Resource Scheduling in QC Laboratories

by Rafi Maslaton

This article presents the various aspects of scheduling in QC laboratories.

Introduction

Today's environment reflects a transition we have been observing for the past decade driven by external economic forces, patents expiration, dwindling pipeline of new drug candidates, and increased competition. Price controls are currently enforced throughout Europe, while, in the US, changes in the healthcare system are expected to reduce profitability and drive increased demand for lower cost products. Over the next five years, $92 billion worth of name-brand drugs will come off patent. The result: more emphasis on efficient drug manufacturing and R&D and greater recognition of the strategic importance of drug manufacturing. Wall Street expects to see companies better manage their expenses, and 2012 is focused on achieving operational excellence as a means to better compete against peers in light of these trends. The labs are a critical component of any drug manufacturing and can have a major impact on the overall supply chain service level, e.g., cycle time and on-time delivery. The importance of resource planning in QC labs to meet both capacity and compliance needs has been written about previously.[1] This article is focused on the scheduling aspect of QC labs; if we are forced to choose a key focus area for a QC labs performance, it will be lab **scheduling**. Scheduling by far contributes to all aspects of the lab operation efficiency and makes it the single most important process in the QC labs. Most of the labs today are using MS Excel based tools, whiteboard, and using LIMS to define the assignments, yet these are still primarily manual scheduling techniques or communication methods that are time consuming especially for the supervisors. Lean labs initiatives have helped simplify the lab scheduling process, yet do not offer a robust and computerized scheduling solution. At the end of the day,

lab scheduling heavily relies on the supervisor knowledge and experience to manage the schedule of his/her team. This article focuses on how to automate the scheduling process in the labs and provides guidance on how to better schedule the labs, and what the critical elements and considerations are for a computerized scheduling solution to enhance the overall lab performance.

Background – The Lab Environment

The following is a typical description of lab situations that could be magnified when it comes to generic or contract manufacturing (also in some of the brand labs), where there are more changes during the week (compared to typical brand labs), more products are manufactured, and less visibility or control on the incoming samples.

It is not uncommon to see a daily meeting with supply chain and the QC labs discussing priority and changes to the schedule that was updated only a few hours ago. The supply chain provides a list of samples that need to be released and asks the QC labs for committed dates. Then, the labs have to make changes in their schedule and assignments, reduce their campaign size, or avoid campaigning to accommodate the supply chain requests. When you have a backlog and every efficiency gain is crucial to remediate the situation, what has just happened is completely the opposite of what needs to have happened. These requested samples by the supply chain group, which does not always fully understand the implications of scheduling changes on the labs, leads to a smaller campaign size, hence reduced efficiency and changes in what the analysts are doing, leading to another loss of efficiency (waste of set up or some preparations that need to be scrapped); this makes the backlog even more severe than a couple of days ago. With overtime, more support, and allocation of resources within the labs we eventually end up reducing the backlog to a more manageable level.

In short, the supply chain group, which does not have the means to schedule the lab or understand the impact of schedule changes on the lab, is making the calls. The labs are under a lot of pressure and are forced to follow up on the demanding requests from the supply chain; the company server is overloaded with emails complaining about the labs and no one is raising the flag saying what we are doing is the opposite of what we should be doing.

What was described is actually the typical behavior of most companies during a backlog situation. This is one of the key reasons for companies to move toward a computerized scheduling solution compared with the schedule/priority list that changes by the time it is being distributed. Going back to our backlog situation, what both the supply chain and the QC labs should have done is actually increase campaign size knowing this will lead to slight delays in the delivery dates of some samples. However, it will increase the efficiency and allow the lab to catch up. The labs will increase their capacity as a result of increased campaign size, reduce the number of daily changes, and gradually will handle the backlog situation. This is not an intuitive strategy, yet it is the only one that could work in this type of situation. Of course there are exceptions and some samples should be prioritized, but the rule of thumb is not to exceed about 10% of the samples to be high priority/rush samples.

