ABZENA

We Move Medicine Forward

At Abzena, our focus is on providing a de-risked and streamlined development pathway for our customers. As the leading CDMO + CRO for complex biologics and bioconjugates, we support customers with fully integrated programs or individual tailored services that span from early-stage research and discovery through commercial launch to ensure that your program progresses smoothly through the critical path and rapidly advances to its next milestone.

Over the past 20 years, Abzena has helped hundreds of customers, ranging from emerging biotechs to the top large pharmaceutical firms, achieve their regulatory and clinical milestones. Our expertise in working with both simple and complex molecules, means that we know what it takes to design and develop programs across the full development pathway.

Our skilled team of experts at our US and UK sites, are not fazed by complexity and have a proven track record in overcoming significant challenges of some of the most novel and disruptive biologics and bioconjugate programs, making us the perfect partner for new and groundbreaking medicines.

We Provide Comprehensive Support For:

- Antibodies
- FAbs
- ADCs
- AOCs
- Radioconjugates
- Bispecifics
- Fusion Proteins
- Growth Factors
- Cytokines
- Recombinant & Conjugate Vaccines
- Nanoparticles
- Biosimilars

With Capabilities Ranging From:

- Early-Stage Research & Discovery, Design and Lead Selection
- Robust Analytics, Bioassays and Immunogenicity
- Bioconjugation & Chemistry
- Antibody Engineering and Developability
- Mammalian Cell Line Development
- Linker Payload Design and Synthesis
- Analytical Method & Formulation Development
- Process Development and cGMP Manufacturing up to 2000L
- Technology Transfer & Scale-Up
- Regulatory Support

Our extensive toolkit of services is designed to ensure our customers achieve their Target Product Profile (TPP). With early-stage research, process development and GMP manufacturing capabilities all under a single organization, we can leverage our vast capabilities and knowledge of the product, along with the requisite In Vitro and In Vivo criteria to ensure that the desired TPP can be accomplished from the project outset.

What Sets Abzena Apart

Access to Genuine Scientific & Technical Experts

- We have over 20 years of experience in delivering solutions at each stage of the development lifecycle from early-stage research and discovery, through lead candidate selection, and onward into process development and GMP manufacture.
- Unlike most other service providers, we can provide technical and scientific support that truly spans early-stage research through process development and GMP manufacturing under a single organization to better ensure that the TPP can be achieved.
- Our global scientific teams have extensive experience in overcoming some of the most challenging and complex biologic and bioconjugate programs, making us the perfect partner for novel and disruptive technologies that other CDMOs may shy away from.
- Discovery and design of lead drug candidates – our diverse expertise in protein engineering, chemistry, bioconjugation and formulation development for optimal drug design where liabilities are avoided or addressed early to reduce risk and maximize likelihood of success for standard antibodies, classical ADCs, and novel/next generation biologics, bioconjugates and vaccines.
- Process development – our optimized upstream and downstream processes provide confidence in yields and quality of drug substance, utilizing a platform approach to streamline standard antibody and classical ADC development, but agility to support next generation and novel drug designs.
- Manufacture – extensive flexibility to accommodate 50L to 2000L scale for antibodies and biologics, and low to 100s of gram scale for ADCs and bioconjugates. With the ability to handle highly potent compounds from bench to manufacturing.

Generation of High-Quality & Trusted Data Early in Product Development

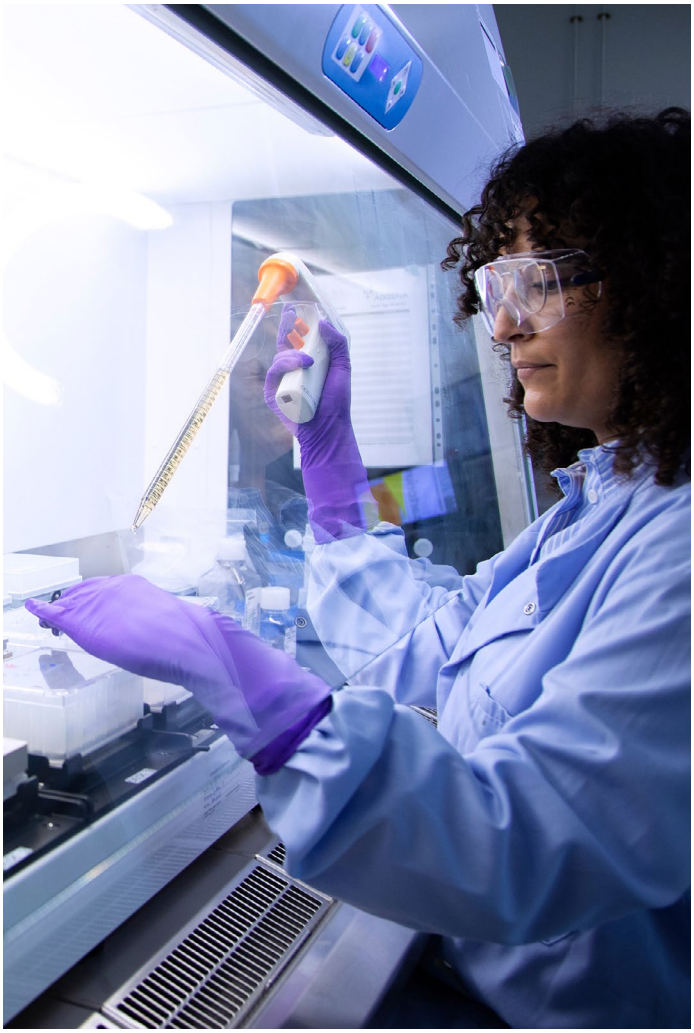
- Good data underpins good decisions. Our stage appropriate analytics & bioassay services that span across each stage of development supports our customers confidently select the best lead target and progress their drug through IND into patients meeting their project goals, regulatory timelines, and budget.
- We have extensive analytics and bioassay capabilities at early stages of development (discovery, design, lead selection) and focused, essential analytics for product release and stability testing of GMP Drug Substance and Drug Product
- Our customers find this data to be incredibly valuable when they are looking for support in attracting investments, regulatory approvals, and licensing or partnering opportunities.

