



Case Study

Taking Formulations to the Next Level

The Challenge Transfer a manufacturing process from a client/CMO site, and propose improvements to formulation.

The Solution After a successful tech transfer, we revised the formulation and process to improve the product's stability, scalability and manufacturability. We also prepared a risk assessment plan, conducted several statistical design of experiments (DoE) under a QbD (Quality by Design) plan, manufactured registration batches, and prepared regulatory documentation.

The Outcome The project was completed on time and on budget, and the customer successfully filed a robust CMC package with their NDA submission.

