



PRODUCT PROGRAM MANAGEMENT

CMC Lead for Early Phase Gene Therapy Program

The client had a broad, gene therapy portfolio and was limited on resources to manage the CMC aspect of one of its programs. They requested Primecore to manage the CMC team for this key pipeline program, which was an AAV gene therapy product. The program was in the middle of process development and did not have an agreed to CMC strategy or execution plan for its development.

THE APPROACH

Primecore's first step was to establish program management practices around the CMC work and develop program CMC strategies.

- Defined the team's roles and objectives in order to develop strategies for all areas of CMC.
- Strategies were developed for drug substance and drug product development, manufacturing, analytical testing, quality and regulatory.
- Once the strategies were aligned and endorsed by Senior management, detailed plans were established.
- A governance process was implemented to manage the program through its execution.
- Additionally, a risk management process was implemented, along with a communications plan and program change control.

THE SOLUTION

- The program was executed per plan and monitored by the team and through governance.
- The candidate product progressed towards IND within budget and established timelines.



THE RESULTS

- *The approach was well accepted by the client's management and they requested to establish a playbook for future programs.*
- *The program made the progress as planned with no deviations or setbacks.*
- *The comprehensive project documentation allowed for a quick and easy hand over to a newly hired internal program manager.*
- *The client's management enjoyed clear and transparent information on the program's CMC status, and with an established playbook, future programs can be aligned to similar approach for consistency of governance.*

