PRODUCT PROGRAM MANAGEMENT

Remediation and Qualification of a Cell Therapy Device

A small cell therapy company was developing a combination product intended for the treatment of malignant tumor cells in patients. The product was a combination product consisting of a biologic drug (cells) and delivery device. The client had completed Phase 1 however the FDA placed the company on clinical hold due to device design and CMC issues. Primecore was asked to manage the transfer of the device design from the original contract manufacturer to a new, qualified contract manufacturer who could better meet the demands of the product design changes which would be utilized in the Phase 2 clinical trial under IND.

THE APPROACH

The first step was to identify all the activities, and key deliverables required to ensure that the device was designed and developed in accordance with established quality procedures and FDA regulatory requirements.

Plans were then developed for the device design, development, manufacturing, and quality. These plans further defined the responsibilities and requirements of key suppliers, the key manufacturing processes, as well as outlined the planned design, verification, validation, and production activities to meet the requirements and ensure quality was maintained during executed activities.

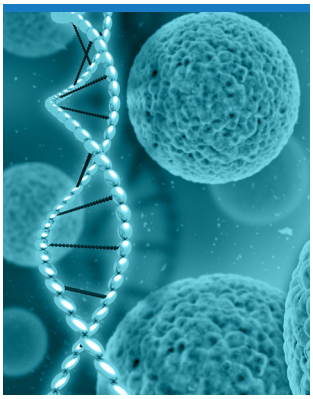
The timeline was then optimized and de-risked by running any necessary tests on the new design as early as possible in the program.

THE SOLUTION

The output of the project provided the client with a device which met all quality, performance, and regulatory requirements.

Device production was switched to a new, better suited supplier for a more robust supply chain.

A Primecore led team managed resources, timeline, communications between all parties to ensure key milestones and deliverables were achieved.



THE RESULTS

- *The client successfully submitted responses to the Agency's clinical hold comments and gained approval to start Phase II trials.*
- *Completed product design verification, validation, and test reports enabled the IND submission and the clinical builds for Phase 2 trials.*
- *With the successful tech transfer of an updated device to a qualified contract manufacturer, the client had confidence in its supply chain to begin Phase 2 trial and their ability to support their oncology patients.*

PRIMECORE