



PRODUCT PROGRAM MANAGEMENT

CMC Program Management of a New Gene Therapy Product

THE NEED

An innovative start-up, C> company advancing a rAAV gene therapy advancing a ground-breaking gene therapy for a rare debilitating genetic condition affecting both neurological and cardiac functions, required a project manager to lead and manage their CMC program. The therapeutic candidate's three plasmids needed to be finalized and the early stage CMC manufacturing program developed in order to supply test article for non-clinical IND enabling studies and the GLP Tox study.

THE APPROACH

- A project charter was developed clearly identifying program scope & deliverables as well as key milestones and the cross-functional team members.
- An integrated program plan was developed, working with key client executive stakeholders outlining the timelines, cross-functional interdependencies, potential bottlenecks and risks.
- A project management structure was implemented for the CMC scope, enabling the program to be governed, managed, and monitored to achieve the key program objective: Manufacture, test & delivery of test article to the non-clinical study sites as per the required delivery milestones.

THE SOLUTION

- Primecore worked with the non-clinical research team to identify the key test article delivery milestones.
- Primecore developed a schedule with team members outlining all key CMC activities and milestones; within the schedule the team identified clear "decision windows" for critical decisions on plasmids.
- Primecore led a cross-functional Risk Management workshop to identify & mitigate relevant program risks.
- Primecore led & documented the minutes for all CMC Team meetings, and followed up on all agreed actions to ensure they were completed and closed promptly.
- Primecore ensured that the CDMO partners were aware of all key program objectives as well as the manufacturing and delivery milestones.



THE RESULTS

- *The therapeutic candidate was finalized as per schedule, to enable the CDMO to begin manufacturing of test article.*
- *Test article was delivered on time to the non-clinical research study centers.*
- *The client recognized the value of Primecore's approach and deployed the same CMC PM for their other program.*

