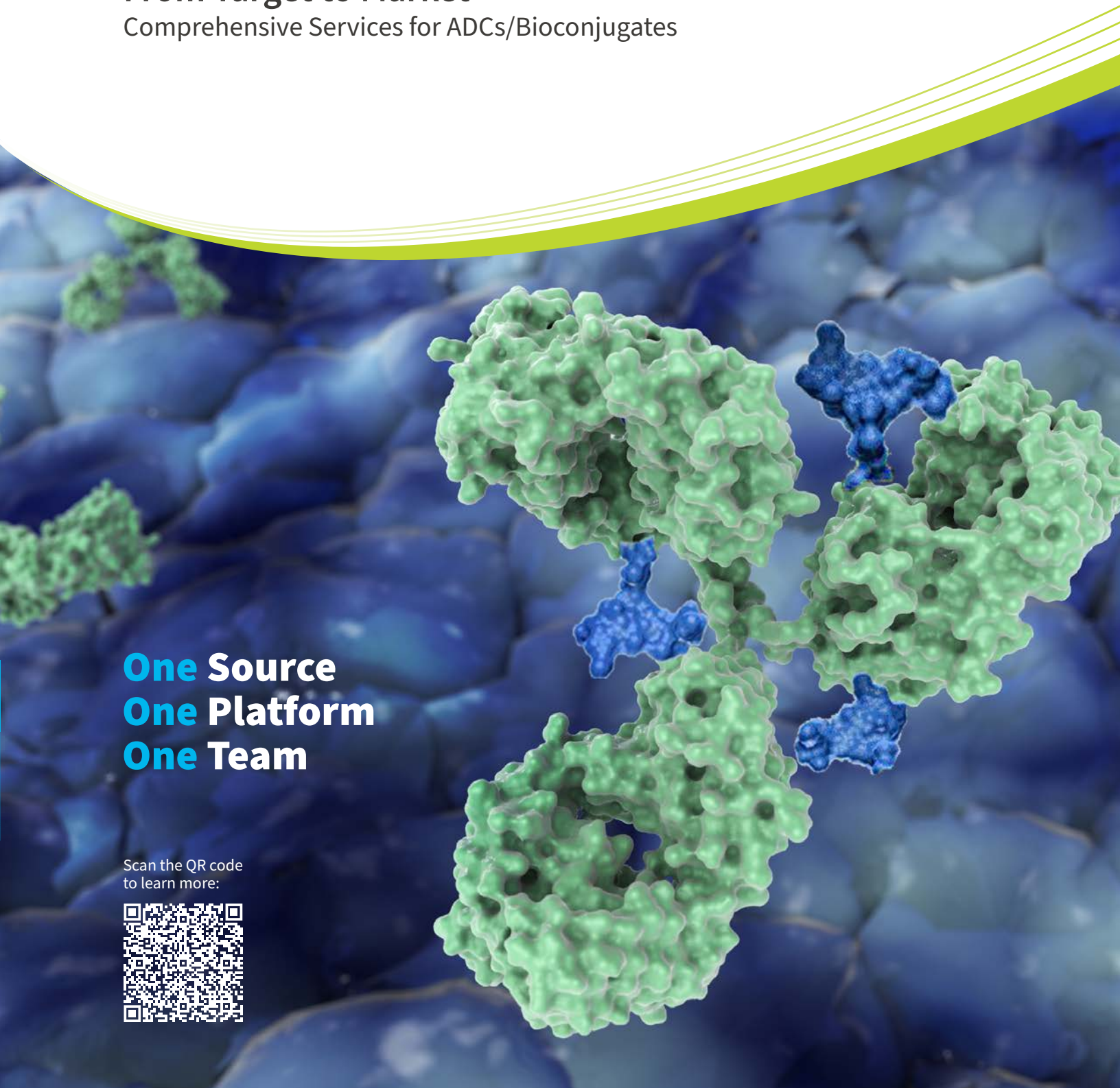
XDC
The Bioconjugation Leader

WuXi XDC:
The Bioconjugation Leader

From Target to Market

Comprehensive Services for ADCs/Bioconjugates



One Source
One Platform
One Team

Scan the QR code
to learn more:

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WuXi XDC:

