

Forecasting and Planning for a Multi-Product Seasonal Production Facility

by

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B.S.E. Mechanical Engineering, University of Michigan, 2005

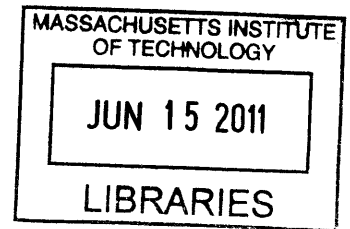
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Partial Fulfillment of the Requirements for the Degrees of

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and
Master of Science in Mechanical Engineering

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Abstract

With increasing cost pressure on commodity vaccine products, Novartis Vaccines & Diagnostics is continually looking for ways to improve operating efficiencies and decrease costs. As the largest drug product manufacturing site for Novartis flu vaccine products, Rosia Aseptic Operations experiences dramatic swings in required man-hours throughout the year to accommodate the seasonal nature of flu demand. This challenge is further exasperated by long training lead times for new aseptic operators and substantial severance costs for a permanent employee headcount reduction in Italy. With over 50% of the aseptic operators in Rosia on temporary contracts, management spends at least 25 hours per month reviewing headcount in order to make assessments on contract renewals and expirations. Therefore, this thesis investigates the hypothesis that understanding resource needs can decrease labor costs as well as save management time.

A labor resource model based on a demand forecast, operational input data, and a scheduling optimization was developed and validated. The outputs of the model support decisions on overall staffing levels by department as well as provide tools to analyze the appropriate mix of temporary and permanent employee contracts and to understand the time lag associated with staffing decisions. Additionally, sensitivity analysis can be performed to see the effect of changes in policies and shift structures.

The model reduces costs and saves management time in the Rosia Aseptic Organization through the longer-term depiction of headcount needs, the cost analysis structure and tools, insights from the production scheduling optimization, and the automatic, pre-crafted graphs and tables. Further discussion of the concepts of aggregate production planning, reveals additional opportunities for Novartis to reduce overall production costs through enabling strategies to match capacity with demand.

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1 Introduction

1.1 Vaccine Business Background

“A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe.” (News Medical)

Vaccines are generally a low-margin, commodity business with large demand fluctuations. Therefore, most major pharmaceutical companies tended toward the more chemically synthesized drug-products with blockbuster potential. However, the “2010 problem” of innovating chemical compounds and maintaining patents has forced companies to reconsider the potential of vaccine business. Additionally, as healthcare shifts to more preventative care, the sales of vaccines should continue to grow. (Nikkei Business Online, 2010)

Novartis AG had 50.6 billion dollars in net sales in 2010 (Novartis). The Vaccines and Diagnostics (V&D) division was responsible for 2.9 billion dollars of the net sales (only about 6% of total group). Novartis Vaccines’ products include influenza, meningococcal, pediatric, adult and travel vaccines. The Vaccines and Diagnostics division employed 5,394 full-time associates as of December 31, 2010. (Novartis)

1.2 Site Background

Novartis Vaccines was established in April 2006 after the acquisition of Chiron. Vaccines are currently produced in five sites worldwide: Siena/Rosia, Italy; Marburg, Germany; Liverpool, UK; Holly Springs, North Carolina, USA; Ankleshwar, India. The focus of this thesis is on work performed for the Rosia, Italy site. The Rosia site was one of the sites previously owned and operated by Chiron. (Novartis)

1.2.1 Challenges and Constraints

Potential challenges resulting from the recent change in ownership in the Rosia site exist.

Employees who have stayed at the site through the transition of ownership need to continually adapt to new initiatives, methods of work, and a largely American based technical leadership team. Therefore, new ideas may take some time to be fully adopted due to the large amount of high priority changes already in progress. Additionally, not all desired process data exists due to the division's infancy. Novartis has placed a large focus on improving the collection, the accuracy, and the use of data to support their processes, which will ease this challenge in the future. However, in the short-term, care has to be given to bridge between the data currently available to what will become available in the future.

The Rosia, Italy site provides more packaged doses of flu vaccine than any other site within the Novartis network; therefore, it faces the inherent timing constraints related to flu vaccine production. The flu vaccine takes roughly six months from identification of the three virus strains until shipment to customers. The World Health Organization (WHO) recommends the strains to be included; however, the final decision occurs on a per country basis as to which vaccine strains will be licensed in their country. This occurs twice a year as the strains are evaluated for Northern Hemisphere flu and again for Southern Hemisphere flu each year. (Centers for Disease Control and Prevention, 2011) This timeline is further restricted by the customers' desire to receive the vaccine on their shelves by the end of September. Therefore, any Northern Hemisphere flu product that is not shipped by September risks not being sold as it is a commodity product with multiple other competitors producing identical products. This compressed timeline causes large seasonal production swings experience primarily over the June through August timeframe.

Additional challenges that the Rosia site face are the large costs associated with a reduction in the permanent work force and constraints listed in the union contract agreements. Italy historically has one of the highest costs of severance, and it can total multiple years of salary for each worker depending on the details of the case.

1.2.2 Thesis Motivation and Project Objective

The Rosia Aseptic site is the largest fill/finish site for the Novartis V&D flu vaccine products.

While the site does produce other vaccines, the seasonal nature of the flu business results in dramatic swings in required man-hours throughout the year. Due to this seasonal demand as well as the H1N1 epidemic and hedging the risk of large severance costs in Italy for headcount reductions, over 50% of the aseptic operators are temporary contract workers. Each month, aseptic operations management spends at least 25 hours reviewing headcount in order to make assessments on contract renewals and expirations.

Therefore, the goal of this project is to create a model structured to provide comprehensive resource information to operations management in a fast, flexible format. The outputs of the model should support decisions on overall staffing levels by department as well as provide tools to analyze the appropriate mix of temporary and permanent employees and to understand the time lag of decisions around staffing.

1.3 Hypothesis

This thesis aims to prove through utilizing a demand forecast to model operational labor hours, resource needs can be understood. As a result of this understanding, production scheduling can be adjusted to minimize large production swings and consequently level required operational labor hours. Additionally, the modeling can be utilized to understand future resource needs and

act as a key input into the decision on the number of permanent and temporary contract workers needed.

1.4 Research Methodology

While the desired result from the model, the number of aseptic operators needed to support production, was well defined and understood, the method, detail and type of data utilized to model it was not clear initially. Therefore, the following research steps were taken to determine the appropriate approach to the model:

- Literature Review – We benchmarked approaches to resource modeling inside and outside of Novartis for both level and seasonal production patterns.
- Stakeholder Interviews – To understand the ways in which this model would be utilized, we considered all organizations that interacted with our production department to see how resource data was collected and utilized.
- Data Collection & Analysis – Operational information was compiled from historical indirect tracking metrics, recent time trials and Kazien projects, and production leaders. Demand data was collected from the rolling forecast and aggregated or disaggregated, as needed, for this model.
- Model Development & Iteration – We tested different structures and logic to the model and iterated based on feedback from the stakeholders.
- Model Validation – After multiple iterations were completed, we used demand data to compare the output of the model to the resources utilized in production.
- Alternatives Review – Steps were taken to evaluate an approach known as aggregate production planning which aims to effectively utilize an organization's resources to balance capacity to satisfy demand while minimizing costs. (Chopra & Meindl, 2010)

The evaluation includes an assessment of the reasonableness of aggregate planning methodology in this application, determination existing barriers to implementation, and a draft an aggregate planning model for future use.

2 Operational Flow and Definitions

This chapter provides the organizational context and manufacturing overview necessary to understand the approach taken to develop the model.

2.1 Overview of Aseptic Operations

The term aseptic operations refers to a method of manufacturing that meets tight classifications for air quality and stringent requirements for sterilization of equipment and components, and it has an overall focus to ensure that the manufacturing environment does not negatively impact the product being produced. Therefore, the process steps are well documented, tracked, and tested to ensure that Good Manufacturing Practice (GMP) Regulations promulgated by the US Food and Drug Administration are followed. These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective (ISPE). While aseptic operations incur large expenses due to these constraints, these controls are necessary to ensure that injectable drug products or vaccines are safe to administer to patients as they bypass the body's natural filtering mechanisms.

Rosia Aseptic Operations receives the vaccine antigen, which can be considered the active ingredient, from an upstream process. They are then responsible for the final formulation, filling, and product inspection. The product is then transferred to a downstream organization that labels and packages the vaccines. Figure 1 below shows the overall flow of a vaccine.

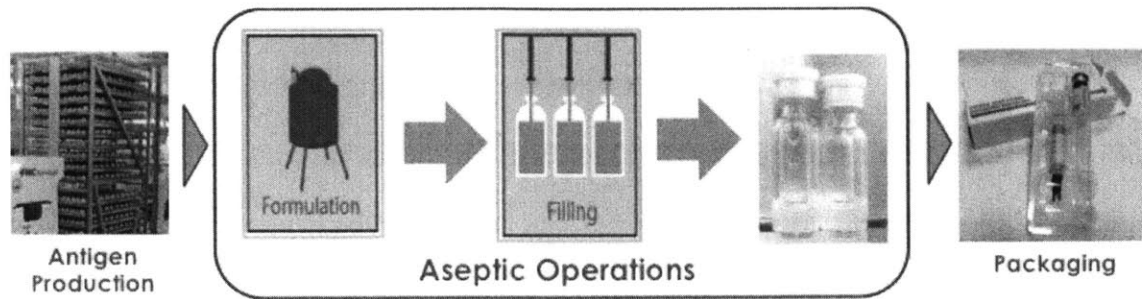


Figure 1: Overview of Aseptic Operations

The Aseptic Operations organization for Novartis V&D consists of roughly 270 employees. While several of these employees represent support staff in departments such as engineering, quality, or environmental monitoring, the focus of this project is on understanding staffing needs for the direct labor operators. These operators contribute directly to either the vaccine production or preparing the equipment or facilities required for vaccine production. They fall into three different departments within the Aseptic Operations organization: Formulation; Filling/Inspection; General Services.

2.2 Formulation Operation Description

Aseptic formulation is the first major step in aseptic operations for Rosia. The formulation department is responsible for mixing and blending the active ingredient with other chemical compounds to achieve the final vaccine formulation as specified by the product recipe. This recipe has been created and tested to ensure the final product will remain chemically stable and can be safely administered to patients. If the active ingredient needs to be filtered prior to the final formulation, the department performs this activity. Additionally, a final sterile filtration step occurs either during this formulation step, or during the filling step. If it occurs during the filling step, is then called point-of-fill filtration.

In order to execute the formulation steps, a dedicated formulation suite, or room needs to be prepared and the necessary equipment needs to be sanitized and sterilized. A formulation suite can only be used for a single batch of a product at a time to ensure there is no cross-contamination risk. The Rosia site has five formulation suites across two buildings. The selection of the formulation suite generally corresponds to the filling line where it is scheduled to be filled. After all formulation steps are complete, this final product mixture is kept in sealed stainless steel tank vessels until filling is ready to begin.

2.3 Filling/Inspection Operation Description

The filling department is responsible for filling the formulated vaccine into the container that will be used to administer the vaccine to the patient. Rosia Aseptic Operations fills the formulated vaccine into one of the following containers: syringe; 3mL glass vial; 5mL glass vial; plastic oral dispenser; ampoule. There are six filling lines: three syringe lines, one vial line, one dispenser line, and one ampoule line. Each vaccine needs to go through validation activities in order to be authorized to fill a given product on a given line. Validation requires a large amount of data collection, additional testing, and a review by regulatory agencies to ensure the product can be made consistently, reliably, and with high quality on a particular piece of equipment. In Rosia, there are several products that are validated on different lines; therefore, a choice needs to be made during the scheduling process on which line to select for the production of a batch of product. Then the associated equipment, components, and room for that line and product need to be prepared, sanitized, and sterilized.

