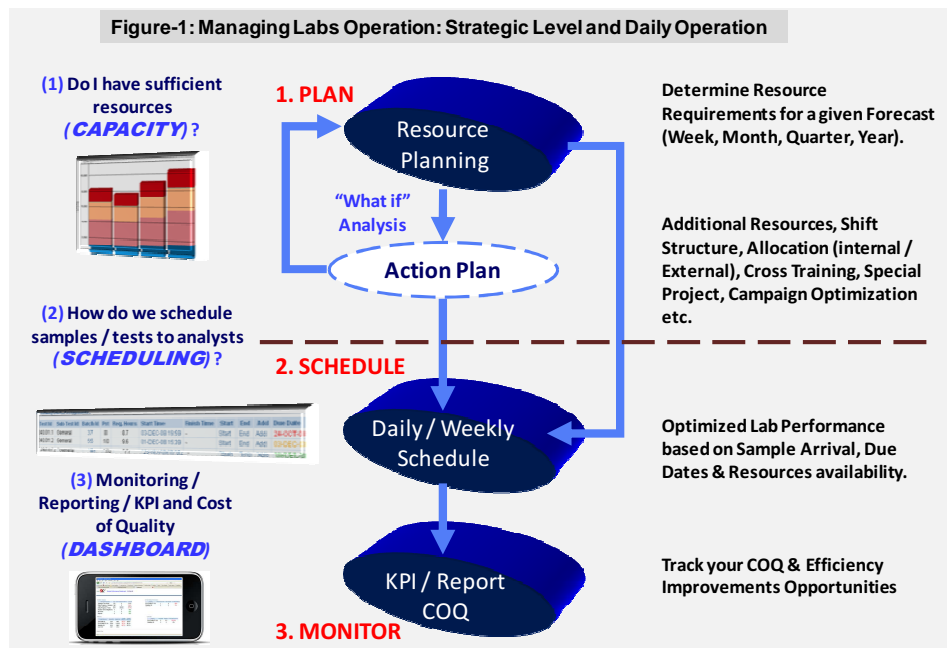


Resource Planning in QC Laboratories

By Rafi Maslaton, cResults

Introduction: Every year when budget time comes, the pressure rises to cut costs, cut spending, reduce staffing levels, yet improvements in service level and throughput are expected. Lean and Six Sigma in some cases fall short when it comes to the QC labs mainly due to its complexity. The savings we see in packaging and manufacturing could not be matched by the quality operation which increases the pressure even further. The biggest single expense item in QC is LABOR (the analysts / chemists) who are relatively high paid work force, therefore you would expect to find in QC the most advanced resource modeling tool to project the expected number of people needed in the lab to support the business based on a given forecast. Scheduling for QC labs can be quite complex; both standards development and translation of the commercial and especially non-commercial forecast into QC samples. Furthermore, with the increased pressure on sites/labs consolidation, space also becomes a constraint, i.e. space for instrumentation, flows, etc. Despite the importance of the above, the modeling capabilities in the lab are very limited or non-existent. We often find that the budget is based on the senior manager’s experience, estimates, using a factor of let’s say 10% more than last year and occasionally the use of MS Excel, but not based on verified data driven models. This article is focused on the methodology and approach to build resources modeling including both analysts and instruments in the QC labs. The proven approach and methodology for laboratories modeling described in this article is based on resource planning and scheduling software solution. **One of the top three Pharmaceutical, one of three top Bio-tech and one of the top three Generic industries have embraced this methodology for their QC Laboratories planning and scheduling. This article contains examples of actual case studies and projects that we have successfully completed.** One thing we all need to agree is that, one of the key reasons why QC laboratories do not have advanced modeling tools is the complexity in both standards development and translation of the commercial and especially non commercial forecast into QC demands. This is mainly an issue for raw materials and new products introductions (NPI) that are usually not well defined when it comes to QC, hence harder to project in terms of labor and instrument requirements. **In addition to the operational significant of having an accurate resource modeling and the financial aspects, resource modeling could become a major compliance risk; In case of underestimating the required QC resources, a significant pressure could be applied on the QC personnel to get a timely release; that can lead to excessive overtime, weekend, which then, leads to human errors and a major compliance risk (1).**

Resource Planning: Instrument and Analyst in QC Laboratories: QC resource modeling is one of 3 major steps in managing lab operations. Before diving in to the detailed approach for modeling let’s look at these 3 key steps. As can be seen in figure-1, the



