Long Range Planning for Pre-phase III Pharmaceutical Drug Production

MIT Supply Chain Management

Emily Chen, MIT SCM 2017
Advisor: Ozgu Turgut, MIT CTL Postdoctoral Associate
Sponsor: Top 5 Pharmaceutical Company

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Background and Motivation

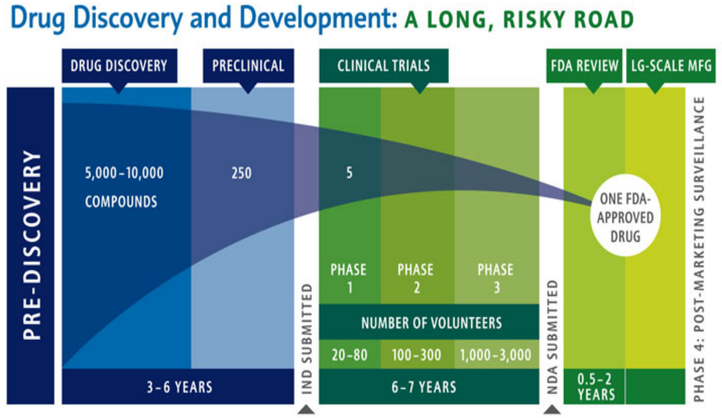
As the supply chain and manufacturing for pharmaceuticals expands in both volume and number of nodes globally, exposure to an increasingly complex manufacturing and regulatory environment develops. It becomes even more important then to be able to forecast the requirements needed for drugs in the development pipeline in order to plan for equipment, personnel, and facilities.

The amount of information available for these early stage drugs specifically surrounding the science and dosages is limited, and the technical manufacturing requirements is often undecided or unknown. However, forecasting capacity requirements for these drugs will assist companies in being better prepared to handle production and serve patients if and when the drug comes to market.

The Challenge

How can early stage (pre-phase III) drug production volumes be forecasted to influence capacity planning and manufacturing decisions for 10+ years out, and how can the significant uncertainty that exists be visualized graphically?

- Success rates for drugs overall from phase I to approval is < 9% and can be as low as 5% (oncology)
- Dosage, efficacy, technical manufacturing requirements, and market dynamics are often undetermined



Source: Pharmaceutical Research and Manufacturers of America

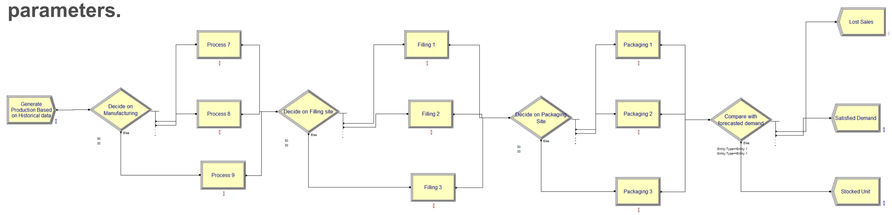
The Approach

1. Forecasting

Drug API and drug product volumes will be forecasted in combination with existing commercial patient flow and market data through ARIMA or regression techniques. Both pre-phase III portfolios of small molecules and large molecules are considered.

2. Discrete Event Simulation Model

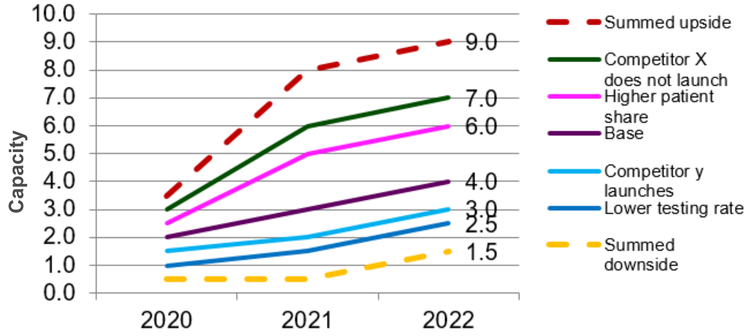
Forecasts will be inputted into DES push and pull models using ARENA software in order to investigate the changes that might occur in the system in terms of capacity requirements and service satisfaction. The system will be built on random values of the stochastic parameters.



3. Visualization of Outcomes

Results will then be displayed in a series of graphs depicting possible ranges of outcomes.

Visualizing Scenarios of Uncertainty



*Numbers are illustrative

Expected Contribution

Develop an alternative model to existing Monte Carlo methods to provide a 10-year capacity outlook for drug production of both large and small molecules in pre-phase III pipeline status in order to better inform leadership in making site production planning decisions.

Selected References

1. Cook, A. G. (2006). Forecasting for the pharmaceutical industry: Models for new product and in-market forecasting and how to use them. Aldershot, England: Gower.
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