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

Global CMC Regulatory Strategic and Operational Support

Why DHC?

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

The Ask

Clinical development of cell and gene therapy products is increasingly an international endeavor, requiring an integrated global perspective. An early stage *ex vivo* gene therapy client requested support with regulatory strategy and the technical writing of filings in multiple jurisdictions.

DHC's Approach

This client was interested in expanding clinical development of their products from a single site academic trial to a multicenter global trial. Each global jurisdiction has specific requirements due to varying governmental regulations. DHC's extensive experience around the world provided knowledgeable support and experience in preparing the technical documents and regulatory filings as well as setting up the regulatory meetings in each jurisdiction.

DHC initially supported the client with regulatory strategy and technical writing of a CMC amendment to support process changes designed to facilitate global manufacturing implementation and improve commercial viability of the existing manufacturing process. That amendment required a comparability study; see DHC's Process Development and Comparability page for details on comparability offerings. Following that stage, simultaneous filings allowed for expansion of the trial across multiple global jurisdictions concurrently. During this process, DHC supported the client in preparing IND, IMPDs, and amendments in a wide range of global jurisdictions spanning North America, the Middle East, the EU, and East Asia.

The Impact

All filings to date have been accepted with no delays. DHC strategic and operational support across other fronts (comparability and manufacturing) simultaneous to the regulatory filings streamlined the international regulatory process, leading to faster approvals, financial savings, and the opportunity to support significantly more patients in need of therapy.

Regulatory Filings, by region

Next/Concurrent Steps

- Comparability Studies
- Process Codification
- Manufacturing Support