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first step is resource planning, this step our main topic, allows us to determine if we have sufficient resources for both analysts and equipments to meet customer / business demands. There may be short term gaps that could be managed via over time, temporary work force, outside labs services and there may be more long term gaps that may require in addition to implement operational excellence improvements, hiring, or/and outsourcing. Once we determine we have sufficient resources, we then move into the second step, the daily scheduling. This is the day to day lab operation scheduling effort performed primarily by the supervisor with lack of 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 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 to all steps is the data set required for the lab resource modeling that is the foundation for planning, scheduling and reporting. **Important to mention that this planning step (step – 1) presents even greater opportunities when dealing with multiple labs across multiple geography; being able to distribute some of the samples (i.e., Stability) to other labs within the network to optimize the overall company supply chain and meet customers' (internal/external) demands.**

How to Model the Lab Resource: Let's now focus on the strategic level of the lab's operation, the resource planning: the first step resource modeling. The key in modeling QC environment is simplifying the labs complexity while maintaining the desired level of accuracy. Also critical is how to avoid falling into the trap of collecting data for 12 months via time studies and other time consuming techniques that usually do not lead to the expected results. The main area in terms of simplification is the standards collection, and often we see throughout the industry that companies are making a huge investment in

performing time studies and having few internal/external consultants running around with a stop watch collecting data. This, without few initial steps as will be detailed below, leads to a major waste of effort and usually does not result in meaningful standards as expected.

In order to effectively collect standards for the lab which are the foundation for resource modeling we will need to start with the following key tables / spreadsheets:

Product List	Includes list of ALL active products, their material/product code and their description. This list could be obtained from LIMS/ERP. In some cases QC may use a different product ID, yet it is critical to link between the ERP and the resource modeling to be able to translate the sales forecast into samples arrival.
Tests List	List of all tests performed in the Lab usually obtained from LIMS.
Product Test	Product Test: This table creates the relation between the product and its associated tests. This table needs to include the stage of the product, which defines the form in which this product arrives to the Lab i.e., In Process, Finish Good, Stability. Each of these forms has different tests and stability has a different forecast as well.
Standard Groups	This is one of the key pieces in the approach to simplify the data collection approach. Instead of collecting standard for each test, we define test group that indicates the Hands On Time (HOT) is similar/same for a given method. For example, we have numerous HPLC tests yet many of them require the same level of effort in terms of sample preparation, setting up the instrument, analyzing the results and performing the audit/document review, hence there is no need to have dozens standards for each test, we could develop few test groups and associate tests to these groups. This is KEY in simplification of the data collection effort since it reduces the number of standards needed by 60-80%. Furthermore, in case of using actual time studies to obtain data, it provides a much larger option to collect data by GROUP vs. by each individual test. So we do not need to see ALL the tests for a given product several times which may take a long time to receive all multiple samples of the same product. Instead, we can observe the HPLC for product A and GC for product B and Physical testing of product C if these are using the same test group for each method.

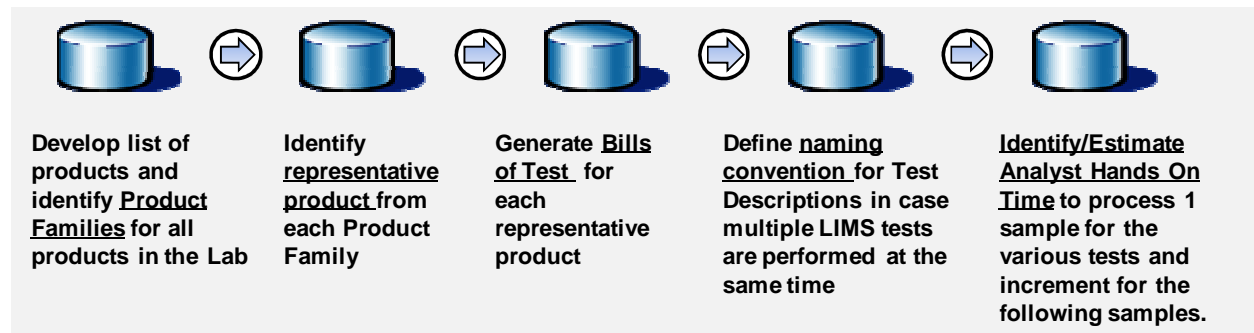
Companies that follow the process described in this article to obtain the data in this table, managed to collect the required information effectively and in a timely manner.

