ABZENA

Formulation Development

Navigate the Complex Concept-to-Market Path

Transforming a biological concept into a market-ready therapeutic involves navigating a complex labyrinth of scientific and regulatory challenges. Biologics, known for their intricate molecular structures and precise therapeutic actions, demand a sophisticated formulation process tailored to their unique characteristics and stability needs. However, mastering the art of formulation development requires specialized expertise, technologies and facilities to ensure a formulation is both safe and stable, and that it can achieve its target product profile (TPP).

At Abzena, our experienced scientific team specializes in developing complex biological compounds. The process of developing novel biopharmaceutical requires comprehensive knowledge of the unique nature and behavioral attributes relative to each unique molecular profile. We harness the latest technologies to assist in optimizing each formulation for solubility, delivery, safety, and sustained stability.

Our customer-centric approach across a broad range of formulation services enables us to support a biopharmaceutical product throughout its entire lifecycle—from initial pre-formulation studies and generation of a formulation to support toxicology and first-in-human (FIH) clinical trials through to clinical in-use studies, formulation optimization, robustness, and device interaction studies. This enables customers to utilize a single organization for all their formulation and manufacturing requirements, which streamlines and de-risks the process and allows any experience and learnings to be shared across teams. This first-hand knowledge of the product can then be applied to rapidly solve any complex problems which may arise downstream.

Fully integrated formulation development support across multiple modalities:

- Monoclonal Antibodies (mAbs)
- Antibody-Drug Conjugates (ADCs)
- Antibody-Oligonucleotide Conjugates (AOCs)
- Radioconjugates (RACs/RDCs)
- Bispecific Antibodies (bsAbs)
- Fusion Proteins
- Cytokines
- Recombinant & Conjugate Vaccines
- Nanoparticles
- Biosimilars

A Customized Step-by-Step Approach

Abzena puts into play a flexible and customizable approach to achieving your target product profile (TPP). With timelines always in mind, Abzena applies practical and phase-appropriate processes with early-stage (pre-Phase I) formulation activities focused on rapid progression to IND—“fast to clinic,” whilst later-stage formulation activities are focused on providing the best product—“best in clinic.” We accomplish this by applying a set of best-practices towards formulation that typically involves several critical stages.

Pre-formulation

A pre-formulation strategy seeks to establish and characterize the fundamental physicochemical properties of the drug substance. This is a fundamental requirement since information obtained can dictate which approaches are taken during formulation development and can impact on the dose, choice of administration route and delivery system.

An initial assessment aims to investigate the impact of factors including temperature, pH, and modifiers on solubility and stability. Typically this involves multiple lead candidates in a limited set of buffers and modifiers with results obtained from this assessment then used to determine parameters for future studies.

Formulation Development

Utilising data from the pre-formulation assessment, formulation development typically focuses on an extended characterisation of a limited number of lead candidates in which real-time stability data is collected to cover the duration of early clinical studies.

Typically, for earlier clinical phases an IV administration at low concentration may suffice, however, depending upon the anticipated dose and route of administration, additional considerations may be required at this stage.

Assessments included at this stage would include freeze thaw analysis and thermal stability with the further potential to assess viscosity, photostability and agitation stability.

Pre-manufacturing Optimization

Optimization focuses on ensuring the final formulation is fit for purpose with respect to long term storage, dose and route of administration.

Additionally, it may be that development of alternative or modified formulations may be required as informed by clinical data. For example, it may be that higher doses are required (or smaller injection volumes etc.), or that administration via SC injection is preferred to IV infusion.

Therefore, understanding the final formulation as early as practicable ensures that the formulation and manufacturing processes can be seamlessly aligned as the molecule progresses towards Phase III / Commercial.

Diverse Experience

Having delivered over 1400+ programs, we excel in developing formulations for a diverse range of therapeutic modalities. Our state-of-the-art laboratories are equipped with the latest analytical equipment to evaluate the integrity of your drug under an array of conditions to inform optimal formulation constituents and forms.

Our capabilities include:

- UPLC/HPLC systems
- Biophysical stability assessment platforms including Nanotemper Prometheus Panta, Unchained Labs Uncle and RheoSense mVROC Viscometer
- Particle size assessment platforms including Malvern Pananalytical ZetaSizer Ultra and Bio-Techne Micro-Flow Imaging system
- Mass spectrometry instruments (TOF MS, QTOF MS)

Viscosity Case Study

Background

Customer X developed a novel monoclonal antibody (mAb) aimed at subcutaneous administration, targeting a concentration of 100 mg/mL. However, they faced significant formulation challenges that threatened the feasibility of their product.

Challenges

- **Particle Formation:** In the original buffer, the mAb began to form particles at concentrations as low as 5 mg/mL.
- **High Viscosity:** Viscosity increased sharply with mAb concentrations above 50 mg/mL, making concentrations over 80 mg/mL unachievable. This high viscosity was a major barrier to subcutaneous injection.

Solution

Through rigorous screening and re-formulation into a bespoke buffer, Abzena achieved a substantial reduction in viscosity, enabling mAb concentrations up to 100 mg/mL. This solution was pivotal in overcoming the technical barriers, allowing for rapid progression to Investigational New Drug (IND) status.

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Partnering with Abzena

We understand the important role that formulation development plays in ensuring both clinical and commercial success for your program. From early discovery through commercial, our experienced scientists work with you side-by-side, functioning seamlessly as part of your team—to ensure that your new medicine reaches patients in need. With quality at the forefront of everything we do, we plan the best route, steering your drug program toward regulatory approval.

Connect with our team today to learn how Abzena can help to rapidly move your complex biologic or bioconjugate formulation forward faster at abzena.com or info@abzena.com.

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