This department is also responsible for inspecting the vaccine after it has been placed inside its final container and sealed. Four of the filling lines feed continuously and directly into inspection. The in-line inspection processes utilize automated inspection machines that use a

series of cameras to check for defects in the container, the seal, and the product. Additionally, there is an inspection line that is detached from the filling process that inspects syringes with similar automated technology. Furthermore, there is a line that uses a combination of automated and manual inspection for solid form vaccine products that are produced at a different site unlike the liquid form products manufactured in Rosia.

The employees staffed on filling operations are generally different from the employees staffed on inspection operations. The filling operations require operators to have additional training in aseptic processes and gowning that are not required by the inspection operations. The product is already in a sealed container when it passes into inspection; therefore, the potential of the environment or personnel to have an adverse effect on the product is greatly reduced. After inspection, the product leaves the control of the Aseptic Operations organization and is transferred to packaging for labeling and secondary packaging.

2.4 General Services Operation Description

The general services department that supports aseptic operations includes two groups of operators: equipment preparation and sanitization. The equipment preparation operators prepare the equipment and components needed for the formulation and filling activities. Generally, for equipment it is first washed in a compartment washer with high quality water to eliminate debris, then it is autoclaved, where sterilization using high-pressure steam inactivates bacteria, viruses, fungi, and spores. There are five autoclaves that feed into aseptic areas. Therefore, the selection of the autoclave used is based on which formulation suite or filling line is chosen for production of a batch. The equipment and components that are prepared depend on what equipment is being used and what product is being manufactured.

The sanitization operators are responsible for ensuring that the facilities have been appropriately sanitized both on a pre-determined, set frequency, as well as between each batch of product manufactured. They sanitize both highly classified areas such as the formulation suites and filling rooms as well as general areas such as hallways in the production areas. As these operators need to be available to sanitize between production batches, their shift structure and staff level is highly dependent on the number of batches being formulated and filled.

2.5 Example of Department Interaction for Production of a Single Batch

Several interdependences between the three departments in Aseptic Operations exist. Beyond the time constraints of when processing from one department must be executed relative to the next step in product processing, there are also product and equipment specific decisions made in both formulation and filling that cascade back and affect the other two departments.

In Figure 2 below, the diagram shows the progression of manufacturing processes required to produce one batch of product. The three departments are denoted by different color blocks, where 'GS' stands for general services, 'FORM' for formulation, and 'FILL' for filling and inspection. While the physical sequence of events flows from left to right, the decision process must begin at the right. The scheduling group knows they need to send a particular number of doses in a particular container to packaging by a certain day to fulfill a customer order.

Everything is then back calculated to achieve that goal. As previously mentioned, the decision on the filling line will effect both of the other departments in the following ways: what rooms are sanitized, which parts are washed and autoclaved, where the parts are prepared, when and where formulation will occur, etc.

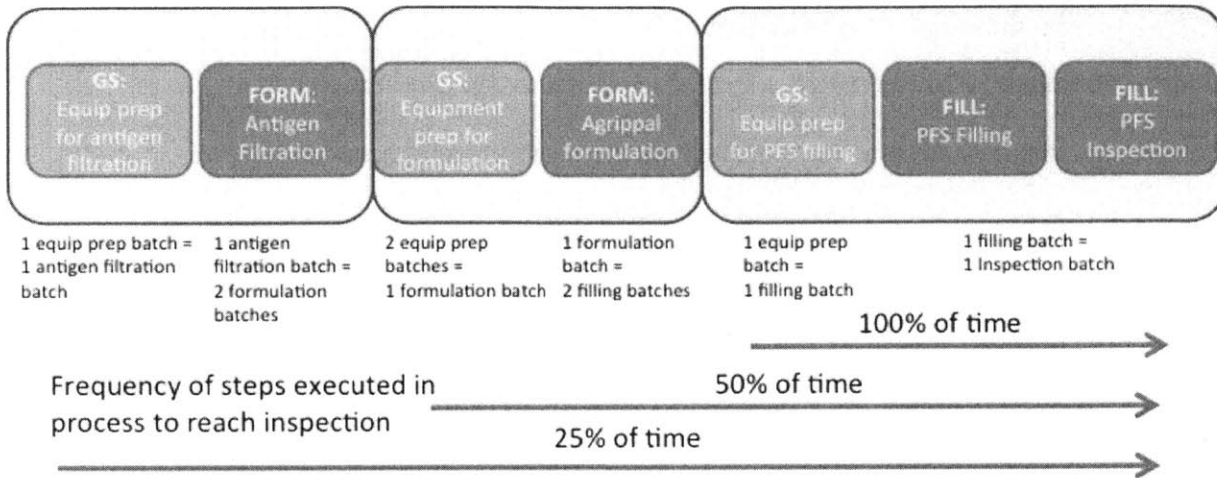


Figure 2: Department Cooperation to Produce Single Batch of Product

3 Model Methodology

3.1 Literature Review on Labor Models

Internal benchmarking within Novartis V&D on labor models uncovered multiple simplistic labor models developed both internally and by external consulting groups. While these models posed some relevance as they were based on pharmaceutical production environment, they were mainly focused on determining minimum staffing on each shift to support production. A key insight gleaned from this review was that over-simplification can lead to inaccurate results and discontinued use of the labor model. Additional external research was conducted to see what models were being used outside of Novartis.

No recent studies or articles could be found on resource modeling in a pharmaceutical company with cyclical production. Additionally, most published research focuses on short-term scheduling of resources opposed to determination of the size of the workforce to meet demand

over a medium-term period. However, a paper by Mundschenk and Drexl proposes a general model for determining the size of the workforce for manufacturing-to-order companies. In this paper, they suggest that future workforce demand can be determined by estimating market demand and the demand of the cumulated processing time for each process that should be predicted from past data. The case study is of a medium-size printing company, and the focus is principally on stratifying work based on skill level to reduce labor needs. (Mundschenk & Drexl, 2007). However, the underlying concept of their labor model can be applied to our problem statement in Rosia. In addition to using demand and operational data to estimate headcount needs, we can also apply the concept of splitting out work based on skill or training level, as is the case in the filling and inspection department.

Research regarding allocation of permanent and temporary workers was reviewed for relevant insights. One study by Bhatnagar, Saddikutti, and Rajgopalan investigated the optimal allocation of permanent and temporary workers. The case study was based on a computer assembly plant ramping up a new product. Many of their findings were related to overtime costs, which is not relevant in our scenario as overtime pay is the same as straight pay in the Rosia plant. However, they did find that labor costs varied greatly depending on the induction costs of the employees. (Bhatnagar, Saddikutti, & Rajgopalan, 2007). Therefore, as we consider hiring new employees we should closely consider the differences in time and cost for each department to more accurately reflect the cost of headcount decisions. Specifically, we want to consider the costs of training, employment, and termination.

Given the complexity of the number of formulation suites, equipment washers and autoclaves, and the filling lines, literature on resource planning in plants with similar complexities were reviewed. A paper by Brown et al., discussed the scheduling optimization in a multi-product,

multi-line, batch production facility for Hidden Valley foods. The food industry poses many similar constraints as the pharmaceutical/biotechnology industry with limited product shelf lives and sanitization requirements between batches. However, the time and costs to train employees are not as significant in the food industry. The paper discussed several requirements for a successful scheduling process in this type of production environment. The following three requirements are pertinent points of consideration for our model: consider all possible equipment combinations to deliver the customer order; respect crew availability; include changeover and sanitization activities in the schedule. (Brown, Dell, Davis, & Duff, 2002). These considerations should be applied to any scheduling optimization related to Rosia Aseptic Operations.

Brown et al. utilized an integer linear program; thus prompting additional research into linear programming. The review, by Silver, Pyke, and Peterson, of the use of a linear program model approach for medium-range planning helps to highlight both the strengths and weaknesses. A linear model approach can be desirable as it can be tailored to the particular costs and decision structures of an organization. One of the largest weaknesses mentioned is that this approach requires the assumption of deterministic demand. However, adapting the model as new forecast information becomes available can offset this challenge. Therefore, it is important to consider the format of the rolling-horizon forecast as an input to the model. Additionally, they caution against the use of only a single measure of effectiveness as the objective function of a model. (Silver, Pyke, & Peterson, 1998). Thus, this literature suggests that it is important to consider the goal programming to integrate multiple objectives and to mitigate the effect of using deterministic demand through frequent refreshes of the data set.

3.2 High-level Overview of Model

The model discussed in Chapters 3 through 5 is now in use at Novartis and provides a more simplistic approach than the aggregate planning model proposed in Chapter 6. The model in use provides the headcount needs in each of the three departments in Aseptic Operations each month for 12-months and tools for evaluating costs and timing of various labor decisions. The basis for the model is that by converting the demand forecast from doses into batches (or operating units), we can effectively calculate the required labor hours in order to meet the demand each month. The conversion from doses into batches requires multiple steps in order to consider that a single batch in one department does not necessarily equate to a single batch in other departments. This is shown in Figure 2 in an example where a single inspected batch results from multiple batches upstream in produced in different departments, on a different frequency.

Due to this complexity, the model is based off of inspected batches as this is the final output of aseptic operations and is the closest to dose form, with multi-dose vials and dispensers as the exceptions. After the number of batches is determined, the batches can be converted into number of labor hours and then into headcount needs. To determine the number of batches when the same product can be produced on multiple pre-filled syringe (PFS) lines, a linear program outputs a PFS line schedule optimization. This optimization considers the trade-offs between number of operators required to run the line, number of acceptable doses per batch, and the time to execute a batch. For example, while an optimal line based on speed and number of resources required might exist for each product, the optimization also has to balance relative benefit to the overall schedule since every product cannot be scheduled on their ideal line due to capacity constraints. In Chapter 6, we discuss a more complex linear program that looks at trade-offs between costs and various operational strategies to achieve demand.

3.3 Selection of Input Data

Based on the research we conducted internally and externally, it was evident that the forecast demand data needed to be at the root of resource model as we were striving to understand future headcount needs not only for orders that were already scheduled for production, but also for orders not yet planned in the future. Additionally, there needed to be a means for understanding the impact of that demand on the labor resources. We decided that through determining standard labor hours per batch we would be able to translate production into measurable units.

3.3.1 Forecast Data

The question we needed to answer with respect to forecast data was how far out to trust the data. We knew that we were restricted to an 18-month maximum as that is the limit of the internal supply chain rolling forecast. We decided to have the model cover a 12-month window. Based on both historical trends and future forecasts, we knew that we needed to capture at least a full year due to the seasonal demand swings of the flu campaign. However, we chose to limit the window to 12 months since demand uncertainty increases with time. (Silver, Pyke, & Peterson, 1998)

3.3.2 Standard Operator Hours

We selected standard operator hours as our conversion from doses to labor needs as it was used in previous resource modeling attempts and aligned with a corporate initiative to utilize standard costing for accounting purposes. Therefore, we focused on collecting accurate, detailed data on production labor rates capturing all differences due to equipment and product manufacturing.

3.4 Batch Conversion

As previously mentioned, the first step of the model is to determine the number of batches for each department required to meet the demand forecast for each month. The batch conversion needs to begin with the transformation of doses to inspected batches, then calculate formulation

batches, and then compute the associated general services batches due to cascading effects from one department to another.

3.4.1 Filling & Inspection

In order to calculate the number of inspected batches however, it is necessary to first determine which PFS line will be chosen for products that can be produced on multiple PFS line. This is a critical step as the batch size from one line to another can vary up to 250% doses per batch.

Therefore, a linear optimization was utilized to determine the number of batches produced on the PFS lines given that an optimal line for each product cannot always be utilized based on capacity constraints. For all other filling/inspection lines, the number of batches is based on dividing the demand in doses for each product each month by the batch size in acceptable doses for that product, and then rounding up to a whole number.

