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

Technology Transfer and Person in Plant (PiP) Manufacturing Support

Why DHC?

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

The Ask

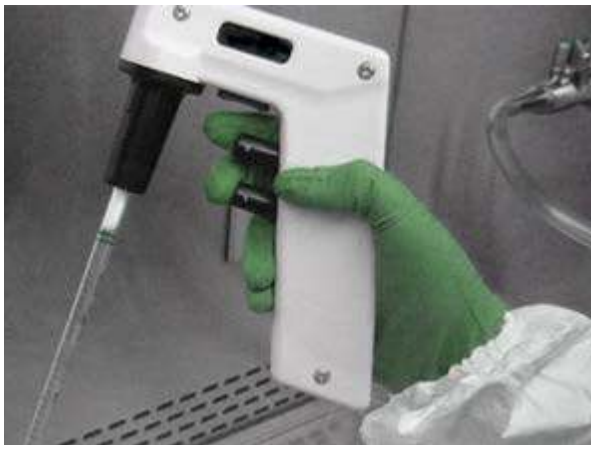
For technology transfers, the devil is in the details. The client requested DHC's assistance in managing dose preparation training of clinical sites during international tech transfer of their flagship cell therapy program.

DHC's Approach

- To ensure that the tech transfer would adhere to GMP standards, Dark Horse employed a kitting strategy for dose preparation assembly, put additional controls in place, matched GMP safety-testing techniques, and worked only with appropriately qualified medical technicians.
- The DHC PiP began on-site in the original location for a rigorous train-the-trainer exercise: multi-part training on the dose preparation method.
- DHC then worked with supply-chain vendors for part-matching, temperature control, supply payment, international regulations for tech transfer, and subject matter expert review and confirmation.
- DHC also contracted with a rigorously vetted FACT (Foundation for Accreditation of Cellular Therapy) lab that would ultimately be responsible for the dose preparation.
- The PiP began the process of the same multi-part training—this time, at the FACT lab with the technicians who would ultimately be performing the dose preparation for each patient. In order for an operator to complete the training satisfactorily they had to demonstrate that they could perform each element consistently and to GMP equivalent specifications.
- To support operational consistency throughout the entire process, the DHC PiP trained operators to package the doses for shipping, confirmed courier capacity and temperature-control procedures for transit to clinical sites, and trained those clinical sites and their medical professionals to ensure correct receipt and usage of the final product.
- Once dose preparation, transit, and clinical-site training were completed, the final procedures and expectations were documented and transferred back to the client so that they would remain operationally self-sufficient.

The Impact

Working with Dark Horse provided the client with a highly successful (and reproducible) tech transfer—without loss of even a single batch. The client was able to move forward independently, assured of documentation, training procedures, third party vendor relationships, and supply chain agreements that allowed for an easy transfer of responsibilities.



Next/Concurrent Steps

- Regulatory Support
- Process Development (including Comparability Studies)