



OPERATIONS AND CONTINUOUS IMPROVEMENT

Operational Evaluation of a Biopharmaceutical Plant

THE NEED

The client was a small, EU-based biopharmaceutical company that was experiencing challenges manufacturing its product. They had a single manufacturing site that continuously missed production slots, produced out of specification batches, had significant numbers of recurring deviations, and had delays in releasing products to the market. These issues jeopardized the company in meeting its financial goals and limited any progress on strategic initiatives. The client attempted to correct performance on an Individual basis but there was a need to understand and solve the systemic causes of the issues.

THE APPROACH

- The Primecore team first developed a charter to get alignment on the objectives, scope, milestones, and risks of the program. This initial charter focused on data gathering, root cause analysis and generation of tangible recommendations.
- After discussion with the senior leadership on the first site visit, it was clear that immediate action was needed. The charter was updated accordingly and parallel tracks of implementing immediate, 'no regret', actions while also analyzing for systemic causes were undertaken.
- As part of this new approach, the Primecore team was on site bi-weekly and engaged in coaching and mentoring team members across all levels of the operations organization.
- Immediate actions focused on providing elevated support to plant-floor operations and Right First-Time documentation. Changes implemented included increasing the presence of key functions on the plant floor, installation of visual management tools, and strengthening of the tiered meeting structure.
- An organizational assessment was conducted, and many collaborative discussions were had over the appropriate operating model for the site.

THE SOLUTION

The client received a detailed roadmap of how to improve internal operations based on a systemic, holistic approach to root cause analysis and solution finding. The client also received training from Primecore's team of Operations experts and Six-Sigma black belts on best practices and methodology in optimizing and de-risking manufacturing.



THE RESULTS

- *All short term actions were completed, and the site saw increased engagement and alignment from all functions.*
- *A detailed two year roadmap for operational improvement was collaboratively developed and endorsed by the leadership of the company.*
- *A new, hybrid operating model and a corresponding organizational design was developed and accepted by the senior leadership of the company.*