3.4.1.1 Filling Line Optimization

Due to the difficulty in understanding the impact of a single decision on other potential decisions as well as overall capacity concerns, we chose to develop a linear optimization to select how demand can be met utilizing the three different PFS lines. The following sections give an overview of the optimization. For more details on the optimization structure, see Appendix 9.1.

3.4.1.2 Objective Function

As the reason for developing an optimization was to be able to look holistically at the impact of the decisions made, it is logical to have the objective function of the model focus on the aggregate effects on resources. The optimization is considering the trade-offs between the number of operators required to run the line, number of acceptable doses per batch, and the time to execute a batch with two possible objective functions:

- minimize total labor hours to meet demand
- minimize total equipment hours to meet demand

While it would have been possible to incorporate a relative cost to each of these in order to minimize for both, this choice in objective functions allows the user flexibility to decide which is of greater importance to minimize at a given time. For example, if the site knows that it is near the maximum equipment capacity, then the greater concern is to lower equipment usage to allow for additional production, such as during the flu campaign. Conversely, if the site wants to focus on keeping labor costs down, then minimizing labor hours is more important. We chose to offer two separate objective functions instead of prioritizing within the objective function, as we felt this provided more flexibility and sensitivity to changes in organizational goals. As discussed in Chapter 4, the results from each objective function can be compared from a cost perspective as well as a part of this model.

3.4.1.3 Input Data & Constraints

The optimization utilizes the following aggregated data for each batch both by line and by product:

- Acceptable number of doses
- Number of equipment hours for set-up, production, and changeover
- Number of operator hours for set-up, production, and changeover
- Number of equipment hours for a format change between products
- Number of operator hours for a format change between products

The major constraints are the need to have the number of doses produced meet or exceed the number of doses in the demand forecast and the requirement that the total equipment and

operator hours per month do not exceed the maximum allowance as determined by shift structure agreements in the union contracts.

3.4.1.4 Output Data

The optimization outputs the number of batches per month, per product, per line that should be produced on PFS 1, 2, & 3 rounded to the nearest whole number.

3.4.2 Formulation

After the number of filling batches has been calculated, then the number of filtering and formulation batches can be determined. Data for the number of filling batches that each filtering and formulation activity produces is included in the model. The number of filling batches is imported from another worksheet then simple division is used to determine the corresponding number of filtering and formulation batches for each product for each month are required.

3.4.3 General Services

For general services, only equipment preparation headcount is dependent on the number of batches. Therefore, the number of batches for general services is based on the number of equipment preparation batches required to support the number of filling and formulation batches previously calculated. However, the number of batches per filling line and whether or not point-of-fill filtration is used are the most important factors in affecting equipment prep labor. Therefore, data on the number of batches per filling line per month is aggregated and an assumption on the percent of batches using point of fill filtration is used in the conversion.

3.5 Labor Hours Conversion

To convert batches into labor hours, standard labor hours per batch must be determined. Then, the total number of labor hours per department per month is calculated by multiplying this standard by the number of batches. Generally, this standard is based on the number of operators

needed to operate the equipment multiplied by the number of hours needed to execute one batch including set-up and end of batch activities. There are a few exceptions that are included in the model such as the use of ‘relief’ operators desired to cover lunch and dinner breaks that do not follow a standard shift structure.

3.6 Headcount Conversion

After the number of total labor hours per activity per month is calculated, it is divided by the number of available hours for each operator to work per month. The number of available hours per month depends on the shift structure, (i.e. 3x7 operators work 16 less hours per week compared to 3x5 operators). Therefore, there is a selection field in the assumptions tab for shift structure for each area and line by month.

In addition to the contribution to headcount from batch-related activities, there are other items to add to have a more complete headcount picture. Training & administrative time, vacation, illness, and shutdowns all contribute to headcount needs. These items are all flexible for the user to adjust under the assumptions tab in the model.

3.6.1 Training and Administrative Time

Training and administrative time is calculated as a percentage of total time spent on production. However, if there is shutdown time in a given month, only the training hours beyond the number of shutdown hours is counted based on the assumption that operators can complete their training during the production shutdown.

3.6.2 Vacation

Vacation is based on an estimated number of days off, varying by month for both permanent and temporary employees. The two types of employment contracts differ in number of allowed days off, especially during the summer months when the flu campaign is at its peak. Therefore, each

department must designate the percent of temporary versus permanent contract employees they have in the assumptions tab.

3.6.3 Illness

Illness is calculated as a percentage of total time spent on production. It is a changeable field in the assumptions tab that is linked to all worksheets.

3.6.4 Shutdowns

Headcount due to production shutdowns is based on the average number of employees staffed to support an area or piece of equipment and the number of days of shutdown. This is a necessary consideration for headcount, since shutdown minimizing the number of available production days in a month and the labor contract agreements dictate that temporary changes to staffing should not be made to support something like a short shutdown.

3.7 Selection of Output Format

Through discussions with stakeholders and participation in the budgeting process, the outputs of the model were established. The model outputs the headcount needs of each of the three aseptic operations departments by month as well as aggregated count for the entire Rosia Aseptic Operations organization. Additionally, several other representations of headcount are provided. These include headcount contribution by products manufactured, headcount allocated to operate each filling line, as well as headcount broken down by major processing step within each department. These additional graphs can be used to support headcount decisions to upper management, see the effect of changes to strategy, as well as illustrate to the supply chain department opportunities for leveling production.

3.8 Scenario Construction for Contract Analysis

To assist operations management in understanding the cost implications of their headcount decisions and to speed their ability to make labor contract decisions, the model offers two methods for analysis. The model can be used to conduct a quick analysis comparing only the costs of salary of temporary versus permanent employees over any time period in months. Additionally, it can be utilized for a more detailed analysis of headcount decisions within each department. It compares the headcount needs calculated in the resource section of the model to the number and contract type of operators already employed and demonstrates the effect of decisions per month on hiring, firing and converting temporary contracts to permanent contracts on this comparison. A third benefit of this tool is simply that the cost data is pulled together in a comprehensive manner with a list of other considerations that are not necessarily tied to cost to provide a holistic approach for making headcount decisions.

3.8.1 Input Data

Decisions on staffing require a broader view than simply considering the differences in salary for a permanent versus temporary contract. The following inputs are included in the evaluative analysis in the model:

- Training period for each department for an operator to become qualified
- Salary for temporary contract employee
- Salary for permanent contract employee
- Termination costs for firing a permanent contract employee
- Cost of training any new employee
- Cost of managing contracts
- Current temporary and permanent headcount by department

Beyond these quantitative considerations, it is worthwhile to also incorporate potential qualitative outcomes such as enhanced employee dedication or reduced human errors that can result from having employees on a permanent versus temporary contract. As stated in an article in the *Journal of Operations Management*, the cost savings of using temporary workers can be offset by hidden costs related to temporary employees' learning and forgetting that are revealed in the need for additional labor and quality issues not captured by standard cost account methods. (Stratman, Roth, & Gilland, 2004). Thus, this article provides further motivation to weigh considerations beyond accounting costs.

4 Model Scoping

4.1 Software Selection

We considered a large range of software types based on research and benchmarking. The criterion for selection was as follows:

- ease of transition to area ownership after internship completion
- cost
- modeling features
- optimization capabilities

We ultimately selected Microsoft® Excel® with Solver as the software for our optimization and model. The main driver in our decision was that this software is familiar to both the potential users as well as the potential owners of the model and comes standard on computers in the Aseptic Operations organization. While other software programs, such as ProModel, offer more extensive modeling features, they treat labor resources as an input to the model instead of an

output as we desired. Additionally, the optimization capabilities of Solver are limited due to the constraint on number of decision variables and on the use of mixed-integer programming. However, we were able to overcome these weaknesses. First, we made the assumption that the PFS line scheduling optimization for each month could be made independently of other months. This is a fair assumption since the scheduling optimization does not schedule employees; it only schedules batches for each line. Therefore, we were able to limit the number of decision variables for each solver optimization, and then we wrote a macro to perform the optimization for each of the twelve months with only a single click of a button by the user. Finally, we accepted the assumption that rounding to the nearest batch for the optimization output would be sufficiently close to the actual number of batches found in an optimization with an integer constraint on the batch decision variables as the average number of PFS batches per month exceeds 20 therefore rounding up or down by one batch is not significant. Therefore, we were able to set-up the optimization as linear.

4.2 Data Sources and Data Collection

The major challenges to the development of this model were the ability to collect input data and the accuracy of the data. While all of Novartis V&D is undergoing an effort to improve data availability and tracking, the major initiatives had not yet been implemented at the time of this project. Therefore, the data were collected from a large range of sources.

4.2.1 Operational Data

The operational data were compiled from a combination of operations leadership interviews, validation reports, historical scheduling practices, indirect metric tracking and recent time studies. The operations management team interviews provided a great deal of information on the number of operators required and the variation due to product in the areas of formulation and

equipment preparation. Also, validation reports supplied the documented data on which products are validated to be ran on which pieces of equipment and theoretical batch size in doses for each. In order to understand the variability of the number of formulation batches required to produce a single filling batch, historical production schedules were reviewed. Additionally, the reject rates for filling and inspection for each product on each filling line were pulled from metrics spreadsheets focused on equipment capability. Finally, the Aseptic Operations organization was sponsoring an operational efficiency project in the filling and inspection department. So, fortunately, most of the equipment-related parameters such as line speed and number of operators required to operate a line were documented and future state assumptions were being piloted.

4.2.2 Labor Data

The model incorporates constraints and commitments on labor resources from the contract agreements for both temporary and permanent employees. These data were collected through discussions with operations managers as well as human resource personnel. Examples of this data include: number of working hours per week based on shift schedule, number of guaranteed vacation days, and flexibility of shift structure changes.

4.2.3 Financial Data

The Rosia site finance manager provided the financial data used in the cost evaluation section of the tool. We worked to calculate some of the financial costs from past expenses such as average salary per hour of an employee in quality conducting new operator training, average cost of management time per hour to determine cost of managing labor contracts, and operator severance costs.

4.2.4 Assumptions

The model includes both explicit assumptions that the user can choose as well as implicit assumptions that simplify the logic of the model. The model user can select values for the following assumptions:

- Percent of available working hours per operator spent on training & administrative and out with an illness
- Average days of vacation per temporary and permanent contract employee by month
- Average working hours per day per operator
- Available labor and equipment hours based on shift structure
- Shift structure for each department and each filling line
- Anticipated shutdown days by month for each department and each filling line
- Percent of temporary and permanent contract types for each department by month
- Filling line speeds
- Percent of batches filled on each filling line with point of fill filtration
- Number of sanitization workers needed by month
- Training period for an operator to become qualified in each department

It is critical to also understand the less apparent assumptions that have been built into the model structure. The model is based on the following assumptions:

- Operators within each department have been cross-trained to execute any task within the department except for the filling and inspection department, which is split out separately and only support their respective process. This assumption is critical to allow operators to be considered on an aggregate basis and is supported by the organizational goal for gaining flexibility through cross-training. Houghton and Portugal demonstrate that

fewer resources are required when they are pooled in a batch manufacturing environment. (Houghton & Portougal, 2005).

- Each month can be considered independently of other months from a labor and demand viewpoint. As the model is calculating labor needs based on activities required in a given month the assumption of independence does not preclude different staffing decisions to be made within a month, it only suggests that the work within a month can be evaluated without regard to the following month. Since the model has a requirement that all demand must be met, we do not need to consider rollover of unmet demand. If build-ahead strategies want to be evaluated, the excess demand can be moved to a different month.
- No additional time can be saved running a batch of product if additional operators are supporting the process; each area requires a set number of operators for each activity. While in practice, a small amount of time maybe saved by having additional operators supporting a process if problems arise, this is not the case in normal operation.
- There is one product campaign that spans the start or end of a month. The amount of equipment and labor hours per changeover needs to be included in the model so it is calculated by taking the number of products made on a line in a given month minus one to determine the number of changeovers incurred. In practice, the schedulers make every effort to eliminate changeovers. Therefore, it is assumed that while the months are considered independent, a campaign between months could easily fall at the start or end of a month; thus, justifying the reduction in changeovers.