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Many of these issues could have been resolved with a robust computerized scheduling solution that will take into consideration all the aspects that affect both the labs' efficiency and the service level. One important note is related to resource planning: the planning aspect of the lab may have been poor and the labs were under staffed as a result to handle the requested volume, which brings us back to the
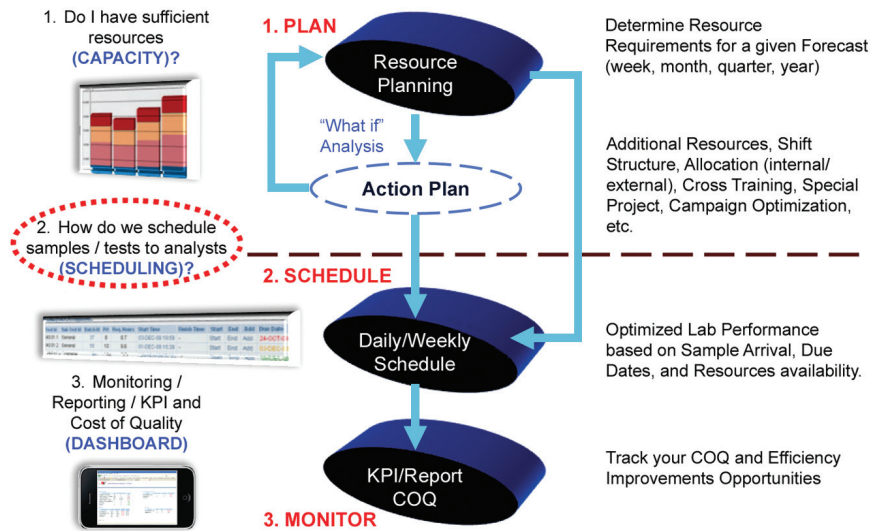

Figure 1. Managing labs operation: strategic level and daily operation.

importance of resource planning as discussed previously.[1] Not having sufficient resources to handle the incoming volume will put the labs in a backlog situation; poor scheduling will make this situation last longer and hinder the overall service level provided by the QC Labs.

Managing Labs Operation: Strategic and Day to Day Operation

Before diving into the scheduling process, let's first establish the overall strategic view and the role of planning scheduling and key performance indicators. QC resource modeling is one of three major steps in managing lab operations. As can be seen in Figure 1,[1] the first step is resource planning, which enables us to determine if we have sufficient number of analysts and equipment resources to meet customer/business demand. There may be short term gaps that could be managed via over-time, temporary work force, outside lab services; there may be more long term gaps that may require hiring and/or outsourcing to implement operational excellence improvements. Once we determine we have sufficient resources, we then move into the second step, the daily scheduling, which is our main topic for this article. This is the day to day lab operation scheduling effort performed primarily manually by the supervisor due to the lack of a computerized solution. In this step, the incoming samples/tests are scheduled to the various analysts based on their qualifications, proficiency, experience level, availability, due date, priority, etc. Unlike the first step of planning, which is the strategic level in managing the lab operations, this is the tactical level and requires a detailed and constant effort to schedule and maintain it. The last step is reports, Key Performance Indicators (KPI), dashboard, and overall monitoring of the lab performance. The common

component of all the steps is the data set required for the lab resource modeling that is the foundation for planning, scheduling, and reporting.

Scheduling Complexity in the Lab

While manufacturing needs to schedule a batch, we have to realize what a batch represents to the lab. One batch includes samples of raw material API and excipients that require 5 to 20 different tests, samples of In Process (IP) testing, Finish Product (FG) testing, and stability. Each sample, similar to a manufacturing batch, needs to go through several instruments and can only be performed by qualified analysts. However, each batch represents several samples and each sample represents several tests. To illustrate this, here is a simple example. We will use Little's Law to make the calculation. Little's Law is named after John D.C. Little, who proved it mathematically in 1961 that "The average number of customers in a system (over some interval) is equal to their average arrival rate, multiplied by their average time in the system." A corollary has been added: "The average time in the system is equal to the average time in queue plus the average time it takes to receive service."

