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PACKAGING CAPACITY ANALYSIS OF A BIOPHARMACEUTICAL PRODUCTION OPERATION

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ABSTRACT

This paper discusses an application of discrete event simulation in analyzing packaging capacity at Bayer Corporation's Berkeley, California facility. A discrete event simulation model was used to estimate output under differing employee staffing and scheduling policies, taking into consideration product and equipment requirements. This model was also used to study the effects on packaging operations due to changes in the manufacturing environment. The model and its recommendations were used to support a major business process decision.

1 INTRODUCTION

Bayer Corporation's worldwide biotechnology headquarters in Berkeley, California houses two major functions: research and development of protein drugs and manufacturing operations for these medicines. The site currently manufactures Kogenate-FS®, a drug based on second generation recombinant DNA technology, which treats hemophilia, a bleeding disorder caused by the lack of Factor VIII protein. This life-sustaining drug needs to be administered at regular intervals; therefore, the facility's primary goal is to ensure a consistent and reliable supply of Kogenate-FS®. This requires consistent and reliable manufacturing operations across all functions.

The Packaging Department, whose responsibilities include inspecting, labeling, and packing the final product, is the major final manufacturing step before the product is released. Equipment, materials and human resources influence the reliability and capacity of the packaging operation. Thus, identifying bottleneck resources and employing an effective scheduling structure for the department were critical. This paper presents how the capacity analysis was carried out for the Packaging Department using simulation techniques; the modeling was done using SIGMA® (Schruben 1994).

2 BACKGROUND

The Packaging Department's main function is to test and package the final product for commercial release. This batch process involves several discrete process steps. Furthermore, there are two different product types. The two types do share a number of process steps, but each product type can only be processed on certain equipment units. Moreover, the remaining unshared process steps depend on customer requirements: some product will need be shipped as individual units, while others will be shipped as bulk units. The sequence of the steps remains the same regardless of these differences. To carry out each process step, specialized equipment along with a specified number of employees are needed.

The equipment layout is such that three equipment units are connected by a shared equipment resource. These shared equipment units create a system where only one of the two connected process equipment units can be utilized at any given moment. All other units are stand-alone units. Moreover, one particular equipment unit can be utilized for two process different process steps. Figure 1 depicts the functions and connectedness of each equipment unit.

Besides its main function, the Packaging Department is required to carry out other tasks, such as the inspections of non-product materials and other miscellaneous projects. The department is currently operating a single shift.

3 PROJECT OBJECTIVES

Management wanted to estimate their current capacity as well as the potential capacity under differing shift policy scenarios. Three policies were under consideration:

1. a single shift, where all employees work the same hours

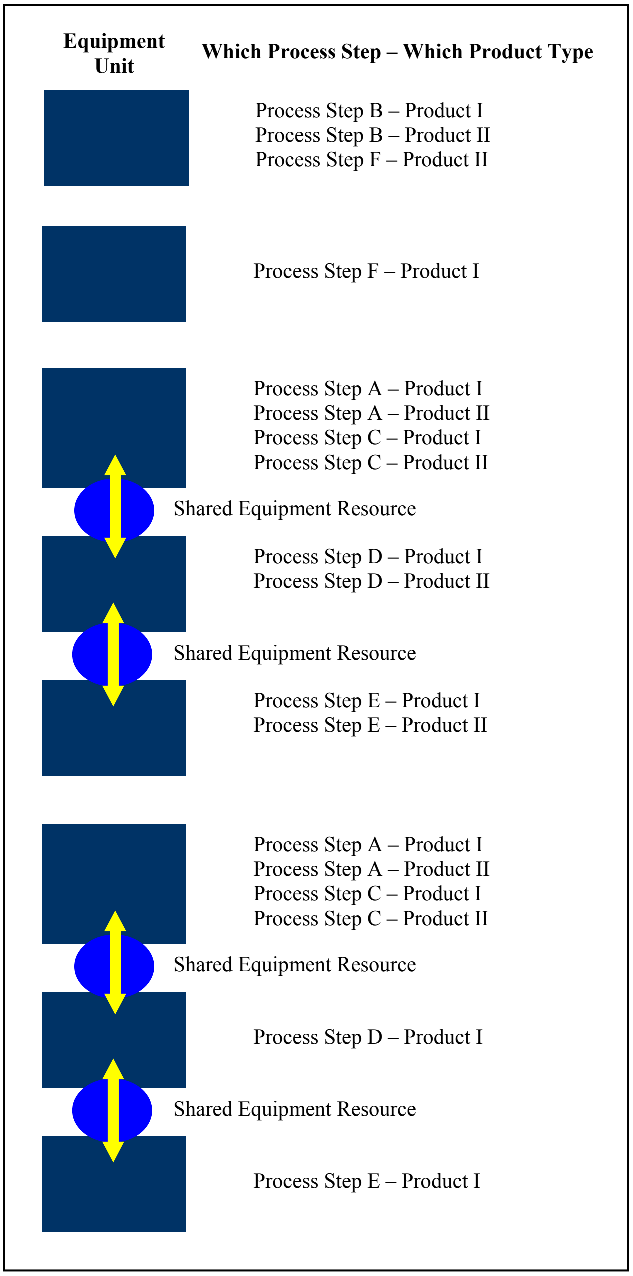

Figure 1: Schematic Equipment Layout

2. a two shift structure, where the number of employees would roughly be divided evenly between two back-to-back shifts
3. a two shift structure, where, again, the number of employees would roughly be divided evenly, however, one shift would cover the beginning of the week while the second would cover the end of the week, with overlapping days in between when all employees would be working.

A graphical representation of the three options is shown in Figure 2.

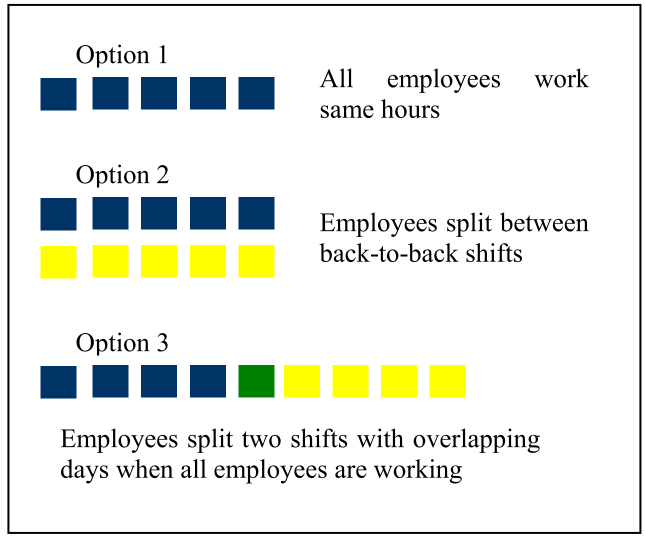

Figure 2: Shift Structure Options

All shift structures maintain the same number of working man-hours, but the number of machine hours varies by 50% - 100%. Management was interested in seeing the effectiveness the different shift structures would have in the near future. Based on these questions, the project had the following set of objectives:

- Analyze the Packaging Department's throughput under production scenarios for 2005 and 2006
- Analyze the effects different shift structures and an increased number of employees have on throughput under the same production scenarios
- Recommend whether the department should change its current shift structure and how many employees would be needed under specified workload scenarios.

4 SCOPE AND ASSUMPTIONS

The Packaging Department's workload was generated to reflect the expected number of product lots to be produced during a given year. Administrative activities as well as extreme failures were excluded from the simulation. Temporary employees were also not included. It was believed that a minimum time unit of one-hour provided sufficient granularity to adequately model the process. Furthermore, we chose the operating time to span one year, since production workload goals are set annually.

5 APPROACH

To build an accurate simulation that is representative of the system and to ensure meaningful results, we carried out a number of standard modeling steps, namely, process mapping, data collection, logic development, model building, validation, experiments, results and analysis.

The process mapping and data collection phases provide a fundamental understanding of the system and its many variables including: the product movement between production stages, the procedure called sub-lotting of product lots, the approximate product-mix, the processing times for various operations and the rates of re-inspections. Logic development was carried out to understand the job-scheduling generation; our main concern here, was with the priority of process steps and the effects of lot rework due to changes in demand.

