



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

Manufacturing Support in CMO Selection Process

The Ask

For companies choosing to outsource manufacturing, selection of the right CMO (Contract Manufacturing Organization) is critical. The client requested DHC's assistance in selecting a CMO that would provide a clear path through commercialization for their preclinical stage gene therapy program.

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.
- Then, DHC put together a detailed RFP (Request for Proposal) to send out to CMOs who were likely fits for the clients' needs. The process of creating the RFP always undergoes a series of client reviews until the document is widely agreed to cover all bases, ensuring that CMOs in consideration have a complete and transparent understanding of the project requirements.
- DHC recommended a short list of RFP recipients based on in-depth knowledge of various CMO's strengths, timelines, availability, etc., as well as consideration of the clients' eventual regulatory expectations. In this case, the RFP went out to five CMOs that met the requirements, in a process parallel to an assessment of the academic CMO that was currently in use.
- DHC actively managed the CMO selection process to expedite decision making. Once RFP responses were returned, DHC used a proprietary RFP evaluation system to turn the qualitative answers into a quantitative measure of each CMO's likely match to client needs.
- In consultation with the client, the initial CMOs were narrowed to two finalists. In-person quality and technical audits were performed for each finalist by DHC subject matter experts, allowing for an in-depth vetting of each manufacturer.
- The client received DHC's executive presentation summarizing the strengths and weaknesses and ultimate recommendations, discussed the results with DHC consultants, and made a decision.



The Impact

The output of this project was the selection of a CMO that would meet the client's needs both today and in the future. DHC was able to deliver on the client's need for a rapid decision-making process by assessing manufacturers on parallel tracks, receiving expedited responses (due to both reputation and industry relationships), and leveraging prior experience to speed RFP preparation and response review. Ultimately, the impact for the client was the identification of and beginning of a relationship with a CMO that will suit their needs for years to come.

Next/Concurrent Steps

- Project & Program Management
- Manufacturing Support (Tech Transfer)
- Manufacturing Support (Person in Plant)

Why DHC?

EXPAND CLIENT BANDWIDTH

PROVIDE ADDITIONAL TECHNICAL EXPERTISE

SOLVE EXISTING PROBLEM (REMEDiate)