Here are some of the key steps to initiate this process of data collection:

A. Develop list of products / raw materials and identify **Product / Material Families** for all products in the Lab (LIMS / ERP should be the source)

- B. Identify **representative Product / Material** from each Product Family
- C. Generate **Bills of Test** for each representative product / material
- D. Define **naming convention** for Test Descriptions in case multiple LIMS tests are performed at the same time (could be consolidated and renamed)
- E. Identify/**Estimate Analyst Hands On Time (HOT)** to process one sample for the various tests and increment HOT for the following samples.

Figure-2: Data Collection Approach



This section outlines the detailed methodology for the data collection.

A. Identify Product Families for all products in the Lab

1. Develop a product / material list (*LIMS / ERP should be the source*)
2. Define potential product / material families based on similarities in testing, product / material name & strength, etc.
3. Identify a product / material family for each product / material in the product / material list.

B. Identify representative product from each Product Family

(this is to simplify the overall data collection process)

1. Review list of products / materials in each family for similarities and differences in products in terms of testing
2. Identify **one product / material** that has most of the tests performed for all products / materials in that family to be the representative of the family

C. Define naming convention for Test Descriptions

1. Identify test descriptions that will provide adequate information on the type of test to the analysts when review the developed standards:
 - Dissolution-UV and Dissolution-HPLC versus Dissolution only
 - Assay-HPLC and Assay-UPLC versus Assay only

- Identification A, Identification B, Identification C versus Identification only (*e.g. same product may have multiple ID tests*)
 - Assay & Description versus Assay only if it is preferred to perform both tests together by the same analyst. (*Revised Test Description for Combined Tests column is used to identify these.*)
2. Similar examples can exist for Assay & CU, Assay/Degradant, and Assay/Impurity.

D. Generate Bills of Test for each representative product

1. Using the representative product / material identified for each family, the laboratory product / material test spec, and the test naming rules defined in step C, generates the **Product / material-Test relationships**. (*LIMS to be the source if available*)
2. Include and mark the tests performed for Release/Finished Product samples
3. Include and mark the tests performed for stability samples
4. Include and mark the tests performed for in process samples
5. Include and mark tests performed for full raw material testing vs. reduced testing

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E. Identify/Estimate Analyst Hands On Time to process 1 sample for the various tests

- For each type of test identify/estimate the total **hands on time** required by analyst to **(1) prepare the sample, (2) set-up the instrument, (3) monitor/operate the instrument run, (4) perform post-run analysis and calculations, and (5) audit the results** if applicable for a one sample run (see table-1)
- The time should include only the **Hands On Time** spent by the analyst and exclude instrument time.

E.g. HPLC may run for 10 hours but the analyst may only be monitoring/checking the run hands on for 30 minutes during that time.

- For each of these test add the increment time required to test additional samples (i.e., ONE Test would take 6 hours to perform ALL the HOT and any additional sample with the same test / method added would take an additional 1hour vs. the 6 hours)

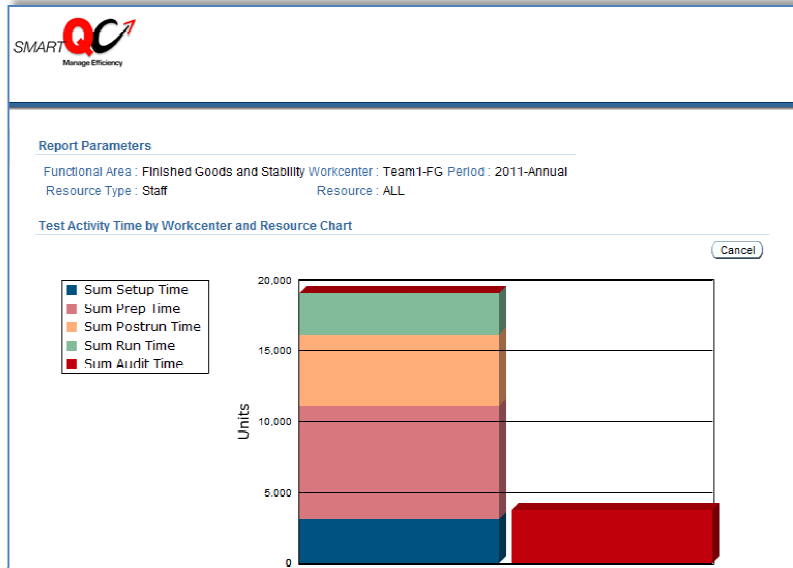
The following (Table-1) examples are suggested definitions for the various key steps in performing a test:

