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

Comparability Package to Demonstrate Manufacturing Equivalence

Why DHC?

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

The Ask

As manufacturing processes are refined and scaled, demonstration of product comparability is critical. An established biotech advancing a gene-modified cell therapy platform requested DHC's support in demonstrating comparability of their improved manufacturing process and streamlining associated filings with global regulators.

DHC's Approach

In this case, the client was implementing two manufacturing changes (detailed below) while simultaneously preparing to open a multi-jurisdictional clinical trial.

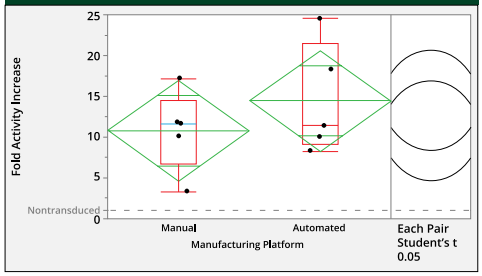
- Initial patient therapeutic dosages were created using a manual process. For this autologous therapy, achieving improved consistency and reducing cost of goods became possible through a shift from a manual process to an automated process.
- To optimize safety, performance and consistency, the client improved the viral vector being used to deliver the gene therapy.

Various considerations including time, cost, and feasibility constrained available study designs to demonstrate equivalency between the old and new processes. DHC worked with the client to design the comparability study plan, analyze the resulting study data, and write up the study findings for submission to global regulators.

The Impact

DHC's strategic design of the comparability package and tech writing for the regulatory submission allowed for a quick and cost-effective proof of equivalence. The comparability submissions were accepted by global regulators with limited questions, resulting in delay-free implementation of the improved manufacturing methods in multiple global jurisdictions.

Manual vs. Automated System Comparison



Next/Concurrent Steps

- Manufacturing Support of CDMO Selection
- Manufacturing Support (Person in Plant)
- Process Codification with Process Development