The Bioconjugation Leader

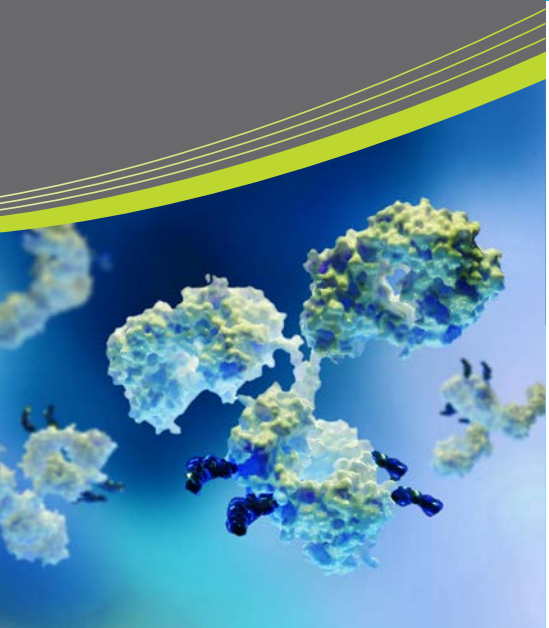
WuXi XDC is a dedicated CRDMO providing end-to-end discovery, development, and manufacturing services for bioconjugates and antibody drug conjugates (ADCs). Our one-stop comprehensive technology platform greatly simplifies Antibody Drug Conjugate (ADC) and other bioconjugate drug development by providing lead screening and selection, preclinical activities, holistic and integrated CMC development, and the entire production supply chain, with one company and in one centralized region.

WuXi XDC's single-source discovery, development and manufacturing platforms include all intermediates (payload, linker and biologics) in addition to its leading bioconjugation R&D programs and high-quality drug substance and drug product GMP manufacturing capabilities.

300+
GLOBAL PARTNERS

110+
INTEGRATED CMC PROJECTS

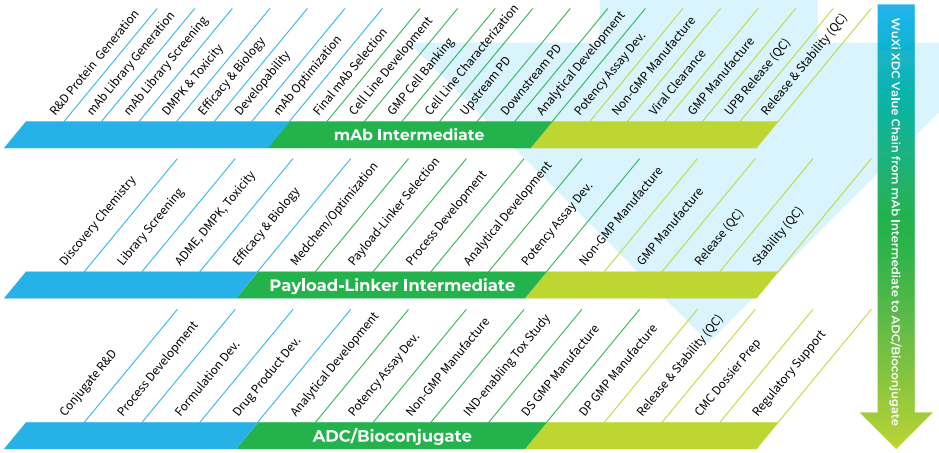
45+
SUCCESSFUL IND'S



Integrated Value Chain

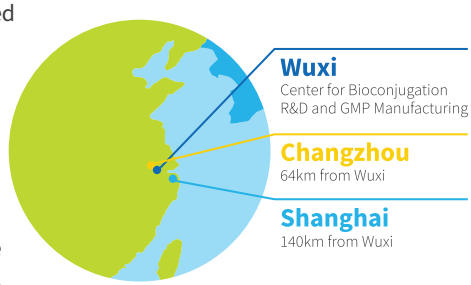
ADC's often come with significant development and manufacturing challenges. WuXi XDC offers extensive multi-disciplinary expertise and experience working with a wide array of bioconjugates across the entire discovery to GMP manufacturing continuum. To help overcome obstacles, our fully integrated end-to-end 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



