meribel
PHARMA SOLUTIONS

Finding the formula for success in complex biologic drug development

Enabling clinical readiness for a novel therapy in myasthenia gravis

Myasthenia gravis is a rare, chronic autoimmune neuromuscular disorder caused by antibodies blocking or destroying nicotinic acetylcholine receptors at the neuromuscular junction, resulting in weakness of the skeletal muscles. Current treatment options include acetylcholinesterase inhibitors, corticosteroids, immunosuppressants and, in some cases, thymectomy or plasmapheresis.

These can help manage symptoms, but complete remission is rare, and all of these treatment options can impact long-term quality of life for patients.

This underscores the need for next-generation therapies that not only offer improved efficacy but also minimise treatment burden and support better outcomes for patients over time.

With this unmet need in mind, Ahead Therapeutics, a biotechnology company specialising in antigen-specific therapies for autoimmune diseases, developed a promising candidate. However, progressing this novel antigen-based therapy for myasthenia gravis into clinical manufacturing required overcoming significant formulation and scale-up hurdles, leading Ahead Therapeutics to engage Meribel's expertise in complex biologic drug development.

The challenge: From academic concept to scalable product

Ahead Therapeutics approached Meribel with an ambitious vision: develop a clinical-grade formulation for a lipid nanoparticle-encapsulated antigen peptide designed to treat myasthenia gravis. The initial formulation was derived from an academic setting and lacked the stability and scalability required for GLP- and GMP-compliant manufacturing to support preclinical and further clinical production and beyond.

The project's primary challenge was stabilising the formulation during early-stage scale-up. Even a four-fold increase in batch size led to shifts in critical quality attributes, pushing assay values outside specification. Recognising these constraints, the development team in Meribel and Ahead Therapeutics prioritised developing a new, stability-focused approach to enable preclinical manufacturing.

> "We knew that to move forward, we needed a partner that could not only solve technical challenges but also help us think strategically about scale-up."
>
> Silvia Rodriguez-Vidal, MSc & Chem. Eng, CTO, Ahead Therapeutics

Our solution:
Refining formulation through technical precision

A methodical, stepwise approach was taken from the outset to overcome the instability challenges. A thorough investigation identified the underlying factors contributing to the formulation's instability, confirming the need to optimise handling and processing conditions to support stability at larger scales.

Identifying these factors was a turning point; Meribel re-engineered aspects of the process with stability at scale as the guiding objective. The Meribel development team optimised the manufacturing steps sequentially, introducing practical innovations such as replacing manual syringes with positive displacement pipettes to improve scalability and control. This structured optimisation reduced the risk of compounding errors and ensured each improvement contributed meaningfully to the overall process.

To address the sterility challenges posed by the formulation's sensitivity to conventional sterilisation methods, Meribel developed a flexible low-bioburden manufacturing strategy tailored to the needs of toxicology studies. Anticipating that future clinical batches would require stricter aseptic control, the team also began evaluating isolated compounding technologies. Although significant validation would be needed, this early planning reflected Meribel's commitment to ensuring regulatory compliance and product integrity as development progressed.

Throughout this process, close collaboration between Meribel and Ahead Therapeutics played a crucial role. Open communication allowed the teams to share analytical data in real time, troubleshoot challenges as they emerged, and align strategies quickly. Meribel's formulation expertise and practical manufacturing insight helped guide critical decisions, ensuring that technical changes remained feasible for future GMP requirements.

Results:
A stable and scalable solution

The collaboration delivered tangible results for Ahead Therapeutics, both technically and strategically. Most notably, Meribel transformed an unscalable formulation into a stable, preclinical-ready drug product. This extended shelf life to six months to the date and enabled a 40-fold increase in batch size. Together, these improvements lay the foundation for clinical manufacturing.

Ahead Therapeutics now has a formulation robust enough to support toxicology testing and a manufacturing process that can be adapted for GMP compliance.

In addition, the formulation work helped shape upstream and downstream considerations, such as excipient selection and material sourcing, giving Ahead Therapeutics confidence in the feasibility of long-term scale-up. With a clear, data-backed path toward clinical readiness, Ahead Therapeutics is now ready to navigate the transition from academic innovation to preclinical application.

> "Seeing our formulation not only stabilised but scaled successfully was a major milestone for us. It gave us real confidence in progressing toward clinical trials."
>
> Dr. Míram Salvadó Molero, Senior formulation scientist, Ahead Therapeutics

A partnership built for the path ahead

Open communication and professional honesty were central to the success of the project, creating an environment where both teams could openly share data, troubleshoot challenges together and build trust.

With Ahead Therapeutics already planning a second antigen-based project, the partnership is set to continue, strengthened by a shared goal of advancing a promising therapy that could make a real difference for patients living with myasthenia gravis.

> "From day one, Meribel showed they were committed to learning with us, growing alongside our project and building something stronger for the future."
>
> Silvia Rodriguez-Vidal, MSc & Chem. Eng, CTO, Ahead Therapeutics

To learn more about Meribel's approach to transforming complex formulations into clinical-ready products, get in touch with our team.