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

Device Development for Cell Therapy Manufacturing Equipment

Why DHC?

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

The Ask

Development of novel cell therapy products occasionally requires bespoke solutions to overcome manufacturing or product delivery challenges. In this case, a cell therapy client wanted to increase the scalability and cost-effectiveness of manufacturing of their drug product by identifying a closed and automated solution for a manual, laborious, open processing step.

DHC's Approach

- DHC's first step was to define the URS (User Requirement Specifications) to ensure that all needs were taken into account. During this process, DHC worked with the client to weight their needs to identify what matters most and why, ensuring an ultimate selection that prioritized the most urgent or required needs.
- DHC conducted a landscape assessment of potential design and technological improvements which could potentially be made to the manufacturing process. DHC utilized expertise in custom device development and process development to propose several existing and custom device and equipment concepts. The client then selected one of the custom concepts that they believed would best fit their needs.
- DHC generated a RFP (Request for Proposal) which detailed the User Requirements for the custom device and equipment concept. DHC identified and vetted Contract Engineering Groups (CEGs)—those which had the necessary design expertise and experience in custom device and equipment development—and submitted the RFP to those determined to be possible best fits for the scope of the project.
- The proposals that were received from each of the CEGs were analyzed, additional information was requested as needed, and project negotiations initiated. Information collected from the proposals and visits were compiled into a presentation providing a detailed analysis of which CEGs would be the best fit.
- Throughout the custom device development process, DHC generated test protocols and reports that identified design specifications and process parameters through the use of Design of Experiments (DoE).
- Dark Horse was also responsible for V&V (verification and validation) testing, including biocompatibility, extractables/leachables, sterilization, shelf life, and user validation. DHC identified appropriate vendors, generated the test protocols/reports, and coordinated the execution of all studies.
- DHC provided a regulatory assessment based on the intended use of the custom device and equipment. DHC then served as the lead author of the submission to the target regulatory body which included coordination with both the client's regulatory team and the Contract Engineering Group.

The Impact

Through the combined efforts of DHC and the CEG, the client received a turnkey solution to address their requirements, from initial design selection to implementation.

Next/Concurrent Steps

- Project & Program Management
- Regulatory Support
- Process Development