4.3 Model Features

While the model does offer a static output of labor resources needed based on a set of demand and operational input data, the model can also be used to instantly evaluate the effects of various changes, decisions, and improvements on staffing levels through the automatic updating built into the charts and tables. The cost tool within the model also allows the user to quantify the effects of changes in headcount. Therefore, this tool can also be used proactively in the decision making process on how to allocate resources, where to focus during labor contract negotiations, or in which capital projects to invest.

4.3.1 Impact of Demand Changes

The demand can be updated either to reflect changes in the demand forecast, changes to the start and end of 12-month time window, addition of new products, or the effect of various potential demand scenarios. This allows for multiple demand scenarios to be run quickly, so sensitivity analysis on headcount decisions can be performed. Additionally, as Novartis V&D considers adjusting their manufacturing strategy, local management can quickly convey the costs and timing required to accommodate demand allocation changes to upper management.

4.3.2 Impact of Staffing Policy Adjustments

As explained, the model allows for a wide selection of assumptions to be made by the user. Therefore, analysis can be easily conducted to see the effect of changing these assumptions. For example, by changing the assumption of the allowed number of vacation days per worker in the summer months, the results may show an overall lower number of operators required, thus leveling production in a peak month. Additionally, it is possible to determine the minimum staffing levels for each department by adjusting the shift structure. If these experiments yield favorable results, they can provide focus for management during union labor contract negotiations and ability to assess the impact of any changes to benefits plans.

4.3.3 Impact of Improvement Projects

As headcount is directly tied to the number of hours required to complete a batch and the number of acceptable doses yielded in each batch, any change to the input data for the area or product specific data on the filling lines changes will affect headcount. For example, if new inspection equipment will minimize the number of false rejects, then the improved yield of acceptable doses per batch will decrease the labor hours required to meet monthly demand. Therefore, the labor cost savings are made evident in this model and can be included in the investment decision.

5 Model Formulation and Results

5.1 User Interface

As the Aseptic Operations organization is very resource constrained, we took care to make the interface of the model as user-friendly as possible to reduce the time required to view meaningful results. The following elements were integrated into the model to reduce errors and speed utilization and can be seen in Figure 3 through Figure 6 below:

- Built-in user guide in Excel® file
- Single button click to run the linear optimization macro for 12 months
- Locked equation cells with messages
- Updateable assumptions worksheet with drop down selections
- Slots for products to be added that are already linked to all equations and charts
- Summary tables by department and for overall organization
- Pre-crafted charts and graphs that automatically update
- Single location to change month and demand that link to all other worksheets

Examples of these model features are shown below.

Figure 3 shows both the user guide that is built into the model as well as the easy, single click objective function selection to run the optimization.

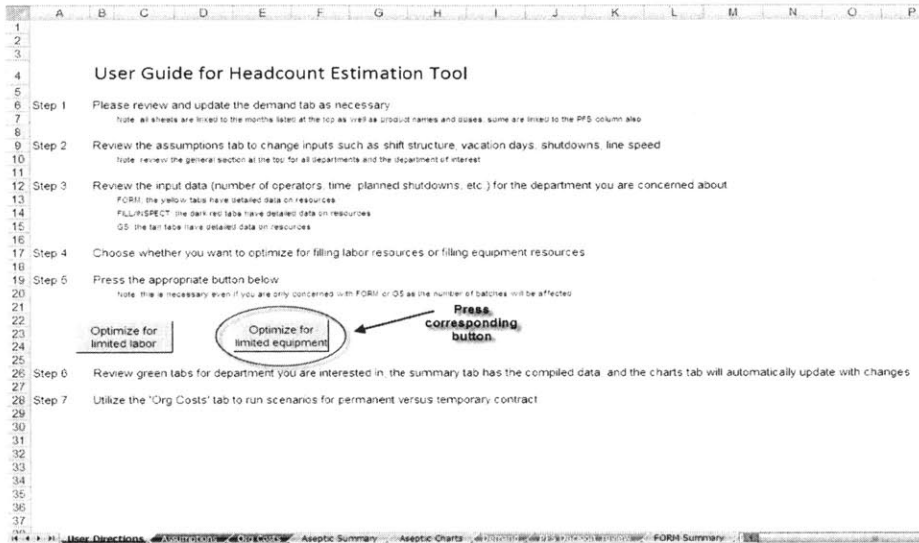


Figure 3: User Guide with Single Click Optimization

Figure 4 provides a quick glance at some of the assumptions that can be easily updated for the entire organization as well as for the individual departments.

Assumptions for All Aseptic Departments													
NOTE: All fields with number are editable, and will effect the other resource tabs													
Training & Administrative Time	10%		of available working time in day										
Illness	5%		of available working time in day										
Update illness to 2% and allow 1 day vacation for temporary workers in June													
Vacation	gen-11	feb-11	mar-11	apr-11	may-11	jun-11	jul-11	ago-11	set-11	oct-11	nov-11	dic-11	Total days
Vacation days/permanent worker	3	1	1	1	2	3	3	4	1	1	1	4	25
Vacation days/temporary worker	2	2	2	2	2	2			2	2	2	2	18
Average Hours / Day / Worker	7.5												
Maximum Hours / Month	1x5	2x5	3x5	3x6	3x7								
Equipment	160	320	480	576	744								
Hours per week per person	37.50	37.50	37.50	36.25	33.50								
Hours per month each employee works	150	150	150	145	134								
Formulation													
Note: Available Labor Hours to Work / Month / Employee field automatically populates													
Shft. Structure	2x5	2x5	2x5	2x5	2x5	2x5	2x5	2x5	2x5	2x5	2x5	2x5	
Available Labor Hours to Work / Month / Employee	150	150	150	150	150	150	150	150	150	150	150	150	150
% permanent workers in formulation	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Shutdown (days)			2										3
Filling & Inspection Assumptions													
Note: Available Labor Hours to Work / Month / Employee field automatically populates													
PFS1	3x6	3x6	3x6	3x6	3x6	3x6	3x6	3x6	3x6	3x6	3x6	3x6	
Available Labor Hours to Work / Month / Employee	145	145	145	145	145	145	145	145	145	145	145	145	145

Figure 4: Updateable Assumptions and Messages on Automated Population of Cells

Figure 5 illustrates one of the graphs that automatically populate. This graph shows over the 12 month time period the changes in headcount within the general services department with a breakdown of the major tasks that contribute to headcount.

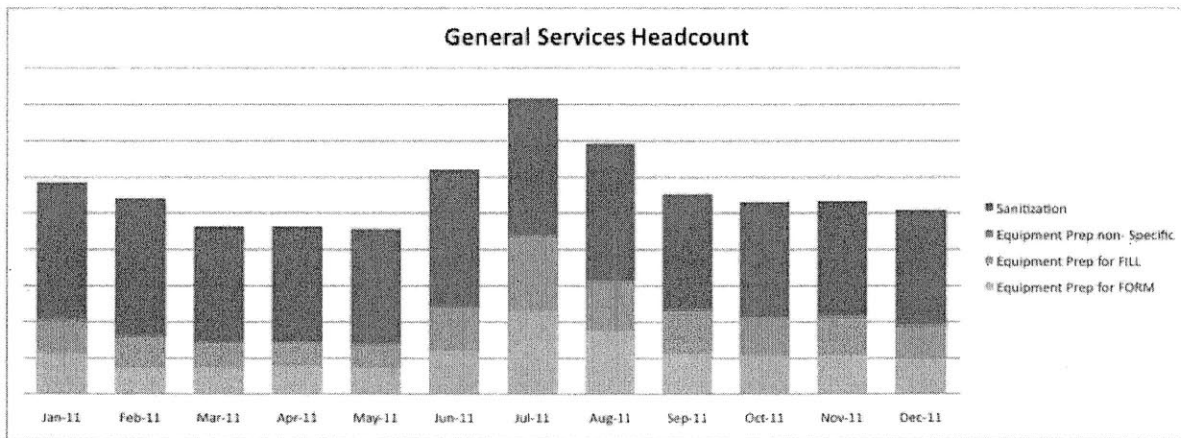


Figure 5: Example of Pre-Crafted Department Specific Graph

Figure 6 is another example of an automatically populated graph. This graph shows the number of people needed in the three departments by month. It also shows the natural cyclical nature of aseptic operations due to the spike in flu production during the summer months.

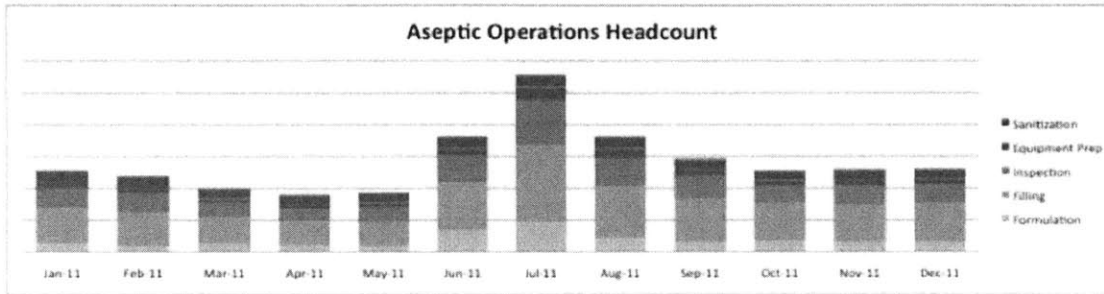


Figure 6: Example of Pre-Crafted All Aseptic Graph

Several of these model enhancement ideas came from watching the users navigate through the tool. By watching users interact with the tool, we were able to learn common pitfalls and watch what type of charts and tables the users would like to generate. Additionally, we elected to leave the more detailed operational data visible to the users. We realized that the detailed operational data we collected could be not only used in training new employees or educating the managers on actual durations and outcomes, but also this allows the user to make adjustments as improvement projects are executed or considered. To limit the confusion of multiple worksheets, we color coded all worksheets by department.

5.2 Model Architecture

As previously mentioned, the model does not consider each of the three departments independently. The nature of the manufacturing process requires each department's resources to

be linked to the required production to meet demand in other departments. The logical flow diagrams for each department show the linkages in the model to other inputted or generated data.

5.2.1 Formulation

The model logical flow diagram for the formulation department resources is shown in Figure 7 below.

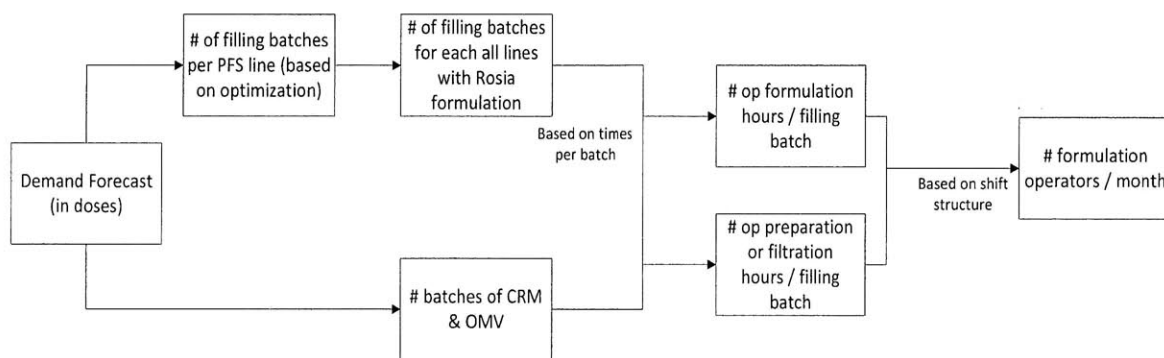


Figure 7: Determination of Formulation Resources

This figure demonstrates that while most activities in the formulation department are tied to filling production there are also a few products that do not get filled in Rosia and consequently, must be handled separately. Additionally, this shows the there can be two steps to complete the formulation process, for example filtering the antigen and formulating the antigen by adding chemical compounds.