Geographic Advantage

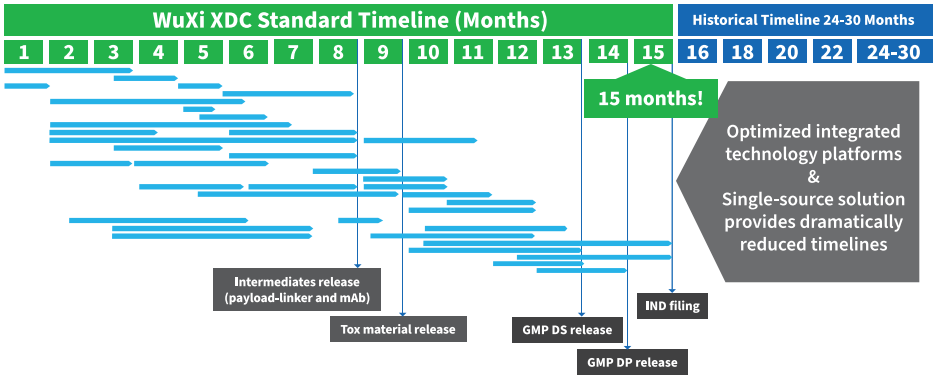
Traditional bionconjugate development required an extensive network of partners often spread across countries or continents. This complicated supply chain can often create geographic and logistical issues affecting overall timelines. WuXi XDC eliminates these concerns as all activities, from discovery to development to GMP manufacturing, are conducted within 1-2 hours (driving). This unequaled advantage streamlines the entire process, reduces overall timelines and project complexity.



Industry Leading Timelines

The integrated, single-source and streamlined WuXi XDC platform provides efficient project management, extensive expertise and premier world-class quality systems that result in right-first-time execution and provide industry leading 13-15 month DNA to IND timelines.

WuXi XDC Expedited CMC Development and GMP Manufacturing Timeline

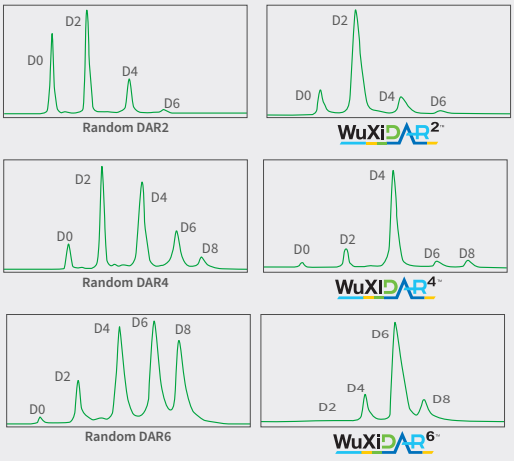


Antibody and Bioconjugate Discovery & Lead Selection

WuXi XDC offers novel technologies and extensive capabilities to expedite the discovery, screening, characterization, optimization, and lead selection of ADCs.

Drug to Antibody Ratio and Enrichment Technology

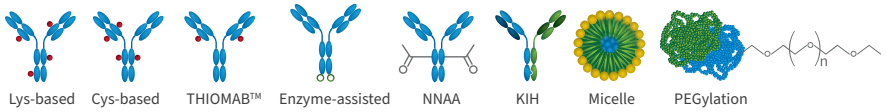
The most clinically validated conjugation sites, including those used by many blockbuster ADCs, are interchain cysteines. Using these sites as a foundation, WuXi XDC developed the novel WuXiDARx conjugation platform. WuXiDARx provides a highly flexible target drug antibody ratio (DAR), demonstrated homogeneity, 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 optimal DAR when screening antibody/linker-payload combos, but also at the CMC stage to accelerate CMC development, reduce development risks and eventual large-scale manufacturing costs.



A Complete ADC Discovery Toolbox

WuXi XDC provides world-class expertise in both platform and novel conjugation technologies and can handle highly potent and toxic payloads. Extensive payload and linker libraries as well as a variety of mAb library generation and screening platforms are available for lead candidate matrix preparation and evaluation. A complete ADC analytical development toolbox can be leveraged to optimize the evaluation and characterization of specific bioconjugates, and to establish the eventual lot release and stability assay panels.

Expertise in a variety of Bioconjugation Technologies

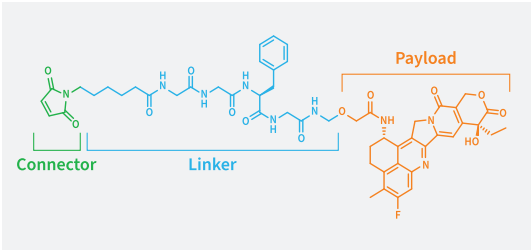


Conjugation Methods

XDC makes ADCs (including PDC, AOC, etc) and other types of conjugates (such as PEGylation) using various chemistries, from conventional cysteine-/ lysine- to site-directed conjugations such as THIOMAB, non-natural-amino-acid-, enzyme-assisted- and GlyConnect-conjugation, and more.

