Supply Uncertainty in Biologics

Background: Risks & Uncertainties

- Variation in Yields: with different manufacturing processes
- Uncertainty in Capacity: production site allocation
- Uncertainty in Production: make or buy
- External Uncertainties: postponed drug approval, patents expiry

Key Question / Hypothesis

How does the variance of production technical parameters (productivity, success rate) impact supply uncertainty?

Hypothesize that technical variance will alter the supply planning result, such as the uncertainty ranges of APIs

Solution Flowchart

- A. Monte Carlo Simulation
  - Scenario Analysis
  - Event-driven
  - Difficult to Communicate
- B. Stochastic Optimization
  - Capacity-based Risk Objective
  - Risk Factors as Parameters
  - Difficult to Apply under Different Compliance Requirements

The Problem

Currently, Pharmaceutical Company’s strategic capacity planning is driven by the long-term demand and its forecast uncertainty.

The impact of manufacturing level uncertainties, such as factory productivity and production success rates, are not taken into account as variables.

Expected Contribution

- Incorporate the technical variance in biologics material and capacity planning
- Find a better way to communicate the uncertainty ranges to senior management