



MANUFACTURING SUPPORT



PROCESS DEV & COMPARABILITY



ANALYTICAL DEVELOPMENT



QUANTITATIVE MODELING



QUALITY SYSTEMS



DEVICE DEVELOPMENT



REGULATORY SUPPORT



PRECLINICAL DEVELOPMENT



PROJECT & PROGRAM MGMT



MARKET RESEARCH



INTELLECTUAL PROPERTY



FINANCING & DILIGENCE

Quantitative Modeling of Cell Therapy Manufacturing Capacity Needs

The Ask

Predicting manufacturing capacity needs for a pipeline of Cell & Gene Therapy products is an exercise with high stakes and enormous uncertainty. A large biotechnology company came to Dark Horse for assistance in identifying the manufacturing facility needs of its cell therapy product pipeline in the face of a wide range of development and commercial assumptions.

DHC's Approach

The modeling software Dark Horse uses is a proprietary, in-house offering, built specifically from the ground up to factor in the many complexities and variables inherent to the C> industry.

As with any model, the output will only be as good as the inputs. DHC's platform has been designed to capture the breadth of input assumptions, such as materials costs, process duration and yield, clinical enrollment, probabilities of success, and timeframes for each phase of development. Our platform then simulates the range of potential outcomes with distributions and Monte Carlo algorithms. Identifying the range for these parameters can be daunting, but our team is equipped to provide help based on process specifics and industry standards. Our platform provides the full range and probabilities of outcomes, making it easier to develop strategies based on risk and control.

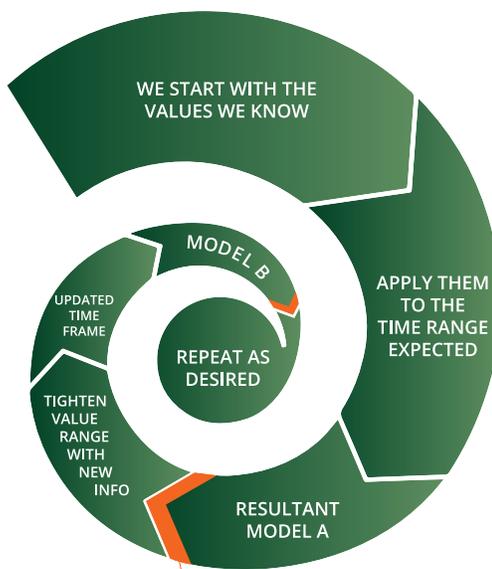
Why DHC?

EXPAND CLIENT BANDWIDTH

PROVIDE ADDITIONAL TECHNICAL EXPERTISE

SOLVE EXISTING PROBLEM (REMEDiate)

Forecast By Design



SOME CHOOSE TO STOP HERE; SOME CHOOSE TO GO THROUGH ANOTHER CYCLE WITH UPDATED DATA.

We use Quality by Design (QbD) elements in nearly all of our engagements, meaning that the process and manufacturing used are developed to allow for continual evolution. Think of our proprietary quant modeling software and resultant capabilities as a Forecast by Design (FbD). In other words, we don't simply take the known variables and apply them...we instead use a neutral real range of numbers and the ability to revise/pivot the model to eliminate guesswork at each stage, and continually improve forecasts.

- The first step necessary (from the client) is a completed questionnaire to help nail down all known elements and variables. Again, DHC can provide levels of help and guidance in completing this assessment, depending on each client's need.
- DHC then takes those initial variables and uses them to build a highly customized model using our proprietary in-house platform. Check-in meetings are scheduled every week or two for updates, to show interim data, and to alert the client to any places where the model requires more information or where there's conflicting guidance from within the organization.
- The ultimate deliverable is an excel file and a presentation, complete with a dashboard that highlights major outcomes and walks users through the steps taken. This dashboard allows clients to update input parameters to keep the model current and customized throughout the process.
- The ability to model uncertainty is one of the elements that make Dark Horse's quantitative model offering different. We account for ranges so that you can make a plan and, critically, that plan changes with your real-time experiences because it allows for an adaptive approach. It's the difference between a 2D view of the range of outcomes...and a 4D one.

The Impact

The client received a highly-customized, probability-weighted picture of the likely range of capacity needs and manufacturing costs for its cell therapy product pipeline, based on Monte Carlo modeling of a range of input assumptions. This hard data provided them with the ability to make rational choices in their facility design process, as well as to increase the accuracy of their financial forecasts.

Next/Concurrent Steps

- Manufacturing Support (CMO Landscape, Tech Transfer)
- Process Development & Comparability
- Analytical Development