The model was built in modules, in total consisting of four main modules: 1) workload generation; 2) employee scheduling, 3) product processing, and; 4) lot rework. Each module was developed and tested independently before they were integrated into the single simulation model presented in Figure 3. This modular approach expedited model building by reducing errors. We then proceeded to conduct extreme value checks to verify the range of application for our model. Attention was paid on designing a model that would execute rapidly to allow extensive experimentation.

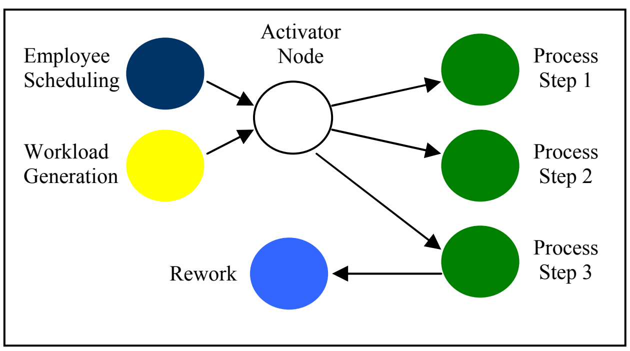

Figure 3: Simplified Simulation Module Setup

We estimated several performance parameters of a new equipment layout: these include the number of completed bulk lots and unit lots, the ratio of sub-lots to one mother lot, and the number of unfinished lots. The simulated results for the new layout for bulk packs and incomplete lots were slightly higher than the current production outcomes (approximately 10 lots and 5 lots, respectively). All other performance measurements of the current process had errors of less than 10% so that the stakeholders accepted the model as accurately representing the packaging process.

After obtaining credibility for the model, the next step was to design a set of experiments to address the project objectives. The first set of experiments was intended to determine if the current shift structure and number of employees would be adequate to complete the workload under specified scenarios. The second set of experiments was designed to examine the effects of the differing shift structures on production throughput. A final set of experiments consisted of running miscellaneous scenarios to estimate the maximum throughput and to identify bottlenecks in the process, all of which were tested under the current production layout and staffing.

These experiments allowed us to examine the impact of individual changes on production throughput. We also were able to analyze potential improvement opportunities and to identify unique characteristics and insights about the system. Since the simulation executed quickly, we were able to carry out a large number of experiments, each with enough replications and providing us with a huge amount of output data, in a short period of time. Ten simulation replications of a year's production with a single shift takes about 1 minute to run, while a two-shift model takes about 1.5 minutes on a Pentium Celeron 500mHz processor with 192 MB RAM.

6 FINDINGS AND RESULTS

We classify our findings into three categories. The first section concerns the impact of different shift structures on the process. The next section discusses the importance of job priorities and its effects on the process. Finally, the last section presents our findings regarding idle employees.

6.1 Impact of Shift Structure on the Process

We used a constant workload and a deterministic scheduling policy to examine the impact that different shift structures would have on the process. We found that although average total throughput was fairly constant among the three options (less than 1% difference), the average number of unprocessed lots and its variability was significantly larger for the single-shift option than for the two-shift options (the number of unprocessed lots for one-shift operation was nearly four times that for the two-shift operation). Furthermore, the queue lengths for some of the process steps were larger for the one-shift structure over the two-shift structures. Extensive experimental replications demonstrated that the one-shift structure was prone to queue buildups due to shared equipment. These trends were magnified when we introduced a more random workload generation.

From these results, we were able to conclude that the two-shift operations were advantageous, with the two-shift structure that had overlapping days being the better option. Although having all employees working together during a single shift maximizes the number of parallel processing opportunities, due to equipment sharing, this advantage was not dominant. Increasing the number of available machine hours, although decreasing the number of parallel processing possibilities, allows the system to compensate for variations in the workload as well as increase throughput by 15% - 20%. Furthermore the overlapping days leveled the queues in the system, whereas the back-to-back two shift option had a few average queue length spikes for certain process steps. Instead of hiring more employees, changing the shift-structure would allow for increased potential capacity and a more stable system.

6.2 Impact of Job Priorities

The next set of experiments tested the impact that changes in job priorities would have on output; we used a constant workload with a deterministic schedule. We tested four priority types: 1) one particular process step took highest priority and the other jobs followed suit depending on where they were in the process, resulting in a fixed process-step priority; 2) a FIFO job priority; 3) the simulation assigns a random, but fixed, priority for process steps for each replication, resulting in a randomized process step priority and; 4) all jobs take on a random priority.

