



PRODUCT PROGRAM MANAGEMENT

Providing Program Management for a Phase 3 CMC Program

THE NEED

The client required the development of an integrated program approach for a schedule driven Phase 3 program. There were several key workstreams such as process development, tech transfer, analytical methods development and transfer, capital project delivery and operational readiness. There was also the need to have these sub-teams become part of an integrated team that were fully coordinated and working to a common critical path. Program delivery risks, particularly those related to schedule, needed to be identified and mitigated.

THE APPROACH

Primecore ensured that all the key workstream leaders became part of the overall program team with clear roles and responsibilities reflected in the integrated plan. There was a program charter created that identified the key business drivers to be tracked.

A weekly coordination meeting was held to ensure the team was held accountable to the agreed integrated plan. Each of the key workstreams reported on progress, issues, and risks to ensure the overall team understood the status of each other's challenges and progress.

The Primecore Program Management Team ensured sub-teams such as capital project, analytical, tech transfer, and process development met regularly and progressed their deliverables. Governance meetings were focused on key business decisions that needed to be made.

Additionally, work was closely coordinated with the CMOs to assure they were ready to start Engineering and GMP batches. Documentation and material trackers were reviewed weekly.

THE SOLUTION

The integrated schedule provided an ability to indicate time to Phase 3 product availability, whenever any workstreams' progress versus plan changed.

The risk register communicated the key risks that potentially could arise in any of the workstreams, who owned the mitigation of the risk, and what its residual effect could be on the program. The Governance meeting transitioned from labored progress reviews to a focused decision making forum.



THE RESULTS

- *Schedule planning paved way to Phase 3 product availability*
- *Standard procedure for handling of key risks were developed*
- *A shift in Governance meetings sparked key decision making*