5.2.2 Filling and Inspection

The model logical flow diagram for the filling and inspection department resources is shown in Figure 8 below.

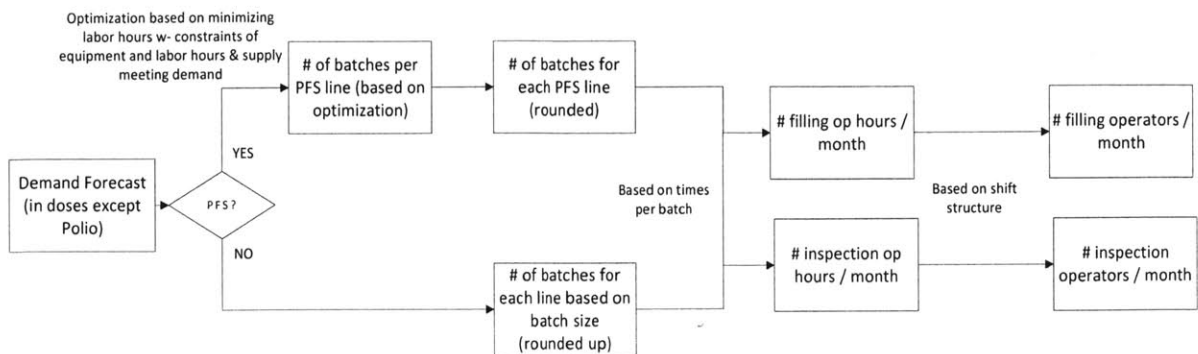


Figure 8: Determination of Filling and Inspection Resources

Due to the difference in difficulty and potential product impact between the filling and inspection process steps, we chose to separate out the labor resource requirements for the two operations in the department. This figure also demonstrates the different decisions made with respect to rounding on number of batches to produce. For the batch results from the PFS line selection operation, the batches are rounded to the nearest whole number. This was chosen due to the likelihood that the resulting average number of batches on these three lines should approximate the right number of batches for each. However, the number of batches required to meet the monthly product demand in doses for all other lines was rounded up because there is only a single line that is able to produce the product. Therefore, there is no possibility of batches sizes from various lines averaging to meet the minimum number of doses needed.

5.2.3 General Services

The model logical flow diagram for the general services department resources is shown in Figure 9 below.

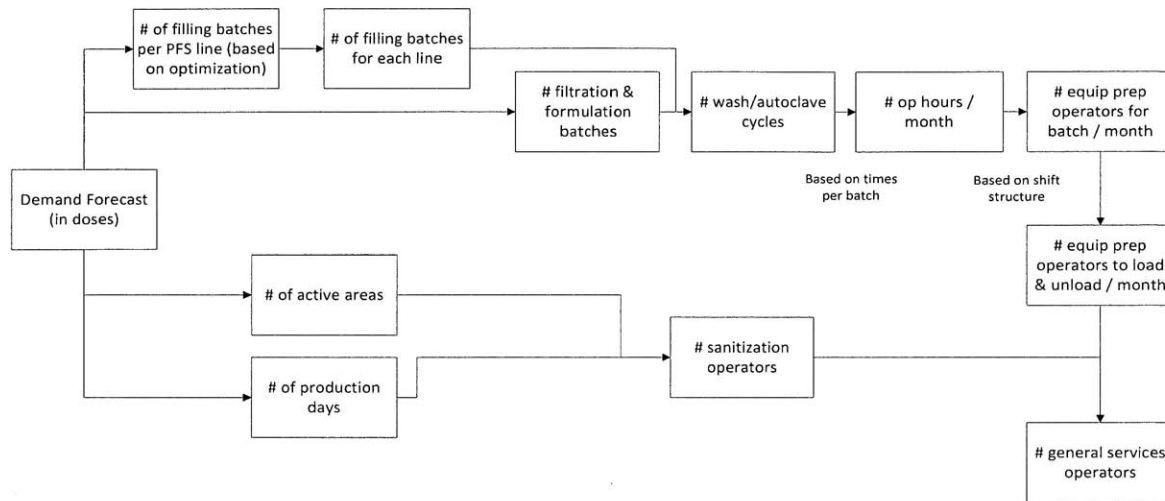


Figure 9: Determination of General Services Resources

This diagram displays the dependency on general services staffing needs on all other departments. The equipment preparation operations depend on both filling and formulation. Sanitization operations depend heavily on overall production levels for the Rosia Aseptic Operations organization and the shift structure established in the other departments.

5.3 Validation Experiment

Through feedback discussions with supply chain and operations managers in aseptic operations, we were able to iterate the model multiple times. These iterations included adding processing steps, adjusting equipment parameters and batch sizes, and altering our method of converting batches to labor hours for equipment prep operations. After all feedback from stakeholders was incorporated into the model, we wanted to validate the model prior to using it. In order to validate the model, we compared the number of resources needed to meet a particular demand outputted by the model to the current method for resource allocation. In the current method, the production scheduler creates a schedule and the operations manager for each department reviews the schedule and determines the number of operators needed to execute the schedule.

5.3.1 Interpretation of the Schedule Optimization Results

When we compared the results of the PFS line selection from the two methods, we found that there were substantial differences. These differences were attributed to informal management dictation of priorities and a lack of understanding on the capacity limiting function. The newest of the PFS lines was experiencing challenges due to differences in a non-critical filling processing step. This challenge led to an overall slower production rate for this line. However, management wanted the issues with this line resolved so the line could achieve a rate much closer than the theoretical line speed, which is the fastest of all three lines. Therefore, this line was selected for more of the batches by the production scheduler than by the optimization to encourage resource allocation to this line. We addressed this difference by adjusting the line speed in the model to reflect the anticipated line speed agreed to by the organization as this model was assessing scenarios in the future for a one-year time span, not the current state.

The other difference was related to being in an off-peak period and not having a method for comparing multiple parameters at one time. Without clear direction on whether the production scheduler should be minimizing the number of labor or equipment hours, there was not focus given to either goal. When the organization is in the peak period of flu campaign, the scheduler is instructed to maximize the number of batches. However, the model is able to accomplish a more complicated goal of maximizing the number of acceptable doses produced (not batches) by either minimizing the number of equipment or labor hours. Therefore, we kept our model the same and transferred learnings from the model selections in various scenarios to the production schedulers.

5.3.2 Interpretation of the Headcount Results

We were pleased that the model results on the number of resources needed for each department based on a schedule of batch production was very close to the current method results. We found

that overall the standard hours per batch aligned well. This was anticipated positive affirmation since while our data was very detailed and based on metrics whenever possible, the operations managers know on aggregate how long and how many people a batch takes to complete in their department.

We did experience some differences in the overall staff levels. We found that some managers accounted for the indirect items that affect headcount such as vacation, shift structure, training and administrative time, and illness, some managers did not. Therefore, the model was able to provide a standardized approach to what should be included in headcount estimates for the operations managers, especially during peak period production given the large number of operators who take vacation during the summer months. Therefore, no changes to the resource conversion portion of the model were necessary.

5.3.3 Limitations of Model

Through testing various potential demand scenarios in the model, we were able to identify failure points of the model. Since the linear optimization includes a constraint of meeting the demand forecast, if there is insufficient available equipment capacity in a given month, another constraint, the model will not return the correct number of labor hours for the month. We found the best way to identify this failure mode was to have the optimization software, Solver, flag that a feasible solution was not found. This allows the user to do a number of different things: change shift structure to work an additional day or two, thus, increasing equipment capacity, adjust the number of doses in the demand forecast, or relax the constraint.

An additional limitation of this model is the aggregation of labor needs for a month. While we selected a month for the balance between accuracy and simplicity, there is some smoothing effects of labor needs as a result. This smoothing effect can fail to alert management to weeks

where resources are highly constrained and understaffing could result. We feel that this weakness in the model is manageable through communication of the concern and use of managerial levers. In practice, some items such as time spent on training and administrative activities for operators or shutdowns in a particular week can be adjusted to accommodate these peak weeks seen within a month.

5.4 Employee Contract Selection

To ensure that we captured all relevant factors in the model related to staffing decisions and costs, we reviewed this section of the model with finance and operations management. We received feedback that this model encompassed more aspects than they usually consider and provides a comprehensive grouping of these quantitative and qualitative items. However, we acknowledge that this tool does not provide answers on what managers should do, only tools to assist in the decision making process. For example, we do not quantify several of the factors we list for consideration such as uncertainty in demand effects, criticality of position, or limitation on contract renewals.

5.4.1 Results of Scenario Analysis

In the regulated vaccine industry, it is necessary to have a well-documented training program for the operators who interact with the product. The length of the time to become a trained operator varies on department and responsibilities. Figure 10 below shows a fake scenario analysis for one of the departments.

HEADCOUNT PROPOSAL	Jan-11	Feb-11	Mar-11	Apr-11	May-11
# of new workers hired as temporary	3	0	0	0	0
# of new workers hired as permanent	0	0	0	0	0
# of workers converted to permanent from temporary	9	0	1	0	2
# of temporary workers terminated	1	5	0	0	0
# of permanent workers terminated	0	0	0	0	0
# of current qualified temporary	13	8	7	7	5
# of current qualified permanent	2	2	3	3	5
# of qualified workers	15	10	10	10	10
Workers needed from model - # of qualified workers	2	1	2	3	0
# of temporary workers	15	10	10	10	10
# of permanent workers	11	11	12	12	14
# of total workers	18	13	13	13	13
Cost of labor (including training & severance costs)	€ 92,567	€ 71,567	€ 74,800	€ 74,800	€ 81,267
Total Annual Cost	€ 919,567				

Figure 10: Cost Analysis Scenario Example

The user inputs responses to the green questions in the top section, and the bottom section automatically populates based on the costs connected with the decisions. While this is only one aspect of the cost analysis section, we are able to very quickly run multiple scenarios and assess the effects of timing and various decisions on the ability to have enough qualified operators to support production based on demand while minimizing costs.

5.4.2 Insights from Analysis

Beyond specific scenario comparisons, this evaluative section of the model provides some overarching insights. One key point is that given the time and cost to bring on temporary employees, most departments do not benefit at all from hiring temporary contract employees to cover the peak three month period during the year. In many cases, it is less expensive to keep those employees year round. Additionally, the model reinforces the point that if demand remains relatively stable or increases over the next couple of years, a large portion of the current temporary contract employees should be converted to permanent contract employees, assuming they are solid performers. However, it also shows that a conservative level of temporary contract employees should be maintained, as it is very expensive to terminate a permanent contract

employee. The model also helps to identify what portion of the filling and inspection activities are critical, and consequently, what portion of the department should be permanent contract employees.

6 Aggregate Planning

As mentioned in Chapter 1, the goal of aggregate planning is to effectively utilize an organization's resources to balance capacity to satisfy demand while minimizing costs (Chopra & Meindl, 2010). An aggregate planning approach is particularly useful in a setting in which demand is fluctuating, uncertain, or seasonal. Aggregate planning generally occurs over a three to 18 months time horizon, and consequently, it is used for medium range capacity planning. It is a process of determining both the appropriate mix of input resources as well as the output levels (Pan & Kleiner, 1995). The four levers of aggregate planning are the following: hire or fire decisions, inventory levels, overtime, outsourcing of production. Two major strategies are available to aggregate planners: level and chase. Level strategy utilizes back orders or inventory levels to achieve a steady production rate and/or a steady employment rate. Conversely, the chase strategy aims to match demand and capacity period by period to keep inventory carrying costs low though it usually is achieved through dramatic swings in hiring and firing of employees. Aggregate planners can use either pure strategy or a mix of the two.

