ABZENA

Developability for Complex Biologics & Bioconjugates

Understanding the Developability Challenge

Bringing a biopharmaceutical from discovery to market is an immensely challenging and expensive endeavor. Along the way, many promising drug programs fail to reach their full potential due to developability challenges. These setbacks can not only affect timelines and budgets but can also mean the difference between success and failure in bringing life-saving therapies to patients.

At Abzena, we de-risk the drug development process by assessing developability as early as possible. Developability refers to the likelihood that a biologic or bioconjugate will become a manufacturable, safe, and efficacious drug and, when employed effectively, aims to improve the likelihood of a molecule successfully making it to regulatory approval.

Our Unique Approach to Developability

The more you understand about your molecule earlier in the process, the better.

Developability is fundamentally about understanding your molecule. At Abzena we approach this by trying to answer two simple questions right from the outset:

1. **Can we make it?**
2. **Does it work?**

To answer these questions, we combine decades of design experience together with the application of stage-appropriate assays to identify a handful of candidates with desirable properties from hundreds (or more) of initial candidates. However, developability isn't static, with selection criteria needing to be continually refined in order to de-risk a project and move closer to that ideal drug.

Innovative Tools & Techniques

We combine advanced scientific methodologies, cutting-edge technology, and a deep understanding of biologics to deliver unparalleled developability solutions. In particular, we focus on four main areas:

- **Biologics Design and Optimization:** Ultimately, everything leads back to getting the design of the molecule right. At Abzena, we have developed a range of innovative design and engineering solutions across a range of modalities, from traditional mAbs to bispecifics and bioconjugates.
- **Binding and Function:** Biologics are complex molecules often with multiple mechanisms of action. For example, for an antibody, this could be both target-driven (via the Fv) and effector mediated (via the Fc), and so understanding the mode of action of a biologic provides critical insights into a drug's potency, efficacy and safety.
- **Immunogenicity and Safety:** At Abzena, we're committed to understanding both the immunogenicity and safety of biologics and bioconjugates. For this reason, early prediction and mitigation strategies to reduce the risk of both are integral to our approach to developability. To assist with this, we utilize multiple platforms ranging from our high throughput *in silico* MHC Class II prediction algorithms (iTope-AI) through to our PBMC-based immunogenicity risk assessment assays such as EpiScreen® 2.0 and whole blood cytokine release assays to look at safety.
- **Manufacturability:** A biologic therapeutic candidate is only as good as it is stable—and that's why we put so much weight on in-depth analytics. From the beginning where we look at the sequence for potential liabilities through to later stages where we perform studies that stress the molecule for potential weaknesses, we're continually looking to identify candidates that have the desired manufacturability profiles. Furthermore, by understanding how the drug will be used, for example understanding route of administration and dosing, we can ensure molecules have the appropriate properties.

Choosing Your Developability Solution

We recognize that each biologic is unique and can tailor work packages so that you can get exactly what your project needs.

Our stage-appropriate development packages are designed to meet your specific needs:

- **Early Stage:** A rapid multi-parametric assessment of multiple variants allowing candidate triaging.
- **Later Stage:** A more extensive biophysical assessment of a small number of variants, with a focus on aggregation, thermal stability and forced degradation studies.
- **Biological and Functional Assessment:** In-depth evaluation of function and MoA.
- **Immunogenicity and Safety:** Critical assessments to ensure patient safety and minimize immunogenic risks.

ABZENA

Partner with Abzena to Advance Your Biopharmaceutical

Abzena is dedicated to transforming science into life-saving therapies. Our integrated approach to developability ensures that your biologic or bioconjugate is not only viable but optimized for success. By continually refining our selection criteria and asking the right questions early, we de-risk projects and move closer to developing ideal drugs.

Connect with our team of experts today to learn how we can help to de-risk and streamline your asset so that you can start smart and finish fast on your journey from the lab to the clinic at **abzena.com** or **info@abzena.com**.

CAMBRIDGE, UK | BRISTOL, PA, USA | SAN DIEGO, CA, USA | **ABZENA.COM**