

# Optimizing Multiproduct Drug Substance Production for Increased Throughput



SANOFI

## BUSINESS PROBLEM

The Sanofi Massachusetts Biocampus employs state of the art integrated continuous biomanufacturing (ICB) to produce multiple drug substances. This new technology allows for multiproduct production, but its flexibility introduces operational complexity not previously faced in industry. Shared resources between products makes production capacity difficult to quantify. The biocampus is focused on better understanding of their process capabilities.

## DATA SOURCES

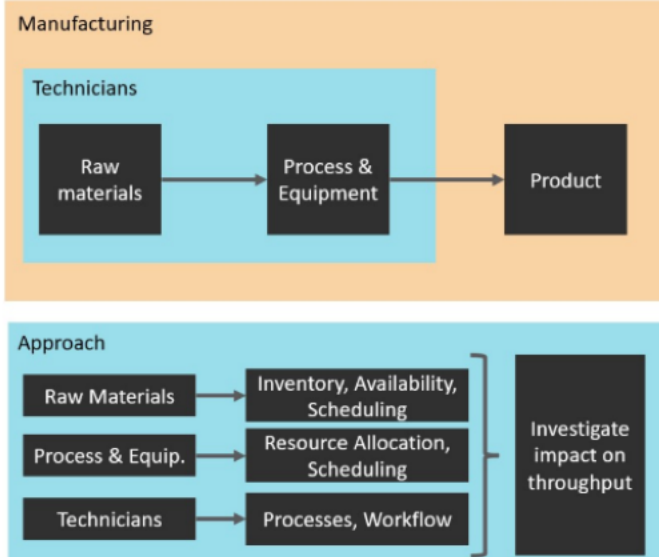
The primary data required is manufacturing data such as the labor and time needed to complete the process. The process must also be divided into a series of steps or operations. Some of this data can be obtained through Sanofi's manufacturing systems and process documentation. Other data, such as required technician labor hours per operations was collected via time studies.

## Data Types and Format

The majority of the data was collected and stored in Excel spreadsheets. Some data was available for export from the site's AP system.

## APPROACH

To increase throughput at current resource limits, linear optimization will be employed to improve resource scheduling and to increase capacity utilization. The model will also provide leaders with a framework to understand operations and resource needs. Lean principles will be applied to inventory balancing and storage techniques to increase material availability on the production floor.



## IMPACT

This project seeks to provide a deeper understanding of multiproduct drug substance production in an ICB facility. Current understanding of unit capacity considers each product's process individually, without regard for the shared resources which all processes utilize; labor, equipment, floor space, etc. The gap between theoretical single product capacity and true multiproduct capacity has led to scheduling and planning issues such as scheduling more daily operations than resources allow. To understand the site's true capacity, the operations will be modeled in two parts: upstream production and downstream production. These models will account for resource constraints to throughput so that better decisions can be made. In addition to the models, optimization algorithms will be developed as tools to aid in operations scheduling so that constrained resources are fully utilized. The expected impact is better understanding around resource and hiring needs to operate at desired throughput levels.

### DRIVERS

The central question being answered is if technician hiring should be increased. The thought at the site, at the time of this investigation was that increased labor might increase throughput. The thesis develops a detailed understanding of the system's available capacity and labor requirements. The final result being that labor is not the capacity constraint.

### BARRIERS

Data availability was the biggest hurdle. The site had an abundance of data on the process itself, flows, weights, cell counts, etc., but less data collection regarding the operation run times, technician labor, scheduling milestones, etc. Modeling system capacity as a function of labor began with careful collection of job takt time data.

### ENABLERS

Trust and openness between teams made this thesis possible. I was aligned to the supply chain organization, but was asked to answer manufacturing questions. The culture at the site is one of helping other teams. The trust already present allowed for earnest discussion with manufacturing and observation of their work for the purposes of data collection.

### ACTIONS



Implementation was not fully realized at the end of the thesis. The work was centered around increased understanding of the process to better inform leadership decisions. The impact that was left was a curiosity to question long standing process assumptions and find new ways to collect data and model the system.

### INNOVATION

The solution challenged the site to rethink how they operated their system as a whole. Previously, the upstream and downstream operations were artificially coupled which was a self-imposed constraint. Through cross-functional collaboration, design, planning, and manufacturing organizations were all part of the project and each organization came away looking at their system in a new light.

### IMPROVEMENT

The solution provides a potential to increase downstream throughput by 36%. This does not relieve the upstream bottleneck, and therefore does not increase overall throughput, however, excess downstream capacity means that inventory can build ahead of downstream and downstream can be run to best match the shipment schedule and dampen upstream variability.

### BEST PRACTICES

Careful and rigorous collection of takt time data is critical to the success of this approach. The models require good data to produce good results.

### OTHER APPLICATIONS

The thesis sets out a framework which can be used by any manufacturing facility to examine system capacity as a function of a resource of interest. In this case, labor was the resource, but the same methods can apply to modeling resource availability in a different process.