

Case Study: Translating the Business Requirements into a Manufacturing Strategy

The Ask:

For companies transitioning from the early clinical phase to late phase clinical and commercial launch, a clear manufacturing and CMC strategy is critical. The client requested Primecore's assistance to develop their near to mid-term manufacturing plan, including a make vs. buy analysis, that would provide a path through commercialization for their pipeline programs.

The Approach:

- Primecore's first step was to define the User Requirements for Operations to ensure all needs were considered. In this case, the requirements included a detailed layout of the portfolio schedule and an understanding of the trade-offs between the CMC requirements and the clinical timelines.
- Once the requirements were defined, a set of manufacturing scenarios were developed to assess against the requirements. These included a mix of make and buy scenarios that best represented feasible and realistic options for their products (biologics requiring BSL2).
- Primecore worked with the client to capture all the relevant inputs and assign variances or probabilities to each of them. The goal was to capture the parameters associated with the 3 main risks: product risk (such as probability of technical success), market risk (market share, pricing, and competitors) and program risk (such as supply timing, yields, and costs).
- Once all the data was captured, the Primecore team built a probabilistic model that quantitatively predicted future outcomes for capacity, costs and value for each scenario. Sensitivity analyses were also performed which allowed the team to investigate the drivers of the results.
- Additionally, strategic factors were assessed with a structured multi-attribute utility analysis which quantified non-financial criteria important for choosing the optimal manufacturing strategy.
- Each manufacturing scenario was then evaluated based on its potential capacity, costs and value delivered along with its strategic fit for the Client.
- Ultimately, all the options were assessed using this balanced approach, which allowed for a more informed decision.
- The client received Primecore's final report which summarized the relative strengths and weaknesses of each strategy along with the final recommended roadmap for implementation. Risks were highlighted for each and the recommendations included back-up options if near term risks could not be retired.

Outcomes:

The output of this project provided the Client a clear manufacturing strategy for execution which met their clinical and commercial aspirations and best captured the portfolio value. A secondary outcome was the development of a probabilistic model and framework which the Client can use for future decisions in the coming years as more information is known. The model helps quantify future outcomes when there is great uncertainty.