Little's Law can be written as:

$$L = \lambda \cdot \omega \quad \text{or} \quad \omega = \frac{L}{\lambda}$$

Where:
- L = average inventory (tests in the lab);
- λ = Start rate (batches/FG samples per week);
- ω = Cycle time (weeks)

Also:
- L = average # in queue + average # in process

Let's take the Finish Product (FG) sample and let's assume there are 10 tests per sample, the lab cycle time is (ω) 14 days, and we have (λ) 50 batches per week (assuming one batch represents one sample). This means (based on Little's Law) on average there are (L = $\lambda \cdot \omega$) → (50 • 10) • (14 / 7) different tests/tasks that need to be scheduled and managed which is equal to 1,000 tasks (some of the tests may require multiple instruments, i.e., dissolution and HPLC which increases that complexity). In comparison, manufacturing cycle time, as an example, also will be 14 days and we have a solid dose process that includes pharmacy, granulation, compression, coating, and packaging (five areas), so the number of batches needed to be managed throughout the process will be (L = $\lambda \cdot \omega$) → (50) • (14 / 7) equal to 100 (10% of the volume compared with the lab). Now if we add the raw materials, the in-process and the stability samples and tests we are looking at 10 times the amount of activities that need to be managed and scheduled at the lab.

Now let's focus on the lab, with the exception of stabil-

ity, the lab has limited control over incoming samples, and the campaigning strategy of manufacturing may not always be aligned with the lab requirements, which leads to loss of efficiency. In addition, each analyst has a different training profile; we have 50 HPLCs vs. 5 to 6 compression suites, and the pressure in the lab is much higher because the lab is a downstream operation (closer to the end of the supply chain), and hence delaying the shipments. Next we should look at the breakdown of tests and the complexity associated with scheduling each one to the appropriate center of excellence, and to the proficient and available analysts. In short, lab scheduling complexity is significant and presents additional difficulties compared with manufacturing, especially in terms of the sheer volume of activities.

The Effect of Scheduling on QC Lab

Optimizing the schedule will help maximize campaigning, while ensuring service level is not negatively affected. This is a key focus area for the supply chain in order to avoid the service level focus leading to a reduction in the lab campaigning level, which could majorly contribute to a labs inefficiency. Optimizing the schedule will ensure assigning the samples/tests to the best available analysts who are the most efficient in this method. Optimized campaign level leads to efficiency improvement, which affects the overall lab costs and service level. Other key performance indicators that are directly influenced by the scheduling effectiveness are: cycle time and on-time delivery. Optimizing the schedule will ensure the right tests are started at the right time and all tests related to a given sample are completed at approximately the same time. Poor scheduling may lead to starting with the wrong test or missing a test and finding out only later on that this test was not started, at which point it is too late and the cycle time goal is missed. On-time delivery, similar to cycle time, is significantly affected by scheduling. While cycle time focuses on getting the samples completed within the allowable negotiated cycle time with the supply chain on average, on-time delivery ensures that the exceptions are being managed as well (e.g., expedite sample although it may meet its regular cycle time, but miss its due date). Finally, with optimized schedule, the overall organization can eliminate waste associated with numerous meetings, emails, and telephone calls to manage the incoming samples. This leads us to the next related aspect of scheduling, which is the automation or the computerizing of the actual scheduling process.

Why Automate

The schedule, as discussed earlier, has a major effect on several key performance indicators in QC labs. The schedule complexity can be greater than the manufacturing or packaging. Furthermore, in more dynamic labs, the priority and due dates are frequently changed and this directly affects the lab priority and schedule. Automating the lab schedule

Figure 2. Scheduling attributes.

makes sense when one considers all of the complexity, flexibility, and dynamics of the supply chain in addition to the time required to produce and change a schedule. Automating the schedule could result in freeing up more time for supervisors to manage investigations, conduct FMEA, lead root cause analyses, coach analysts, develop a training road map, analyze key performance indicators, identify areas for improvements, and communicate the lab schedule with the supply chain, etc. In a complex and dynamic lab, the scheduling process may consume two to three hours daily from each supervisor if it is done correctly, e.g., maximizing campaigning in general, identifying campaigning between finished goods and stability, and managing the on-going schedule changes. In order to automate the schedule, we need to assess what attributes are associated with the scheduling process that supervisors use during the scheduling process. Automating the schedule also will provide improvements in many of the key performance indicators as a by-product, as well as providing a more real time labs' dashboard that we can use to more accurately trace the progress on the samples/tests that are being scheduled and processed. Leveraging the scheduling algorithm can provide the supply chain with a cycle time projection for the samples in the labs, including when these are expected to be released.

