MANUFACTURING SUPPORT | **PROCESS DEV & COMPARABILITY** | ANALYTICAL DEVELOPMENT | QUANTITATIVE MODELING | QUALITY SYSTEMS | DEVICE DEVELOPMENT

REGULATORY SUPPORT | **PRECLINICAL DEVELOPMENT** | PROJECT & PROGRAM MGMT | MARKET RESEARCH | INTELLECTUAL PROPERTY | FINANCING & DILIGENCE

Preclinical Comparability Testing

Why DHC?

- EXPAND CLIENT BANDWIDTH
- PROVIDE ADDITIONAL TECHNICAL EXPERTISE
- SOLVE EXISTING PROBLEM (REMEDIATE)

The Ask

In vivo comparability testing, when required, can be difficult to design and execute optimally. A cell therapy client hired DHC to design and outsource preclinical efficacy and safety studies to demonstrate comparability of a changing clinical stage manufacturing process. This engagement combined two overlapping areas of DHC services: preclinical development and comparability studies.

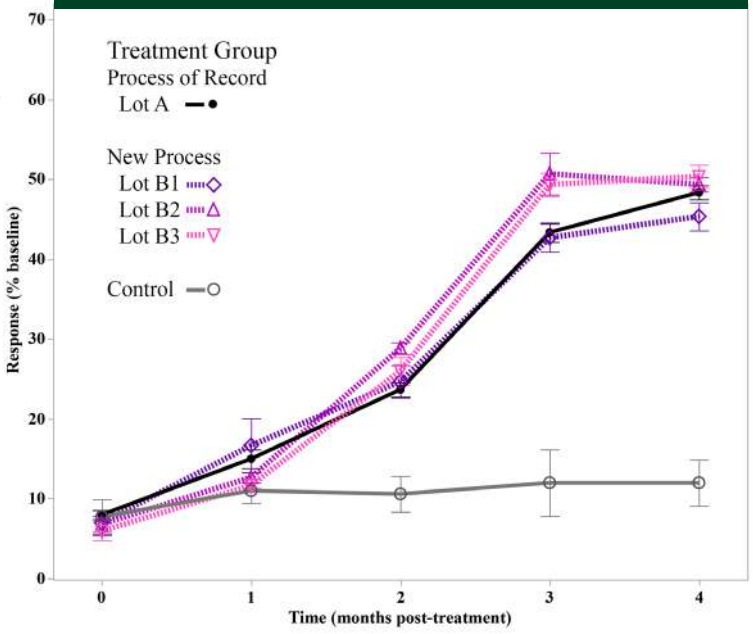
DHC's Approach

- The first step was to evaluate existing preclinical data and identify the critical efficacy and safety outcome measures required to demonstrate drug product comparability.
- Dark Horse then drafted complete study protocols for the efficacy and safety studies, including documents necessary for IACUC committee review. DHC provided detailed guidance on the study parameters required to meet the project objectives, including (but not limited to): *model selection, treatment groups, sample sizes, in-life duration, endpoints, surgical and husbandry expertise needed, and prospective statistical analyses.*
- To facilitate study outsourcing, DHC reviewed candidate preclinical contract research organizations (CROs) and provided the client with a list of recommended preclinical CROs weighted by *expertise, equipment and housing, timeline and availability, training/oversight needs, and cost.*

The Impact

By working with Dark Horse, the client received a clear vision of the preclinical development path and comparability package needed to support the manufacturing process changes for their clinical stage drug product. Additionally, the client identified and forged relationships with the preclinical CROs best suited to support ongoing development of their cell therapy program.

Comparability Plots: tracking new process vs. original



Next/Concurrent Steps

- Process Development/Comparability Studies
- Analytical Development
- Regulatory Support
- Manufacturing Support