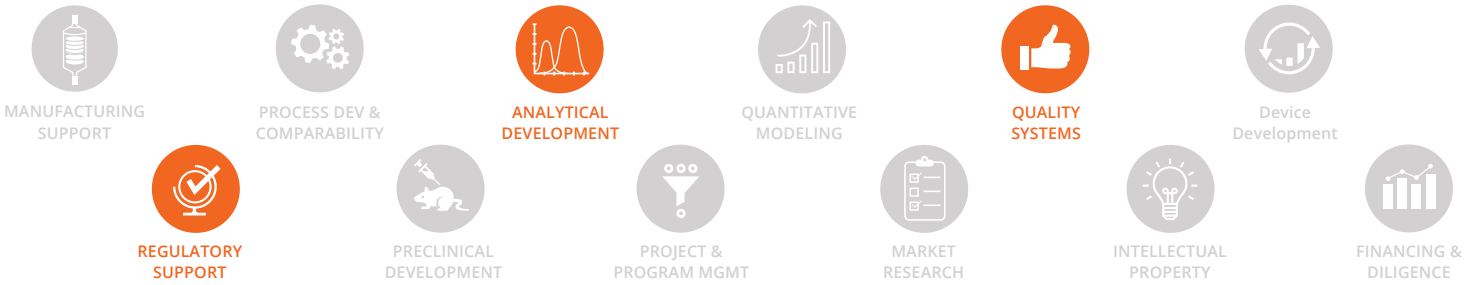

Comprehensive Analytical Support Package for Licensure

Why DHC?

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

The Ask

In C&GT, analytical methods (and the ways in which we apply them) carry even more weight than they might for a standard therapy, due to the high level of complexity inherent in C&GT products. Add in the complexities of development in multiple global jurisdictions with different requirements simultaneously, and the required resourcing for analytical characterization of many C&GT products often approaches (or even exceeds) that needed for manufacturing. This late-stage cell therapy client was preparing to file their licensing applications for a product that was currently in multinational clinical trials. DHC provided a broad scope of analytical guidance, ranging from high-level strategic planning of the licensure-enabling analytical strategy to the tactical execution of specific critical tasks.

DHC's Approach

Dark Horse offers varying levels of analytical support, ranging from high-level strategic oversight to detailed tactical operational support. As with all of our services, these options are *à la carte*, customizable to each client and each situation so as to optimally complement the client's internal capabilities and bandwidth. In this case, DHC's support included the following:

- Establishment of a potency assay, including providing guidance regarding overall strategy and rationale for mechanism of action, reduction to practice and method validation, and assistance in drafting and review of related study protocols and reports
- Establishment of other release and characterization methods, including reduction to practice and method validation, and assistance in drafting and review of related study protocols and reports
- Establishment of specifications and associated acceptance criteria for raw materials, drug substance, and drug product
- Establishment of a defined stability program for raw materials, drug substance, and drug product, including providing guidance around setting retest/expiry periods and data trending for shelf-life projections
- Providing guidance regarding strategy and approach for comparability, and assistance in review of related study protocols and reports
- Review of testing plan for delivery device suitability study
- Drafting and/or review of relevant CMC sections for regulatory submissions
- Preparation for and participation in communications with external stakeholders

The Impact

Dark Horse's breadth of analytical support on both strategic and tactical matters provided this late-stage program with a wide-angle view of their needs in preparing licensing applications in multiple jurisdictions. Armed with all necessary information, the client was able to accelerate their timeline by making strategically informed and data-based choices about how to use their time/money/personnel most efficiently. An analytical perspective naturally prioritizes long-term thinking, which in this situation will decrease the likelihood of delays as the client proceeds towards commercialization.