Scheduling Attributes

In order to computerize the scheduling process in the lab, the various scheduling related attributes that should be considered must be identified. Based on the lab

goals and business environment, these attributes should be configured to meet these goals. For example, considering the qualifications of a resource (analyst) is a requirement, this should be aligned with the learning/training management system. Adding proficiency can enhance the assignments and provide the lab with the ability to determine which analyst will be preferred to receive a certain assignment vs. other analysts. This is currently performed by the supervisor based on his/her knowledge of his/her team. In order to computerize some of these preferences, we need to communicate this information to the scheduling algorithm. Due date and priority helps determine the order in which a given test should be performed. It is important to note that two tests with the same due date may need to be assigned differently since one test may have two days of analyst and instrument time vs. perhaps five days for another test. Looking at the due date alone will not provide the proper priority. This leads to the need to project the expected completion time of these tests and compare it to the due date. One of the key aspects of scheduling is to assign the longest test (critical path) first, including the instruments involved. This is intended to ensure the analysts start on the longest test before starting a short test. When few samples of different products have arrived to the lab and if these samples once campaigned have a long test in terms of analyst hands on time and instrument time, the overall schedule adherence will improve by starting these long tests first before moving on to others. (This is generalizing yet it provides the most likelihood scenario.) The chart in Figure 3 illustrates the approach of initiating the longest test (critical path) first and while the longest test is being processed in one of the instruments, other tests could start. Other attributes are listed in Figure 2 and include items such as workload balancing between the various lab teams to enable a more rapid execution of the tasks on
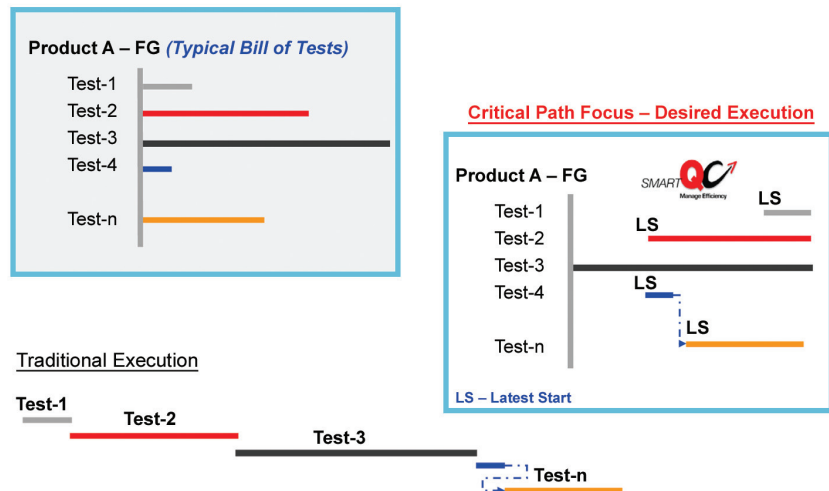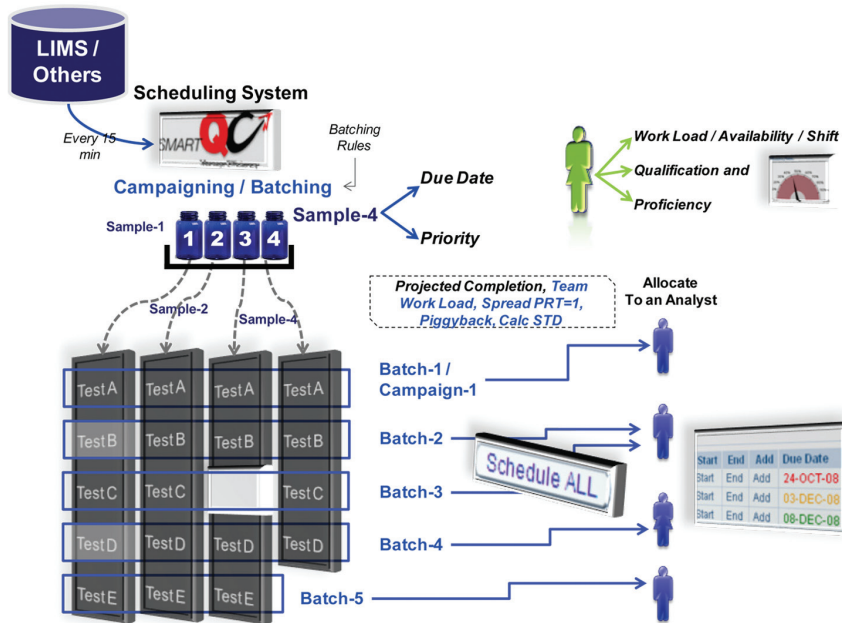