6.1 Literature Review

A literature review provided data on both the applications and evolutions of aggregate planning as a tool. As stated by Singhal and Singhal, aggregate planning has evolved into the common business practice of developing a sales and operating plan. This is supported through various documented applications and special notice given to case studies at four companies. The case

studies walk through various goals of utilizing this methodology, including setting inventory levels, increasing overall profits, allocating production or determine changes in the workforce. (Singhal & Singhal, 2007). While none of the examples sited took place in pharmaceutical or biotech manufacturing, these planning processes do exist in Novartis V&D. However, V&D has not yet fully invested in all the applications of aggregate planning, specifically to determine appropriate headcount needs.

Due to the large number of potential applications, a more intensive literature review of aggregate production planning with the desired outcome of determining headcount needs was conducted. This search uncovered an article by Troutt, Hou, and Pang that proposed the use of mixed integer logic to include the consideration on whether to utilize a second and third shift of operators. Essentially, the logic introduced binary decision variables to indicate whether or not additional shifts were being utilized, and then those decisions were linked to the costs contained in the objective function. (Troutt, Hou, & Pang, 2006) This research highlights an important point that additional costs can be incurred based on your shift structures. The Rosia Aseptic plant is already operating three shifts; therefore, this consideration is not as relevant currently. However, this logic should be used in the case of expansion to additional operations or significant decline in production based on demand.

A recent paper, by Chen and Huang, sought to expand the use of aggregate production planning to problems with unclear, or fuzzy, input parameters such as demand using the concepts of α -cuts and Zadeh's extension principle. (Chen & Huang, 2010). While this proved to be effective in handling fuzzy parameters by providing a wider-range decision information on the outputs of aggregate planning, this may not be necessary in the case of Novartis V&D. Novartis is undergoing an initiative to clarify and properly bound their market demand projects; thus,

minimizing the usefulness of this technique. However, without this more precise demand information, this technique could be very helpful.

6.2 Application to Headcount Planning

While the Excel® model we created did incorporate some of these concepts of aggregate production planning and hopefully will enable conversations and decisions to achieve capacity and demand balance, our model does not consider the use of all four aggregate planning levers. As previously stated, the levers in aggregate planning are the following:

1. hire or fire decisions
2. inventory levels
3. overtime
4. outsourcing of production

In our model, we only include the first lever to adjust headcount. However, we recognize the benefit to the organization if we can consider the other three levers as well given the large seasonal production swings. There are several reasons why we feel that only one lever can be adjusted at this time.

6.2.1 Challenges with Inventory Levels

Currently, we are not in a position in the operations organization to influence inventory levels.

The process that supply chain uses for production scheduling is to back calculate and consequently back schedule, all production processes from the shipment of a very specific order. This is a standard Materials Requirements Planning (MRP) approach. For example, to meet the shipment of a meningitis drug product filled in a syringe to be sent to Mexico on March 6, they will back up and determine when it should be packaged, then when it should be filled, then when

it should be formulated, etc. until all processes are scheduled. Currently, inventory is viewed as an indirect result instead of a direct decision. However, this mentality could change with time, but first holding costs and risk associated with expiration need to be determined to understand the impact of build-ahead strategies. The organization does not currently have these figures.

6.2.2 Challenges with Overtime

In many countries across the world, overtime is a frequent practice to temporarily supplement the workforce during peak production periods. However, the union agreements in Italy make this practice much less common. Our organization has a maximum number of times when forced overtime can occur across the year. Additionally, the incentive structure is different in that employees only receive straight pay per hour instead of receiving an overtime premium, as frequently used in the United States. Therefore, it can be difficult to enlist an entire shift required to support a line or area. While voluntary overtime is utilized, two of the three departments in Aseptic Operations just added an additional day of production so there is not a significant opportunity to increase capacity through overtime.

6.2.3 Challenges with Outsourcing

Outsourcing in the pharmaceutical and biotech industries is possible, but it is more challenging to establish than in several other industries. As previously mentioned, each production process needs to be approved by regulators to produce each product. This approval process can be time consuming and costly. Therefore, very few of Rosia Aseptic Operations' products can be outsourced at this time.

6.3 Optimization Based on Aggregate Planning

While we are not yet able to affect these other three levers in a meaningful way, we drafted an aggregate planning optimization model for future consideration by the organization. The model

can be seen in Appendix 9.2. Beyond the improved ability to balance demand and capacity that aggregate planning optimization allows, it also quantitatively answers the critical questions of the mix of permanent and temporary contracts and when headcount decisions should be made. Compared to our Excel® model, which essentially provides the ability to test out decisions and timing relative to headcount, this optimization outputs responses to these questions directly from a cost perspective.

6.4 Selection of the Software

We chose to create this model optimization in IBM ILOG CPLEX. After creating the optimization on paper, it was clear that the number of decision variables being proposed would require software with strong capabilities in optimization. Therefore, we reviewed papers written with similar levels of complexity, and CPLEX was the predominant software used. Additionally, we wanted to keep costs down, as we were unsure if the model output would prove to be beneficial to the organization. Through the academic version of IBM ILOG CPLEX, we were able to create a pilot of the model for free. Thus, this software met both the needs of capability and cost. For Novartis to implement this model in the future, they would need to purchase the full software; however, a copy of the code (seen in Appendix 9.2) that was drafted was left with Novartis for future implementation.

6.5 Selection of Objective Function

The primary goal of this optimization was to keep all production related costs as low as possible while still meeting the demand forecast. The costs we included were the following:

- Permanent and temporary contract trainees' and qualified employees' salaries
- New employee training costs

- Severance costs for permanent contract employee termination
- Inventory holding costs for each product
- Management time spent on contract management
- Increased cost of producing each product at a contract manufacturer

These costs capture our ability to adjust the levers of headcount adjustment, inventory, and outsourcing. Since overtime wages are the same as straight time wages, this also encompasses those potential costs as well.

6.6 Model Flexibility

We understand that interfacing with a program like CPLEX is likely more difficult than interfacing with Excel® for a user in the organization. Therefore, we aimed to make the ILOG coding independent from the input data. We housed all of our input data in a spreadsheet and used tuple commands in our .mod file and a .dat file to pull the data from Excel®. This allows changes to be made to anything simply, such as demand forecasts, costs, or production rates, and have these changes immediately reflected in the optimization when executed. Additionally, the model structure was built to include as many considerations as possible with the option of zeroing the costs associated with it; thus, effectively eliminating those considerations as the user sees fit.

6.7 Expected Results

As a result of the challenges with truly utilizing all four levers, key information was missing and therefore, the aggregate planning optimization has not yet been executed. However, when the optimization is ran, we expect that the model would produce interesting insights into the trade-offs between permanent and temporary contracts and between build-ahead, outsourcing, or

increased staffing strategies to meet the demand forecast. Specifically, we would anticipate an increased use of inventory in order to level production based on initial estimates on holding costs being very low relative to the alternative strategies. Thus, the organization would employ a level strategy due to the low inventory holding costs, inability to quickly train employees, and expensive severance for terminated permanent employees.

We believe that even if all the inputs to this model are solidified and all of the strategies can be used to achieve balance, there will still be a desire by operations management to supplement final decision making with the Excel® model. Because of the complexity of this aggregate planning model, it can be difficult for a user to trust the results without clarity of the logic and validation of the model. Validation will only be able to occur after these strategies (i.e. outsourcing, inventory) can be used in practice and discrete scenarios can be tested on the model and compared to actual results. While this aggregate planning methodology is very powerful, it is important to recognize the natural inclination for people to use what they understand. Thus, we recognize that the Excel® model, despite its relatively limited functionality, may prove to be more frequently used.

7 Conclusions and Recommendations

We learned a great deal about the process and implementation of modeling that we believe are transferable. In this chapter, we seek to motivate key modeling considerations through examples as well introduce recommendations for future implementation.

7.1 Conclusions on the Modeling Process

The modeling process includes many steps beyond the initial development of logic and the collection of data. One critical step is to engage the key stakeholders multiple times throughout

the process and to iterate the model based on their feedback. For example, the structure and logic behind the equipment preparation headcount conversion changed four times in order to test hypotheses to achieve the most representative results with aggregated data sets. This commitment to piloting and adjusting the model ultimately leads to the ability to sell the model to the users. The operations managers and head of the Aseptic Organization all employed their own methods to estimate headcount previously; therefore, it was crucial to demonstrate that this model was quicker and at least as accurate as their method. We were able to show this, but only as a result of their input and frequent iterations.

Keeping the end-user in mind throughout the development of the model and the user interface is a key factor in success as well. We attempted to keep the model logic as simple to follow as possible by developing the flow charts and creating presentations to explain the logic. Also, we tried to be innovative in developing solutions to balance capabilities with ease of use. For example, we were able to segment the scheduling optimization by month and use a macro to provide a simple user experience while not sacrificing optimization capability. Additionally, it is vital to build in flexibility and linkages into the model for the user. Therefore, we linked all the assumptions and demand figures through a single sheet and allowed for products to be added as they are validated.

Additionally, we found that the modeling process helps to uncover inconsistencies and voids of knowledge. Input data collection was one of the most time intensive activities to create this model. Through this collection however, we were able to identify areas for improvement that were not evident until the data was analyzed in a different way. For example, data on reject rates for each inspection line is reviewed by line, but it was not previously reviewed by product and by

line. This kind of analysis can help to disaggregate the data to find underlying causes for equipment performance based on product specific characteristics.

7.1.1 Results & Benefits

Overall, the model meets our goal of providing comprehensive resource information to operations management in a fast, flexible format. Consequently, it reduces costs in the Rosia Aseptic Organization through the depiction of the production swings, predictability of headcount needs, tools to analyze timing and contract decisions, and optimal production scheduling. One key outcome is that the model has created a clearer view of the production peaks and valleys and acts as a platform for discussion between departments. As previously discussed, the supply chain organization plans production based on a method of back calculating from the customer order delivery date. This model enables the operations organization to demonstrate and quantify the effect of scheduling peak workload periods, and the supply chain organization can make adjustments to the production schedule as appropriate and possible.

Additionally, this longer-term view of headcount allows for critical decisions to be made both at the Rosia site and corporate level. The tables and graphs outputted from this model are used during the business planning and budgeting process. They provide the justification for decisions made with respect to headcount such as increasing or decreasing overall employee numbers or converting temporary contract employees into permanent. Consequently, each operations manager can make faster, educated decisions on temporary employees contract extensions or terminations in their department based on the predictability that the longer-term view provides.

Furthermore, the model provides a tool for evaluating changes in policies and shift structures. One clear example is that the scheduling optimization offers insights into the optimal combinations of products and lines given labor or equipment hour constraints to assist in

scheduling. It also offers another means for evaluating new projects or shift structure changes through a cost analysis on labor changes.

Finally, this project helped to highlight the many ways in which aggregate planning methodology can be useful to an organization. At the root of the challenge for Rosia Aseptic Operations organization is that the seasonal production cycles lead to fluctuations between over- and under-staffing. Therefore, helping to level out the peak of these cycles through aggregate planning levers is something that the organization can now work toward.

7.1.2 Model Accuracy

As previously mentioned, the model was validated with the key stakeholders. The stakeholders trust the input operational data as well as the logic of the model. Therefore, the largest opportunity for error lies in the demand forecast. We needed to make the assumption that the demand was deterministic for the structure of the model. This assumption can greatly affect the accuracy of the model, especially if the demand data has a high level of uncertainty associated with it, or it is not updated frequently. It is important to consider that this uncertainty increases with time; therefore, the accuracy of the model decays each month. (Silver, Pyke, & Peterson, 1998)

7.2 Recommendations

In order to realize gains from not only this project, but also from having an outsider working within the Rosia Aseptic site, recommendations for the model and the organization have been compiled.

