



## NETWORK AND SUPPLY STRATEGY

# Translating the Business Requirements into a Manufacturing Strategy

## THE NEED

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

- The first step was to define the User Requirements for Operations to ensure all needs were considered.
- Once the requirements were defined, a set of manufacturing scenarios were developed to assess against the requirements.
- 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 three 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.
- Additionally, strategic factors were assessed with a structured multi-attribute utility analysis that 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.
- Ultimately, all the options were assessed using this balanced approach, which allowed for a more informed decision.
- The client final report summarized the relative strengths and weaknesses of each strategy along with the final recommended roadmap for implementation.

## THE SOLUTION

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. During the process, the client team also learned about the critical data points that have a direct bearing on the decision process.



## THE RESULTS

- *The key results showed the strategic fit versus NPV for each option*
- *In the project process, a probabilistic model and framework was developed, which the client can use for future decisions in the coming years*
- *This model will help quantify future outcomes when there is great uncertainty, thus providing a better chance of efficiencies within the organization*