

Advanced Linker Payload Solutions

Tailored Solutions for Unmatched Precision

Antibody-Drug Conjugates (ADCs) represent a transformative approach to cancer treatment, combining the targeting capabilities of monoclonal antibodies (mAbs) with the potent cytotoxic effects of small molecule payloads. At the heart of effective ADCs is the linker payload architecture; a critical component that determines the therapeutic efficacy and safety of the drug. The design of the linker not only affects the stability and distribution of the ADC but also ensures the precise release of the cytotoxic agent, minimizing effects on healthy tissue.

The design of linker payloads is pivotal in the development of ADCs and Bioconjugates. Effective linkers are engineered to be stable in the bloodstream but to release the drug payload once inside the tumor environment. This controlled release is crucial for maximizing the therapeutic window and reducing systemic toxicity.

Abzena's Expertise and Capabilities

At Abzena, we specialize in the strategic integration of mAbs with meticulously designed linkers and payloads to enhance clinical outcomes. Our expertise encompasses:

- **Precision Engineering:** Developing linkers that maintain stability in circulation and release the payload specifically in the tumor environment.
- **Custom Solutions:** Tailoring the properties of the linker and payload to match the unique characteristics of each target and therapeutic application.
- **Innovative Linker Technology:** Our team excels in the synthesis of innovative linkers that optimize the therapeutic index of ADCs. This includes our unique ThioBridge™ technology, a robust and versatile linker solution that enhances the stability and efficacy of ADCs.
- **Robust Payload Options:** Abzena works with a wide range of cytotoxic payloads, from traditional chemotherapeutics to novel molecules designed for greater potency and fewer side effects. Each payload is meticulously selected and tailored to ensure optimal performance of the ADC.

We not only provide tailor-made solutions but also ensure that each component of the ADC — from mAbs to linkers to payloads — is designed to meet the highest standards of safety and effectiveness. Our dedication to advancing ADC technology reflects our commitment to moving medicine forward, with each linker payload solution bringing us closer to more effective and safer treatments.



Our Linker Payload Services

Linker Payload Design and Synthesis

At Abzena, we prioritize the development of highly specialized linker payloads that enhance the therapeutic efficacy and safety of ADCs. Our approach includes:

- **Candidate Ranking and Selection:** Using advanced predictive models and data, we help prioritize drug candidates by their potential for success in clinical settings.
- **Comprehensive Assessments:** We conduct a series of rigorous evaluations including:
 - **In silico Modeling:** Predictive computational models to forecast behavior and interactions of ADCs within biological systems.
 - **In vitro Testing:** Laboratory testing to assess the cytotoxicity and stability of ADCs under controlled conditions.
 - **Ex vivo Studies:** Analysis using tissues from the target organism to evaluate the biological relevance of our ADC formulations.
- **Matrix Evaluation and Developability:** Our matrix evaluation process strategically streamlines ADC development, scaling, and manufacturing. This approach helps de-risk the development process, ensuring scalability and manufacturability from an early stage.

Highly Potent Materials

Handling and manufacturing highly potent materials requires precision, control, and safety. Abzena is equipped with:

- **Engineering Controls:** Dedicated facilities designed to handle compounds with strict occupational exposure limits (OELs) to ensure the safety of our personnel and the environment.
- **Capabilities:** Small-scale handling of gram quantities of compounds with OELs down to 1ng/m³ in our research and development labs.
- **Large-scale production capabilities** of kilogram quantities for the same OEL range in our high potency process labs and cGMP suites.
- **Scale-Up Facilities:** Our cGMP compliant production facilities are designed for the seamless scale-up of ADC manufacturing, ensuring consistent quality and efficiency.

Analytical Method Development

Ensuring the quality and compliance of the Linker Payloads from discovery through to commercialization is critical. Our analytical method development includes:

- **Phase-Appropriate Methods:** Tailored analytical strategies are employed at each phase of development to ensure the ADCs meet all regulatory and scientific standards.
- **Product Quality Attributes are determined using a range of Analytical Techniques:**
 - **General characteristics**
 - Appearance, pH determination, water content by Karl Fisher titration
 - **Identity**
 - Chromatographic behaviour by HPLC
 - Functional group identification by FT-IR
 - **Structure characterization**
 - High resolution 1D and 2D NMR experiments
 - High resolution Mass Spectroscopy
 - **Product related impurities**
 - Process impurities and degradants by RP-HPLC, uHPLC
 - Stereoisomers by Chiral HPLC
 - Residual solvents by GC-FID
 - Elemental impurities by ICP-MS
 - **Contamination**
 - Bioburden and Endotoxin testing

These comprehensive services are designed to ensure that each linker payload developed meets Abzena's high standards of efficacy, safety, and manufacturability, contributing to the advancement of effective ADC's and related bioconjugates.



Our Customers Say

“We required a partner who not only shared our commitment to innovation but also possessed the deep technical expertise necessary to guide us through the complexities of ADC development. Abzena has been that partner for us. From the initial stages of linker payload design to the final steps of regulatory submission, their team has demonstrated exceptional proficiency and dedication. Working with Abzena, we have been impressed by their ability to integrate sophisticated design with rigorous analytical validation, all while maintaining a clear focus on regulatory compliance. Their proactive communication and adaptability have been particularly invaluable, ensuring that our projects not only meet but exceed the rigorous standards required in our field.”



Summary

At Abzena, we are dedicated to advancing the frontiers of medicine through our specialized linker payload solutions for ADCs. Our comprehensive suite of services encompasses everything from precise payload design to GMP manufacturing, backed by a deep understanding of monoclonal antibodies and innovative linker technologies. With state-of-the-art facilities and a robust approach to analytical method development, we ensure that every ADC we help develop is not only effective and safe but also tailored to meet the unique challenges of targeted cancer therapy.

At every step, Abzena is committed to quality, innovation, and partnership, ensuring that our clients' projects advance from concept to clinic with the highest standards of excellence.



Connect with Abzena today to leverage our expertise in linker payload development whether you're at the early stages of drug development or preparing for commercial scale-up, our team is here to support you every step of the way. Contact us at [abzena.com](https://www.abzena.com) or info@abzena.com to discuss your project needs and discover how our tailored solutions can accelerate your path to clinical success.