7.2.1 Model Sustainability

While the model is currently operational, it is important that the model's benefits are sustained over time. To sustain these benefits the model must remain as accurate and easy to use as

possible. In order to maintain accuracy, the operations manager should review and update the input data for their respective departments quarterly for changes due to operational improvements or regulatory changes. A formal inventory of implicit assumptions should also be created so that users can revisit and verify the accuracy of both implicit and explicit assumptions in the model. Additionally, every time the model is ran the demand data should be updated to reflect the most recent rolling-forecast.

Efforts were made to ensure competency and comfortability operating the model for all the stakeholders. These efforts included the following: a presentation visually demonstrating how to update and run the model; a transition document explaining all the underlying logic, assumptions, and sources for input data; sessions with operations managers to practice using the model; built-in step by step instructions within the model. Beyond these efforts, model sustainability would be greatly improved by having a dedicated model owner within the Rosia Aseptic Operations organization to troubleshoot any issues and implement any further improvements to the model.

7.2.2 Future Model Improvements

Some additional improvements to the model could increase the speed to update input and demand data, improve the accuracy of the model, and save additional money. As previously mentioned, a large effort was required to collect the data needed to construct this model. We recommend utilizing an IT solution to collect and track key operational metrics. Having these metrics readily available would decrease the time needed to update the model, and these metrics updating automatically would also highlight production changes real-time that might otherwise be missed. Another step to dramatically decrease the time required to update the model would be to automatically pull the demand data from SAP® instead of manually entering the data into the

spreadsheet. Rosia SAP® resources could write a script to pull the data from SAP® into a spreadsheet.

Along the lines of demand data, it would be beneficial to utilize a Monte Carlo simulation to model demand uncertainty. V&D is undergoing an effort to increase the available information on the demand forecast through identifying upper and lower bounds on demand, in addition to reporting expected demand. With these bounds determined and a probability function applied, this method would improve the key issue leading to inaccuracy for the model.

Finally, we recommend completing the aggregate production planning optimization. The first step toward implementing this recommendation is to enable the other levers of aggregate planning. Specifically, the inventory lever should be considered first as that is the least cost intensive and has the highest probability for use in this production environment. This can be enabled by determining inventory holding costs, developing risk profiles for expiration of each product, and realigning supply chain planning practices to accommodate build-ahead strategies. Then, the draft model in ILOG CPLEX should be updated and adapted to reflect the current state of the business. We believe the results of this aggregate planning optimization will further decrease the costs for the Rosia Aseptic Organization.

7.2.3 General Recommendations

During this project, we developed other recommendations for Novartis' consideration. The first of which is to utilize all the input data collected for this model to update the recipes in SAP® for each product. With the Rosia site moving to a standard costing approach, the validity of the information in SAP® is even more critical. Additionally, correct SAP® data will increase the use of SAP® for scheduling over spreadsheets. Furthermore, the insights that the schedulers gain from the scheduling optimization in the model can be applied to SAP® by assigning

preferences to lines based on products; thus, further improving the ability to schedule within SAP®.

From an organizational perspective, the Aseptic Organization is largely focused on improving operations in the filling and inspection department. Therefore, some of the remaining large improvements exist in the other two departments. We suggest reconsidering the formulation department shift structure. As more products move to point-of-fill filtration, the maximum time between the formulation and fill steps can be increased. Thus, more batches could be produced in advance of the filling line being prepared. While formulating a product prior to a filling line being ready increases the risk of scrap, if managed effectively, it could allow for labor savings in formulation. Currently, the formulation department operates two shifts, five days a week structure with overtime on weekends to cover weekend filling activities as needed. Several of the products take 5-7 hours to formulate a batch. However, due to the shift structure, one formulation may be the only activity executed in an eight-hour shift since they cannot start and finish another batch in the remaining time. Therefore, if at least a couple days each week the department ran 24 hours, they maybe able to scale up production to match increasing demand without adding additional operators since they would essentially 'recover' those hours lost due to shift structure constraints.

Furthermore, we recommend considering all potential uses for the model and the information contained within it. For example, schedulers can use the scheduling optimization to test out weekly scheduling scenarios and see the trade off between equipment hours, labor hours, batch size, and reject rate. While it was not built for short-term planning, this is one potential application where it could provide additional insights into the planning process. Another potential use is for training new support staff. Currently, there is not a master document listing

which lines products are validated on, and that document could be easily compiled from the model. Similarly, data on line speeds, batch sizes, set-up and changeover times could be used to train new department heads or to benchmark with other aseptic plants.

Finally, we recommend that upper management review these recommendations for application across multiple organizations in the Novartis V&D network. Through a holistic view and an understanding of the concepts of aggregate planning, additional cost savings could be realized by optimizing over the entire value chain opposed to only one organization within it. As stated in an article in Biopharm International, “To make sound tactical and strategic decisions that impact profitability, decision makers must have better control over the planning function.” (Tauton & Feinbaum, 2006). Therefore, while the Aseptic Operations organization can still influence efficiency and bottom-line savings, those with authority to influence operations as well as the supply chain function can achieve an even greater impact.

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9 Appendix

9.1 Model Formulation for Scheduling Optimization

9.1.1 Decision variables

$B_{i,j,l}$ = batches in month i of product j made on line l

$A_{i,j,l}$ = 1 if any batches are produced in month i of product j made on line l ; 0 otherwise

9.1.2 Constants

D_{ij} = Demand in doses in month i of product j

$S_{i,j}$ = Supplied doses in month i of product j made on line l

$Y_{j,l}$ = yield in acceptable doses per batch of product j on line l

$O_{j,l}$ = operator hours to make one batch of product j on line l

$E_{j,l}$ = equipment hours to make one batch of product j on line l

$OC_{i,l}$ = maximum operator hours in month i

$EC_{i,l}$ = maximum equipment hours in month i

M = big M set equal to 1000

FE_l = Increased equipment time to do format change instead of change over on line l

FO_l = Increased operator time to do format change instead of change over on line l

9.1.3 Objective Function (can select between the two)

Minimize $\forall i, l \sum_j (O_{i,j,l} \times B_{i,j,l}) + FO_l \sum_l A_{i,j,l}$: Minimize operator hours per month

Minimize $\forall i, l \sum_j (E_{i,j,l} \times B_{i,j,l}) + FE_l \sum_l A_{i,j,l}$: Minimize equipment hours per month

9.1.4 Constraints

$\forall i, l (\sum_j (O_{i,j,l} \times B_{i,j,l}) + FO_l \times \sum_j A_{i,j,l}) \leq OC_{i,l}$: Operator hours per month per line cannot exceed the operator capacity of line for that month

$\forall i, l (\sum_j (E_{i,j,l} \times B_{i,j,l}) + FE_l \times \sum_j A_{i,j,l}) \leq EC_{i,l}$: Equipment hours per month per line cannot exceed the equipment capacity of line for that month

$\forall i, j D_{i,j} \leq \sum_l S_{i,j,l}$: Demand must be met

$\forall i, j S_{i,j,l} = \sum_l (Y_{j,l} \times B_{i,j,l})$: Supply is based on yield of each batch based on line and the number of batches on each line

$\forall i, j, l B_{i,j,l} \leq M \times A_{i,j,l}$: Big M constraint to force $A_{i,j,l}$ to 1 if batches are produced

$A_{i,j,l} \in \{0,1\}$: Binary constraint

9.2 Model Formulation for Aggregate Planning

9.2.1 Model Formulation with Explanation

Sets

$l \in L$ – Set of Job Types (Form, FILL, General)

$i \in I$ – Set of Months

$j \in J$ – Set of Products

$m \in M$ – Set of Job Classes (Permanent, Temporary)

$k \in K^{FILL}$ – Set of actual machines in the FILL area

Constants

$c^{m,SAL}$ – Monthly salary of an employee in class m (Perm or Temp)

c^{LAY} – One time cost of Laying off an employee

c^{Δ} – Cost of management changing the headcount

c^{TRAIN} – Cost of training an employee

c_j^{Hold} – Cost of holding one unit of product j

c^{SWITCH} – Cost of switching one employee between products

$Q_{i,j}^{FILL}$ – Demand for product j in month i that is *FILLED*

$B_j^{FORM,MACHCAP}$ – Max number of product j for *FORM* per month

$B_{j,k}^{FILL,MACHCAP}$ – Max number of product j on for FILL on machine k per month (zero if infeasible)

$B^{l,TRAIN}$ – Max number of workers that can be trained at any one time for area l

$B_{i,j}^{GEN}$ – Min number of workers required in month i on product j for *GENERAL*

$B_{i,j}^{l,SSTOCK}$ – Safety stock required for product j in month i for area l

$t^{l,TRAIN}$ – Months required to train a worker on area l

R_j^{FORM} – Amount of product j of *FORM* produced by one worker

$R_{j,k}^{FILL}$ – Amount of product j of *FILL* produced by one worker on machine k

M – A very large number (E.g., total number of possible employees times total months times 10)

Variables

$x_{i,j}^{l,m}$ – Number of employees to hire of class m for area l in month i for product j

$y_{i,j}^{l,m}$ – Number of employees to layoff of class m for area l in month i for product j

$z_{i,j}^{l,m}$ – Number of employees able to work of class m for area l in month i for product j

$w_{i,j}^{l,m}$ – Number of employees TRAINING of class m for area l in month i for product j

$s_{i,j^1,j^2}^{l,m}$ – Number of employees switched from product j^1 to product j^2 of class m for area l in month i

$v_{i,j}^l$ – Units of product j at the start of month i in state l we have

$p_{i,j}^{FORM}$ – Units of product j FORMULATED in month i

$q_{i,j,k}^{FORM-FILL}$ – Units of product j FILLED from FORMULATION in month i on machine k

$h_i^\Delta \in \{0,1\}$ – Binary variable: did I change the headcount in month i ?

Constraints

$$z_{i,j}^{l,m} = z_{i-1,j}^{l,m} + x_{i-1,j}^{l,m,TRAIN} - y_{i-1,j}^{l,m} + \sum_j s_{i,j}^{l,m} - \sum_j s_{i,j,j}^{l,m} \quad \forall l,m,i,j \quad (1.1)$$

$$p_{i,j}^{FORM} \leq B_j^{FORM,MACHCAP} \quad \forall i,j \quad (1.2a)$$

$$q_{i,j,k}^{FORM-FILL} \leq B_{j,k}^{FILL,MACHCAP} \quad \forall i,j,k \quad (1.2b)$$

$$v_{i,j}^{FORM} = v_{i-1,j}^{FORM} + p_{i-1,j}^{FORM} - \sum_k q_{i-1,j,k}^{FORM-FILL} \quad \forall i,j \quad (1.3a)$$

$$v_{i,j}^{FILL} = v_{i-1,j}^{FILL} + \sum_k q_{i-1,j,k}^{FORM-FILL} - Q_{i-1,j}^{FILL} \quad \forall i,j \quad (1.3b)$$

$$\frac{p_{i,j}^{FORM}}{R_j^{FORM}} \leq \sum_m z_{i,j}^{FORM,m} \quad \forall i,j \quad (1.4a)$$

$$\sum_k \frac{q_{i,j,k}^{FORM-FILL}}{R_{j,k}^{FILL}} \leq \sum_m z_{i,j}^{FILL,m} \quad \forall i,j \quad (1.4b)$$

$$\sum_{i-1,j,k,m \leq i} x_{i,j}^{l,m} = w_{i,j}^{l,m} \quad \forall i,j,l,m \quad (1.5a)$$

$$\sum_{j,m} w_{i,j}^{l,m} \leq B^{l,TRAIN} \quad \forall i,l \quad (1.5b)$$

$$\sum_m z_{i,j}^{l,m} \geq B_{i,j}^{GEN} \quad \forall i,l \quad (1.6)$$

$$v_{i,j}^l \geq B_{i,j}^{l,SSTOCK} \quad \forall i,j,l \quad (1.7)$$

$$Mgh_i^\Delta \geq \sum_{j,l,m} x_{i,j}^{l,m} + \sum_{j,l,m} y_{i,j}^{l,m} \quad \forall i \quad (1.8)$$

