Optimization-Enabled Strategic Capacity Planning at a Biopharmaceutical Manufacturer

BUSINESS PROBLEM

Amgen's Drug Substance (DS) network planning process was built around manual spreadsheet scenario analysis, with each long-range capacity case taking roughly 2-4 analyst-hours to construct and evaluate. This limited the breadth of scenario exploration and offered no guarantee of feasibility or optimality. At the same time, planners had to manage uncertain demand, long capital lead times, regulatory filing constraints, single-source requirements, and plant ramp-up limits. The business need was a faster, more rigorous way to evaluate network options while protecting service levels and reducing costly capacity imbalances.

DATA SOURCES

1. Commercial demand forecasts by product, market, and year

2. Facility parameters including throughput, yield, runtime, availability, and batch success assumptions

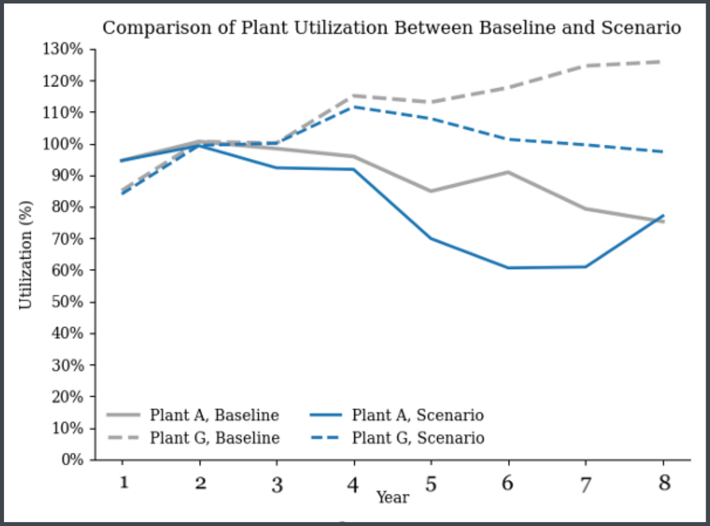
3. Regulatory filing matrices, PPQ/PAI commitments, and scenario inputs for product-to-plant allocation

Data Types and Format

Boolean, Count, Numeric, Structured, Time series

APPROACH

The project developed a Mixed-Integer Linear Program (MILP) to assign product lots to manufacturing sites across Amgen's DS network while enforcing demand satisfaction, regulatory filing rules, process performance qualification (PPQ) and pre-approval inspection (PAI) commitments, and new-site ramp-up constraints. The optimizer was paired with local sensitivity analysis, global sensitivity analysis using XGBoost metamodels and SHAP, and Monte Carlo simulation to evaluate risk under uncertainty. Together, these methods turned strategic capacity planning into a reproducible scenario engine rather than a manual what-if exercise.



Jeremy E. Rosenblatt
MIT Leaders for Global Operations, Class of 2026

IMPACT

Validation against Amgen's manually developed Long-Range Supply Plan showed 93.2% overall plan similarity while reducing cumulative volume-weighted capacity overage by 20%, avoiding an estimated $20.7 million in inventory holding costs over the planning horizon. The work also showed that scenarios previously requiring hours of analyst effort could be evaluated far more quickly, enabling broader and more repeatable exploration of the scenario space.

Beyond speed, the tool improved decision quality. It produced traceable, constraint-based plans; increased explainability through sensitivity analysis and SHAP; and highlighted that structural levers such as demand management, externalization, and new product-site filings matter more than incremental operating improvements when relieving network bottlenecks.

Overall, the thesis demonstrates that optimization can improve efficiency, strengthen service-level planning, manage capacity constraints, and create a scalable foundation for future multi-echelon planning at Amgen.

DRIVERS

Rapid demand growth, pipeline uncertainty, and multi-year capital lead times made strategic network planning a high-stakes operations problem. Leadership needed faster scenario evaluation, stronger reproducibility, and better visibility into where the DS network would face future bottlenecks.

BARRIERS

Manual spreadsheet planning was slow and difficult to scale. Regulatory constraints, filing lead times, uncertain demand realization, yield variability, and site-specific runtime assumptions complicated the planning problem. Cost data was also not yet standardized enough to support full cost optimization.

ENABLERS

Amgen already had a defined Long-Range Scenario process, strong subject-matter-expert involvement, and high-quality structured planning inputs for demand, capacity, and regulatory status. The optimization model could therefore be calibrated against real planning outputs and adopted within an existing governance process used by OSBR and network planners.

ACTIONS

Mapped the DS planning workflow and business rules. Built and calibrated a MILP for product-to-plant lot allocation. Added local sensitivity analysis, XGBoost-and-SHAP-based global sensitivity analysis, and Monte Carlo simulation. Validated results against the 2025 long-range plan and tested realistic business scenarios to identify the highest-impact capacity levers.

INNOVATION

Introduces the first strategic-level algorithmic capacity planning tool for Amgen's DS network and combines constraint-based optimization with explainable machine learning and probabilistic risk analysis. The thesis shows how optimization can be used not just to generate one plan, but to support strategic dialogue and network design decisions under uncertainty.

IMPROVEMENT

Reduced capacity overage, accelerated scenario evaluation, improved traceability of assumptions, and made network tradeoffs more transparent for decision-makers.

BEST PRACTICES

Use optimization as a scenario engine, not just a one-time solver. Keep business rules explicit and auditable. Pair prescriptive models with explainability tools so planners can trust the outputs. Focus improvement efforts on structural network levers when the system is truly capacity-constrained.

OTHER APPLICATIONS

Applicable to other biopharma planning problems, including downstream drug product and final drug product networks, as well as other regulated manufacturing environments where service, capacity, cost, and filing constraints must be balanced over long planning horizons.