MedPharm

CASE STUDY

Cost-Effective Process Development Delivers Critical Clinical Trial Supply

Optimizing process parameters to ensure consistent quality and on-time delivery of clinical trial material

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The Challenge

A global pharmaceutical company required multiple 25 kg batches of a complex cream to support a Phase 2 atopic dermatitis clinical trial. Any delay or failure in supply would have resulted in significant financial and program risk.

The formulation involved a multi-stage manufacturing process, where variability during scale-up could impact product quality and reproducibility.

Approach

MedPharm applied a structured, science-led process development strategy to ensure successful scale-up and manufacturing:

- Leveraged deep expertise in semi-solid formulation and scale-up
- Identified critical process parameters (CPPs), including homogenization speed, homogenization time, and cooling rates
- Designed a 12-run factorial study using 1 kg lab reactors to model commercial-scale manufacturing
- Evaluated process impact on key product attributes
- Focused on understanding the relationship between process conditions and product performance
- Established precise operating ranges for robust scale-up

Outcome

- Identified rheology as the key critical quality attribute (CQA)
- Determined sensitivity of rheology to homogenization time and speed
- Defined optimal processing parameters for consistent manufacturing
- Successfully scaled up the process with a confirmed large-scale run
- Manufactured over 15 clinical batches with reproducible quality
- Reduced risk of material loss and process failure
- Ensured on-time delivery of clinical trial supply

Why This Matters

Process variability can create significant risk during scale-up, particularly for complex semi-solid formulations. By identifying and controlling critical process parameters early, MedPharm enables robust manufacturing, reduces risk, and ensures reliable clinical supply.