(1.1) - Workers today equals workers last month plus those that were hired t months ago minus those that were laid off plus all those that switched in minus all those that switched out

(1.2a) - You can't produce more FORM than you have capacity for each product

(1.2b) - You can't produce more FILL than you have capacity for each product ON EACH MACHINE

(1.3a) - New inventory for FORM equals old inventory plus whatever was produced minus whatever when to FILL

(1.3b) - New inventory for FILL equals old inventory plus whatever came from FORM minus whatever goes to our customers

(1.4a) - You can't FORM more than you available labor (num workers times production rate)

(1.4b) - You can't FILL more than you available labor (num workers times production rate)

(1.5a) - The number of employees in training equals everyone who was hired within t months

(1.5b) - The number of employees in training can't exceed the training threshold

(1.6) - You must have the minimum number of GENERAL workers every month

(1.7) - You must have more than the minimum safety stock level each month

(1.8) - If you changed the headcount, you have to set the headcount variable (h) to 1

Objective Function to Minimize

$$\sum_{i,j,l,m} c^{m,SAL} (z_{i,j}^{l,m} + w_{i,j}^{l,m}) \quad (2.1)$$

$$+ \sum_{i,j,l,m} c^{LAY} g_{i,j}^{l,m} \quad (2.2)$$

$$+ \sum_{i,j,l,m} c^{TRAIN} g_{i,j}^{l,m} \quad (2.3)$$

$$+ \sum_l c^{\Delta} g_l^{\Delta} \quad (2.4)$$

$$+ \sum_{i,j,l} c_j^{HOLD} g_{i,j}^l \quad (2.5)$$

$$+ \sum_{i,j^1,j^2,l,m} c^{SWITCH} g_{i,j^1,j^2}^{l,m} \quad (2.6)$$

(2.1) - Cost of Useful and Training workers

(2.2) - Cost to lay off workers

(2.3) - Cost to train workers

(2.4) - Cost of changing headcount

(2.5) - Cost of holding inventory for each product

(2.6) - Cost of switching workers among products

9.2.2 ILOG .MOD File Draft

```

/*****
 * Novartis Rosia Aseptic Headcount Model
 * Creation Date: Oct 18, 2010 at 4:47:10 AM
 *****/

// -----
// Sets
// -----

{string} JobTypes = ...;
{string} Months = ...;
{string} Products = ...;
{string} Contracts = ...;
{string} FillMachines = ...;

// -----
// Constants
// -----

int horizon = ...;
range time = 1..horizon;
float CostSalMonth[Contracts] = ...;
float CostLayoff = ...;
float CostChangeHead = ...;
float CostTrain = ...;
float CostHoldPerMonth[Products] = ...;
float DemandFill[Months][Products] = ...;
float LimitMachineCapacityForm[Products] = ...;
float LimitMachineCapacityFill[Products][FillMachines] = ...;
float LimitTrainCapacity[Contracts] = ...;
float LimitMinGeneralWorkers[Months][Products] = ...;
float LimitSafetyStock[Months][Products][JobTypes] = ...;
float ConstantTimeRequiredToTrain[JobTypes] = ...;
float ConstantProductRatePerWorkerForm[Products] = ...;
float ConstantProductRatePerWorkerFill[Products][FillMachines] = ...;
float BigM = ...;

// -----
// Demand info - need to update to include 24 months
// -----

tuple DemandData
{
    float Month1;
    float Month2;
    float Month3;
    float Month4;
    float Month5;
    float Month6;
    float Month7;
    float Month8;
    float Month9;
    float Month10;
    float Month11;
    float Month12;
}

```

```

};

DemandData DemandFill[Products] = ...;

// -----
//Current Headcount Data
// -----

tuple InitialHeadcount
{
    float PERM;
    float TEMP;
};

InitialHeadcount Var_EmpUseful[0][JobTypes] = ...;

// -----
//Current Headcount Data
// -----

tuple InitialHeadcount
{
    float PERM;
    float TEMP;
};

InitialHeadcount Var_EmpUseful[0][JobTypes] = ...;
// -----
// Primary Decision Variables
// -----

dvar float+ Var_EmpHire[Months][Products][JobTypes][Contracts];
dvar float+ Var_EmpLayoff[Months][Products][JobTypes][Contracts];
dvar float+ Var_EmpUseful[Months][Products][JobTypes][Contracts];

// -----
// Secondary Decision Variables
// -----

dvar float+ Var_EmpInTrain[Months][Products][JobTypes][Contracts];
dvar float+
Var_EmpSwitchProd[Months][Products][Products][JobTypes][Contracts];
dvar float+ Var_OnHandInventory[Months][Products][JobTypes];
dvar float+ Var_ProduceForm[Months][Products];
dvar float+ Var_ProduceFill[Months][Products][FillMachines];
dvar boolean Var_HeadcountChange[Months];

// -----
// Objective Function
// -----

minimize
    //salary for useful employees and those in training
    sum(i in Months, j in Products, l in JobTypes, m in Contracts)
        CostSalMonth[m] * ( Var_EmpUseful[i][j][l][m] +

```



```

Var_EmpInTrain[i][j][l][m])
+
  //severance costs for permanent contract lay offs - need to specify only
for permanent in Contracts
  sum(i in Months, j in Products, l in JobTypes, m in Contracts)
    CostLayoff * Var_EmpLayoff[i][j][l][m]
+
  //training costs for new employees
  sum(i in Months, j in Products, l in JobTypes, m in Contracts)
    CostTrain * Var_EmpHire[i][j][l][m]
+
  //cost of management time to adjust headcount
  sum(i in Months)
    CostChangeHead * Var_HeadcountChange[i]
+
  //holding costs for inventory
  sum(i in Months, j in Products, l in JobTypes)
    CostHoldPerMonth[j] * Var_OnHandInventory[i][j][l]
;

// -----
// Constraints
// -----

subject to
  forall(i in Months, j in Products, l in JobTypes, m in Contracts)
    ctEmpEqual://Define qualified workers
      Var_EmpUseful[i][j][l][m] == Var_EmpUseful[i-1][j][l][m]
      + Var_EmpHire[i -
ConstantTimeRequiredToTrain[l]][j][l][m]
      - Var_EmpLayoff[i - 1][j][l][m]
      + sum(j1 in Products) Var_EmpSwitchProd[i
- 1][j1][j][l][m]
      - sum(j1 in Products) Var_EmpSwitchProd[i
- 1][j][j1][l][m]
      ;

  forall(i in Months, j in Products)
    ctFormMachCapacity://Cannot produce more than the capacity of form
      Var_ProduceForm[i][j] <= LimitMachineCapacityForm[j]
      ;

  forall(i in Months, j in Products, k in FillMachines)
    ctFillMachCapacity: //Cannot produce more than the capacity of each
machine
      Var_ProduceFill[i][j][k] <= LimitMachineCapacityFill[j][k]
      ;

  forall(i in Months, j in Products)
    ctInvEqualForm:
      Var_OnHandInventory[i][j]['Form'] == Var_OnHandInventory[i-1][j]['Form']
      + Var_ProduceForm[i-1][j]
      - sum (k in FillMachines)
Var_ProduceFill[i-1][j][k]
      ;

  forall(i in Months, j in Products)

```

```

ctInvEqualFill: // define available filled inventory
  Var_OnHandInventory[i][j]['Fill'] == Var_OnHandInventory[i-1][j]['Fill']
    + sum (k in FillMachines)
Var_ProduceFill[i-1][j][k]
    - DemandFill[i-1][j]
;

forall(i in Months, j in Products)
  ctProdLimitedByWorkersForm:
    Var_ProduceForm[i][j] / ConstantProductRatePerWorkerForm[j] <= sum(m in
JobClasses) Var_EmpUseful[i][j]['Form'][m]
;

forall(i in Months, j in Products)
  ctProdLimitedByWorkersFill:
    sum (k in FillMachines) Var_ProduceFill[i][j] /
ConstantProductRatePerWorkerFill[j][k] <= sum(m in JobClasses)
Var_EmpUseful[i][j]['Fill'][m]
;

forall(i in Months, j in Products, l in JobTypes, m in Contracts)
  ctEmpInTrainingEquate: // define number of employees in training
    Var_EmpInTrain[i][j][l][m] = sum(i1 in Months: i1 <= i-1, i1 >= i -
ConstantTimeRequiredToTrain[l])
    Var_EmpHire[i -
ConstantTimeRequiredToTrain[l]][j][l][m]
;

forall(i in Months, l in JobTypes)
  ctEmpInTrainingLimit: // number of employees allowed in training in each
department
    sum(j in Products, m in Contracts) Var_EmpInTrain[i][j][l][m] <=
LimitTrainCapacity[m]
;

forall(i in Months, j in Products, l in JobTypes)
  ctEmpMinGeneral: // must maintain a minimum number of qualified workers
in sanitization
    sum(m in Contracts) Var_EmpUseful[i][j][l][m] >=
LimitMinGeneralWorkers[i][j]
;

forall(i in Months, j in Products, l in JobTypes)
  ctInvSafetyStock: // minimum staffy stock level must be maintained
    Var_OnHandInventory[i][j][l] >= LimitSafetyStock[i][j][l]
;

forall(i in Months)
  ctChangeHeadcount: //define monthly change in headcount
    M * Var_HeadcountChange[i] >= sum (j in Products, l in JobTypes, m in
JobTypes) Var_EmpHire[i][j][l][m] + Var_EmpLayoff[i][j][l][m]
;

```

```
} //end of constraints  
;
```

9.2.3 ILOG .DAT File Draft

```
/*  
 * OPL 12.2 Data  
 * Creation Date: Oct 19, 2010 at 5:22:02 AM  
 */  
// -----  
// Spreadsheet link  
// -----  
SheetConnection sheet("mockmodeldata.xls");  
  
// -----  
// Input  
// -----  
Products from SheetRead(sheet, "MockDemand!A2:A60");  
DemandFill from SheetRead(sheet, "MockDemand!B2:Y60");  
sheetResources from SheetRead(sheet, "MockResource!E3:AB6");  
horizon from SheetRead(sheet, "InputData!E4:E4");  
Contracts from SheetRead(sheet, "InputData!E7:C7");  
sheetCurrentHeadcount from SheetRead(sheet, "InputData!A8:C13");  
sheetTrainingPeriod from SheetRead(sheet, "InputData!A17:B19");  
sheetMaxTraining from SheetRead(sheet, "InputData!A22:B24");  
sheetMachCapacity from SheetRead(sheet, "InputData!A27:B35");  
LimitMinGeneralWorkers from SheetRead(sheet, "InputData!A36:A38");  
sheetCostSalMonth from SheetRead(sheet, "InputData!A41:B42");  
CostLayoff from SheetRead(sheet, "InputData!A43:A43");  
CostTrain from SheetRead(sheet, "InputData!A44:A44");  
CostChangeHead from SheetRead(sheet, "InputData!A45:A45");  
sheetCostHoldPerMonth from SheetRead(sheet, "InputData!A47:B48");  
BigM from SheetRead(sheet, "InputData!A51:A51");  
  
// -----  
// Output  
// -----  
resultProduct to SheetWrite(sheet, "ProductOutput!A2:E3000");  
resultHeadcount to SheetWrite(sheet, "HeadcountOutput!A2:G3000");
```