PRODUCT PROGRAM MANAGEMENT

CMC Package for Phase II Regulatory Submission

THE NEED

A small cell therapy company was developing a novel patient-specific immunotherapy vaccine for cancer. The client had very good efficacy data in a Phase I trial, however, the FDA placed the company on clinical hold pending submission of an adequate Phase II CMC package. This is a common occurrence with new companies, which have had success in Investigator-led Phase I trials but have failed to address the stricter CMC requirements of a Sponsor-led Phase II IND. Primecore needed to assist the client to develop an adequate IND Module 3 in order to advance its program.

THE APPROACH

- Initial gap analysis was performed, and then a plan was developed, identified technical, resource and training requirements, adopting a Quality by Design (QbD) approach to product development. A core CMC team was assembled, and key members of the client's team were given training on the principles of QbD and how they relate to CMC, cGMP and Quality.
- The CMC team then set about applying the learnings to process development and the product specification, which also necessitated development of appropriate analytical methods.
- Then a GMP manufacturing partner was identifed (CDMO), where Primecore was able to provide the necessary expertise to fast-track tech transfer and process qualification (PQ) in preparation for clinical manufacture.

THE SOLUTION

Overall, the client experienced rapid progress with their CMC, resulting in an on-time submission of a CMC Amendment to the IND.

- The Primecore led CMC team developed the process for GMP manufacture, which required specification of the final drug product and identifying the analytical package for product testing, including all assays and defining the quality target product profile (QTTP), critical quality attributes (CQAs), target product specification (TPS), critical process parameters (CPPs) and in process controls (IPCs).
- The PQ data generated at the CDMO will complete the CMC package and allow the program to begin its Phase II study.

THE RESULTS

- *Client experienced rapid progress with their CMC, resulting in an on-time submission*
- *With a defined process, Primecore was able to perform a CDMO selection process and initiate the tech transfer with the selected partner*
- *All the GMP documentation including the master batch record (MBR) was drafted for use by the CDMO*
- *Client successfully raised Series C financing and was awarded the accolade of being a Fierce 15 company*

PRIMECORE