Proactive Problem Solving to Ensure Downstream Success

- Our experienced team is focused on getting it right from the start. We identify and address challenges early in drug design to better ensure downstream clinical and commercial success.
- We also have expertise in fixing and optimizing drugs in later stage development to rescue them from the drug development graveyard.

Diverse & Interconnected Expertise Under a Single Organization

- With capabilities ranging from bioassays to cell line development, bioconjugation and clinical & commercial manufacturing, all under one organization, we can reduce the white space in the development path, which ultimately minimizes risk, reduces costs and accelerates timelines for our customers.
- As an integrated service provider, we accelerate timelines through the ease of technical and materials transfer, and improved scheduling.
- Better workflows and processes can also be attained through improved knowledge transfer between internal multidisciplinary experts and the development of a deep understanding of the drug as it progresses from target to lead selection and process development and manufacture.



Driven By Innovation to Streamline Development

Our team is always seeking new ways to innovate and streamline development for our customers. Our extensive scientific capabilities and proprietary solutions like EpiScreen®, Composite Proteins™, Composite Human Antibodies™, AbZelect™ & AbZelectPRO™, ThioBridge™, LabZient™, are designed to give your program the best chance of clinical and commercial success.

- **EpiScreen® –** an extensive suite of bioinformatic and primary human cell-based assays for immunogenicity assessment to inform of potential safety and efficacy risks in the clinic.
- **Composite Human Antibody™ –** a platform used for designing safer, more effective, humanized antibodies.
- **Composite Proteins™ –** a deimmunization technology that designs safer and more effective therapeutic proteins, devoid of human T cell epitopes, to minimize potential immunogenicity in patients without compromising activity.
- **AbZelect™ & AbZelectPRO™ –** high-yielding cell line development (CLD) platforms for accelerating the generation of production cell lines for manufacture of antibodies and recombinant proteins.
- **ThioBridge™ –** a next-generation conjugation linker technology proven to enhance ADC development by overcoming issues with existing technologies to improve stability, potency, and efficacy.
- **LabZient™ –** our analytical platform that combines predictive in-silico evaluation with laboratory methods to de-risk the application of platform analytical procedures and expedites the pathway to IND.

Streamlined Regulatory Support with Guidance and Packages Tailored to Each Program

- Ensuring compliance and a robust regulatory strategy, we develop phase-appropriate qualification, characterization, and analytical method validation strategies appropriate to your stage of product development that will stand up to regulatory scrutiny.
- Utilizing design of experiment (DOE) studies, we ensure the process is fully understood and documented to support successful regulatory submissions. DoEs are also utilized for process improvements and optimization to ensure you achieve your QTPP.
- We aid in the preparation and authoring of sections of global filings as needed to help ensure a successful outcome from the regulators.

Customer Focused Development where We Help Companies Raise Capital Through Robust Stage Gate Data Generation

We have taken numerous customers through key development value inflexion points that have allowed them to raise capital to take them through manufacture and into patients, with many publicly listing or selling their assets or their company on the back of the clinical data from the drugs we designed and developed for them.

The Abzena Approach

At Abzena, we are focused on getting it right from the start. From early discovery through commercial, our experienced scientists work with you side-by-side, functioning seamlessly as part of your team—using real-world insights to bring new ideas to the table and then turning them into action. With quality at the front of everything we do, we plan the best route, steering your drug program toward regulatory approval, and getting it quickly and effectively to patients.

If you would like to rapidly move your complex biologic or bioconjugate program forward faster, connect with our experts today at info@abzena.com or www.abzena.com.

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