

Case Study: Providing Program Management for a Phase 3 CMC program.

The Ask:

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 & 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.

Regular reviews with the sponsor and lead end user were also key to ensuring the program direction aligned with any changes to the business strategy.

The Primecore Program Management Team ensured sub-teams such as the capital project, analytical, TT and process development met regularly and progressed their deliverables.

Governance meetings were focused on key business decisions that needed to be made and risks that required senior management endorsement and support to mitigate.

The Primecore Management Team worked closely with the CMOs to assure they were ready to start Engineering and GMP batches. Documentation and material trackers were reviewed weekly. Lack of CMO resources to keep the project on track were elevated. Primecore communicated to the team sponsor the CMO information requirements, and documents requiring review and approval. Primecore tracked material deliveries, and highlighted potential issues, for example late delivery of Single Use Components.

Outcomes:

The availability of 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 it's residual effect could be on the program.

The Governance meeting transitioned from labored progress reviews to a focused decision-making forum.

“Primecore allowed us to be more efficient and effective with our internal resources, which were already stretched thin, and also provided great examples of best business practices that we were able to carry forward into the rest of our operations.”

