Biopharmaceutical CDMO Pioneer Offers De-Risked Path to Clinic and Beyond

Abzena is the leading complex biologics and bioconjugate CRO and CDMO within the pharmaceutical manufacturing industry. The company supports customers from the initial discovery phase all the way through to the commercial launch of new treatments for patients in need. Following being named Best Novel Treatment Development Partner 2024 – California within the 2024 Global Excellence Awards, we speak with Sean O'Brien, Senior Vice President and San Diego Site Head at Abzena to learn more about the company's expert development and manufacturing capabilities.

Abzena was established in 2013, following the merger of two industry-leading companies, PolyTherics and Antitope. Both UK-based companies, PolyTherics was considered a pioneer in the bioconjugate space, while Antitope was an industry leader in immunogenicity assessment, protein engineering, and cell line development. In 2015 and 2016, Abzena expanded its footprint into the US with the acquisitions of PacificGMP and The Chemistry Research Solution (TCRS), broadening support for its customers with full process and analytical development and cGMP manufacturing capabilities for biologics and bioconjugates through commercial scale.

The company is driven by a commitment to excellence, innovation, and partnership. Abzena's core values include a dedication to quality that is upheld by its unique end-to-end biopharmaceutical services offering that ensures the highest standards of product development and manufacturing. The company's values guide it through each project and is responsible for such effective and innovative solutions that it provides to its customers. Abzena works closely with customers to understand their goals, expectations, and timelines to ensure that every decision made by the company will truly align with the needs of the customer.

Unlike other service providers, Abzena offers a fully integrated and end-to-end service model with the aim of enabling biopharmaceutical companies to transform their scientific ideas into innovative and life-saving therapies. The company is unique from its competitors in its methodologies, electing to offer a complete range of early-stage R&D and lead selection to clinical and commercial manufacturing services all under a single organization to streamline and de-risk the development pathway.

"We pride ourselves on our deep scientific and technical expertise, our extensive analytical and manufacturing capabilities, and our commitment to quality and innovation. Our unique platforms, proprietary technologies, and broad expertise across a range of modalities enables us to tackle some of the most challenging projects in the industry, providing innovative solutions that drive the development of next-generation therapies," Sean tells us.

A pressing issue facing pharmaceutical companies today is supply chain vulnerabilities. "The pharmaceutical supply chain plays a pivotal role in facilitating the effectiveness of partnerships and streamlining the entire drug development process for our customers. In today's climate supply chain challenges continue to grow due to geopolitical tensions, legislation, and pandemics," shares Sean. Thus, making it even more critical to establish a reliable supply chain that meets the necessary regulations."

With CRO and CDMO facilities in the US and UK, Abzena offers an end-to-end and de-risked solution for customers with antibodies (mAbs), proteins, bioconjugates, ADCs/AOCs/RACs, vaccines and bispecifics that spans the entire development pathway. Their robust quality processes ensure accuracy, consistency, and compliance at each stage of the product lifecycle. The company's in-house regulatory services team provides guidance and packages that assist customers in the complex world of regulatory approval. From producing the critical data needed for submissions, to providing assistance with drafting investigational new drug (IND) submissions and biologic license applications (BLA), the Abzena team supports customers at each stage of the regulatory process to ensure the success of their product.

The company has launched numerous platform technologies that have pioneered the biotechnology industry, with one of its most recent being their mammalian cell line development platforms AbZelect™ and AbZelectPRO™. These innovative platforms accelerate the generation of production cell lines for the manufacture of antibodies and recombinant proteins. "Our AbZelect™ platforms enable us to rapidly progress our customer's biological drug programs toward the clinic by reducing timelines from DNA to research cell banks to 15 weeks with exceptional productivity levels," Sean shares. "These platforms provide cost efficiencies and de-risk the drug development pathway by providing rapid production of material, technology transfer, process development, scale-up and manufacturing, all at a single supplier."

In February 2024, Abzena launched LabZient™, an automated, standardized platform that streamlines the assessment and validation of antibodies. "It combines predictive in-silico evaluation with well-established and vetted laboratory methods that de-risk the application of platform analytical procedures," Sean tells us. In doing so, the platform is able to considerably reduce both the timeline and resource costs of drug development by predicting how specific antibody molecules will behave based on a structural assessment, thus eliminating the need for extensive method qualification testing. This provides customers with critical data sooner, which allows them to make more informed decisions earlier in the development process.

In addition to launching new platforms, Abzena also takes the time to develop and enhance existing platform technologies. EpiScreen®, an ex-vivo immunogenicity assessment platform, was created by Antitope, one of the founding companies of Abzena. In April of 2024, Abzena announced the launch of EpiScreen® 2.0, a next-generation immunogenicity tool designed to predict

and evaluate any potential risks of preclinical immunogenicity in protein, antibody, and gene therapy therapeutics. We asked Sean to describe the improvements made to the platform and he tells us, "The EpiScreen® 2.0 platform offers advanced capabilities in predicting and migrating immunogenicity, a critical factor in the success of biopharmaceutical products. The enhanced features of EpiScreen® 2.0 will enable us to provide more accurate immunogenicity assessments, helping our customers de-risk their development programs and accelerate the path to clinical trials and market approval."

Abzena is also considered to be a pioneer in the bioconjugation space with their next generation site-specific conjugation technology, ThioBridge™. When developing Antibody-drug conjugates, or ADCs, linker technologies are a pivotal element to consider. Many linkers, especially those used in the development of first-generation ADC bioconjugation, have limitations that can have an adverse effect on the safety and effectiveness of the ADC. Abzena has designed and implemented ThioBridge™ to overcome such limitations that may arise with traditional linker technologies.

"ThioBridge utilizes the native interchain disulphide bonds of an antibody to conjugate an array of linker payloads, ensuring a consistent and stable drug-to-antibody ratio. This technology allows for more consistent dosing, better control of pharmacokinetics, and more flexibility in choosing the drug type and linker. This means that our customers benefit from a more efficient and reliable pathway to developing ADCs. We have had customers say that our expertise in ADC programs, combined with ThioBridge technology, was crucial in advancing their product to Phase III clinical trials." Sean explains.

Speaking on the future, Sean excitedly tells us, "Our goal is to be the premier CDMO/CRO partner for biopharmaceutical companies, offering unparalleled expertise and seamless, streamlined end-to-end services that ensure their products reach the market efficiently and effectively. Outside of our innovative technologies and platforms, we are taking the necessary steps to support our customer's commercial scale programs in both San Diego, CA and Bristol, PA. With a robust commercialization readiness plan in place, we will be PPQ production ready in 2025.

Judging from the innovative platforms Abzena have launched over the years, it is certain that the future is bright for the industry pioneer. We eagerly anticipate the next advancements from Abzena as the company continues to solidify its position as an industry leader. If you are interested in reading about the latest advancements in biotechnology from Abzena, visit the company website today.

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Company Contact: Kimberly Burrell, SVP of Global Marketing
Email: Kimberly.Burrell@abzena.com
Website: www.abzena.com