



# Project & Program Management, Clinical Stage Cell Therapy

## The Ask

Successful execution of Cell & Gene Therapy clinical trials requires proactive management of a myriad of cross-functional program details. A clinical stage cell therapy client requested DHC's assistance with project management at the interface of CMC and clinical operations.

## Why DHC?

EXPAND CLIENT BANDWIDTH

PROVIDE ADDITIONAL TECHNICAL EXPERTISE

SOLVE EXISTING PROBLEM (REMEDiate)

## DHC's Approach

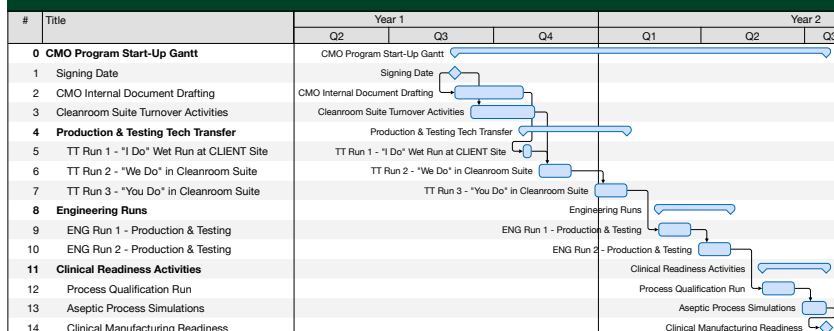
Dark Horse had previously provided support for technical writing of CMC sections of the client's IND submission. Following IND clearance, the client requested DHC's support in the area of project & program management, with a focus on activities at the interface of CMC and clinical, including:

1. Supply chain management activities, specifically, clinical kitting. DHC managed the third party vendor relationship for manufacturing, ordering, and courier activity to various clinical sites for site initiation visits (SIVs).
2. Program and Alliance Management support for the client-CMO relationship. DHC provided project oversight to ensure timely progression through engineering runs and clinical manufacturing.
3. Ongoing cross-functional CMC support between CMC manufacturing and clinical operations. In C&GT this process requires more flexibility than in other spaces. DHC support provided a nimble overhead and pre-production activities schedule to ensure readiness for beginning treatment as quickly as possible once patient(s) were identified and available.

## The Impact

The client secured an immediate resource with deep subject matter expertise able to factor in nuances around the client's own needs and engagement with a third party manufacturer. By hiring DHC (vs. an in-house FTE) the client was able to access a contingent, highly-skilled on-demand workforce, able to achieve results unusually quickly and with minimal onboarding time. This flexible ongoing support helped the client get and stay on track with on-call specialists at the ready.

Example gantt for CMO startup



## Next/Concurrent Steps

- Manufacturing Support (including capacity modeling)
- Quality Systems
- Regulatory Support