From our analysis, we found that assigning priorities based on certain process steps resulted in a significant increase in the number of total lots processed compared to the randomized rules; these results, however, were not as significant when compared to the FIFO option. We did see that the FIFO rule is a better option than having a purely randomized job priority. When examining unprocessed lot behavior, we found that all options were significantly better than the purely random option. Interestingly, setting a specific process step priority resulted in a similar number of unprocessed lots as setting a randomized process-step priority. What may be even more surprising is that the FIFO priority was significantly different and better than the specific process step priority. These results suggest that, generally speaking, a structured priority system is better than following a randomized job-priority. This may also suggest that an optimal priority ordering of process steps exists and is worth further analysis.

6.3 Full-Time Employee Requirement

One property of the current system is that all of the process steps required a group of full-time employees in order to start processing. While attempting to measure employee idle time, we discovered an interesting characteristic; in terms of percentage of time that a certain number of employees were idle, we found that having one idle employee was just as ineffective, processing-wise, as having a group of employees idle. A graphical representation is shown in Figure 4.

We designed an extreme example to clearly illustrate this point to management. The experimental setup was the same in each case except for the number of employees and the number of required employees needed to start a process step; in one experiment, all processes required 1 employee, and we had 4 employees total; in the other experiment, all process steps required 8 employees to start and The idle time results are shown in Table 1.

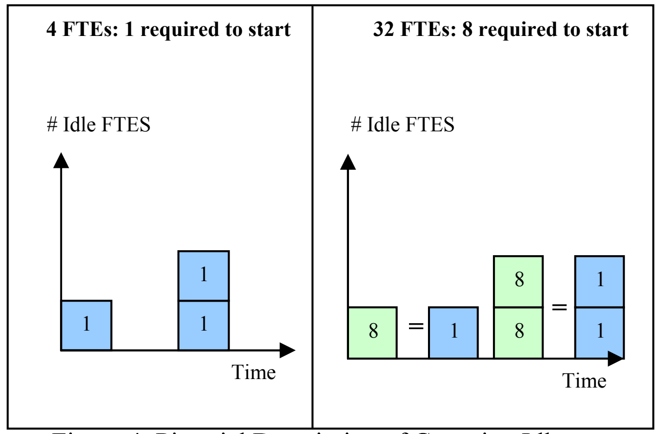

Figure 4: Pictorial Description of Grouping Idleness

Table 1: Idle Time Results Based Solely on Time for 2 Scenarios

Scenario	Number of idle employees	% of total available time that group was idle
Total of 4 FTEs: 1 FTE required to start steps	1	2.74%
	2	0.88%
	3	0.04%
Total of 32 FTEs: 8 FTEs required to start steps	1-8	2.74%
	9-16	0.88%
	17-24	0.04%

As seen in Table 1, the percentages of idle time match; we see that having 1 employee idle in the first case was just as inefficient as having 1-8 employees not working in the second, and having 2 idle employees was as inefficient has have 9-16 employees, etc. Moreover, all other outcomes, when comparing the two scenarios, were identical. Although this is an exaggerated example, it does point out the fact that because our system requires a group of employees instead of a single person to start a process step, we must consider this when looking at idle time measurements. Measuring idle time while taking into account the number of employees not working would explain rising peaks and sudden drops in our results; it also signals that certain numbers of employees are better than others. When we see a peak forming, we can safely say hiring another employee would not be effective because, most likely, that employee will be joining other idle employees waiting for yet another employee to start a job.

7 CONCLUSIONS

Using a discrete event simulation allowed us to analyze a complex, multi-product, multi-resource packaging operation in a biotech manufacturing facility. We were able to provide management with output estimates about how individual changes might improve the department's capabilities. This information was used to provide support for a business decision regarding employee hiring and scheduling that impacted the potential capacity of the department.

This model also provided insights about the system and how management might deal with possible future internal and external changes. Moreover, although touching upon many areas, these insights led to opportunities for further model enrichments that would analyze other aspects of the system not measured with the current model; examples such as storage requirements and more effective equipment setups.

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