XDC conjugation platforms also support other carrier-payload technologies, e.g., antibody-radioactive conjugate, antibody-siRNA/nucleotide conjugate, peptide-drug conjugate, and nanobody conjugate.

Linker-Payloads from mg to kg



WuXi XDC provides a broad range of linkers, payloads and combinations thereof, for early research and manufacturing, from milligram to kilograms scale. Our Payload-linker library includes: vcMMAE, MC-MMAF, SMCC-DM1, SPBD-DM4, GGFG-DXd, CL2A-SN38, and Tesirine. We can also design novel linker-payloads as part of our integrated discovery services. Our payloads include microtubule inhibitors, DNA/RNA synthesis disruptors, PROTAC, and TLR activators. Linkers include non-cleavable and cleavable varieties of various drug-release mechanisms such as protease-cleavable, pH labile, and others.

One-Stop ADC Discovery Service: From Target to Preclinical Candidate

1 Target Nomination
High confident TAAs selection from multiple angle analysis

2 Antibody Discovery
- Regular rodent, human V transgenic rodent, Human V, and camelid VHH
- Hybridoma, phage-display & single B cell technologies

3 Bioconjugation
- Proprietary conjugation technology to improve homogeneity

WuXiDARx™

- Multiple choice of bioconjugation methods

3 Payload-linker Synthesis
- **Payload-linker library:** vcMMAE, MC-MMAF, SMCC-DM1, SPBD-DM4, GGFG-DXd, CL2A-SN38, Tesirine, etc.
- **Customized payload-linker synthesis**

4 Physicochemical & Developability Characterization
- Purity • Homogeneity • DAR
- Yield • Stability

5 *In vitro* Biological Characterization
- Internalization
- *In vitro* killing
- 200+ tumor cell lines

6 *In vivo* Pharmacological Characterization
- Efficacy models
- PK/PD studies
- Exploratory tox

PCC

cGMP Manufacturing

WuXi XDC offers extensive GMP manufacturing for all bioconjugate intermediates (e.g., payload, linker and antibody/proteins) as well as dedicated GMP manufacturing facilities for clinical and commercial supply of bioconjugate drug substance and drug product.

The ADCs/bioconjugates GMP manufacturing site, which can safely handle a wide variety of highly potent or toxic payloads up to OEB 5 classification, has expanded to include 500 L / 2000 L bioreactors and a 20 square meter lyophilizer to handle the ADC industry's increasing commercial manufacturing needs.

Payload and Linker Manufacturing Capabilities Include:

- 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 to OEL limit of 10 ng/m^3
- Isolation/Purification includes prep-HPLC / lyophilization

Complete ADC Bioconjugate Supply Chain				
	mAb	Payload-Linker	ADC	ADC DP
Lab Scale	√	√	√	√
Non-GMP pilot scale	√	√	√	√
cGMP manufacturing	500 L / 2000 L	> 5 kg	Up to 10 kg	2-50 mL vials, 8M doses, 5m^2 & 20 m^2 lyo

Full spectrum and tailored CMC development for bioconjugates and ADCs

We offer a full range of CMC development services including:

- Integrated mAb, payload-linker and bioconjugate process development packages.
- Bioconjugate formulation and drug product process development, includes various dosage forms, e.g., liquid, frozen, and lyophilized fills in vials.
- In-house expertise and state-of-the-art analytical equipment to characterize the distinct intermediates (e.g., protein/mAb, payload and linker) and the bioconjugate drug substance and drug product at various stages of development. Analytical method development, method verification/ validation and full release and stability testing are all conducted in-house, including potency assays.


Conjugation manufacturing


Drug product manufacturing

Meeting Global Regulatory Requirements

Our cGMP manufacturing facilities for ADCs/bioconjugates are designed to meet U.S. FDA, EMA and NMPA GMP requirements and global EHS compliance.

About WuXi XDC

WuXi XDC, a subsidiary of WuXi Biologics, is a leading global contract research, development and manufacturing organization (CRDMO) focused on antibody drug conjugates (ADC) and the broader bioconjugate market. The company's end-to-end services cover antibody intermediates and other biologics, chemical payloads and linkers, as well as bioconjugated drug substance and drug product from concept to commercialization. WuXi XDC has been successful in bringing multiple ADC projects to the Investigational New Drug (IND) filing stage in record time, nearly cutting in half the traditional development timeline.

Your Single-Source for Bioconjugation Development and cGMP Manufacturing

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