Figure 3. Critical path consideration.

Figure 4. Automated scheduling flow.

is not needed for Sample #2, etc. Once the algorithm establishes the batches and their related parameters, the scheduling process begins, and now a broader picture is looked at: the analyst workload, qualifications, and proficiency, and the actual structure of the labs is being considered, e.g., center of excellence, organized by value stream, cell approach. Assignments are determined by the software algorithm and provided to the analysts with various colors of criticality where red indicates lateness, yellow indicates close to being late, and green stands for ahead of schedule. This communicates to the analysts the order of importance of assignments for the business. Once we computerize the scheduling process, other attributes of the lab performance can be managed such as analyst/workcenter/team efficiency, more detailed cycle time assessment and root causes for delays, and as the critical ability to react to changes in the schedule by running the algorithm in one click. Once the algorithm is completed, each analyst will see the changes in their own dashboard and can react accordingly. This is one of the most challenging tasks to accomplish when using a manual whiteboard or simple communication as we need to update each affected analyst by the change.

hand. With a computerized scheduling system, we have the information on what tests are being performed and we can use this information to schedule additional tests that require the same set up to the analyst who has already started a similar test. Other attributes include analyst availability and shift hours that will ensure high priority tests should be scheduled to the current shift if sufficient time remains or to the upcoming shift so these high priority tasks can be executed on time.

The Scheduling Process

In order to illustrate what an automated schedule would look like, I have used one of the commercially available software solutions. The process starts with receiving samples and tests from Lab Information Management System (LIMS). Simple integration between LIMS and the scheduling system will prevent any redundant data entry. (Not all QC Labs are using LIMS; if no LIMS is used, samples could be entered directly to the scheduling system.) Then, these samples are first broken down to the individual tests. Each sample has a due date and priority. With a pre-defined set of batching/campaigning rules, the algorithm will combine the samples and the tests together considering parameters, such as due date and the priority, the probability for these test, to be completed on-time, and maximum campaign size (not to over campaign). In addition, with the projection completion algorithm, we can hold the scheduling process for other upcoming samples without risking a miss of the due date. As can be seen in Figure 4, Test A is common for all the four samples that arrived and are campaigned; however, Test C

In order to schedule this level of complexity, a robust computerized solution is required to minimize the time spent by the supervisors and provide the flexibility to react to schedule changes and optimize the overall lab performance in terms of cycle time, on-time delivery, and efficiency. 🙶

Summary

QC laboratories are one of the most complicated environments to schedule, especially in labs that have a high product mix and diversified products that are tested with large number of analysts and instruments. In order to schedule this level of complexity, a robust computerized solution

is required to minimize the time spent by the supervisors and provide the flexibility to react to schedule changes and optimize the overall lab performance in terms of cycle time, on-time delivery, and efficiency. Improving campaigning by leveraging a computerized solution can significantly reduce overtime and improve efficiency. These are key in reducing lab costs and provide a more reliable supply chain partner to the manufacturing. While having the right number of resources using a resource model is key in ensuring the lab ability to support incoming samples, the ability to effectively schedule the lab will help manage the daily and weekly fluctuations that are inherent in our current business conditions that call for low inventory and an agile supply chain.

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