Table-1: Sample Components

Sample Prep	Activities associated with the preparation of test related samples:
	<ul style="list-style-type: none"> • Dissolution, dilution, extraction, or other processing required by the test method on the samples • Setting up the lab bench / workspace • Media preparation, reagent preparation, buffer preparation • Mobile phase preparation & Standard preparation • Labeling samples • Documentation and LIMS / Other system
	Activities associated with the set up of the test instrument:
	<ul style="list-style-type: none"> • Conditioning or setup of instruments prior starting a test • Locate, retrieve or prepare required testing resources (e.g. specs, notebooks, Logbooks, HPLC column etc) • Retrieve samples, pre-made standards, buffers, reagents, media • Documentation / LIMS / Other system logging related samples or test resources
	Run
	<ul style="list-style-type: none"> • Watch titration process until end-point is reached • PH meter is applied measure the PH reading of a sample • Taking a sample plate instrument reading • Watching the standards through the beginning of a HPLC run etc • Documentation during test method (Data Recording) • Required monitoring / observation time
Post Run	Activities associated with the conclusion of the test run related to recording / processing analysis of results data:
	<ul style="list-style-type: none"> • Data related activities after run completion (transfer, logging, trending, etc.) • Data analysis, Calculations & spreadsheets • Results interpretation, reports & documentations, LIMS entry • Laboratory notebook, Archiving original data • Cleaning the instrument and workspace used
	Audit
	Activities associated with the review of test results:
	<ul style="list-style-type: none"> • Including reviewing test, peer review, paperwork and LIMS / Other system approval

Each of the above categories are further broken down to **first sample** and **Incremental** (for each additional sample) components, to enable campaigning analysis.

Figure-3: Sample Components Breakdown – as can be seen in Figure-3, we have over 8,000 hours yearly for Team-1 alone that accounts for 35% of the overall work load to perform sample preparation activities. Improvement initiatives in this area could have a major return.



vacation, training, meetings, holidays, sick days, etc. and also we have activities (NON TEST) such as Data Monitoring/Trending, Document Creation/Revisions, Equipment Qualification, General Cleaning, Glassware, GMP Checks, Instrument Calibration Verification, Instrument Troubleshooting, Investigations, Method Transfer, Method Validation, Special Projects and more. It is important to note that the above activities typically consume on average 30% of the analyst time. So for example if we need for testing 42 analyst to complete all the required testing in

The same approach is applicable for modeling instruments capacity as well. This would involve grouping by instrument type / runtime and data collection for the first sample and the increment (i.e., Injection time) for additional samples. Instruments up time (Excludes calibration, Preventive and Corrective maintenance) will be collected as well. Although our main focus throughout the article was the analysts, it is not uncommon that instruments can become a lab constraint for reason such as limited space, cost. Other key information for the Lab modeling is the analyst activities outside the bench work. It is a common challenge to communicate the activities that are not directly tests in the lab. We will use the term NON-TEST activities and Resource unavailable time for these activities throughout the article. In other words, we have unavailable time due to

the lab, we need to hire 60 people when accounting for the NON TEST and unavailable time (42 / 70% = 60). Hence, it is critical to have detailed list of activities, identify their frequency, the number of hours required per event and to aggregate these to the percent of total analyst time.

For example:

- Assuming we have 2 weeks of shutdown
- 2 weeks are going toward vacation; 2 week toward GMP/EHS training, meetings, SOP, 1 week for holidays, 1 week for personal days etc. and
- On average 6 weeks are spent toward NON-Test categories (i.e., calibration, method transfer, investigation)
- Then, in this case, we get excluding breaks/lunches the following available hours per year:

52 (Weeks per year) *37.5 (7.5 hours per day excluding breaks * 5 days per week etc.) – 14 (Weeks per year that analyst is unavailable for testing)*37.5 = 1,425 hours per year out of 1,950 potential hours which represents ~ **73% availability for bench work (Testing)**

Once all the data collection effort is completed, the QC team should use historical data to verify the model results. For example we can use the past 3-6

months of samples processed in the lab. These samples will be input to the model as FORECAST and running the calculation on these samples will

provide the required number of analysts / instruments for that period. If this number reflects the AS IS incorporating the overtime, vacations etc. that should be added/subtracted, then we have managed to model the AS IS, if the number is too high we were too generous in the standards / or double counted certain activities and it will need to be reviewed/investigated. The other extreme could be in the same way we projected 40 analyst that were needed for the last 3-6 months, yet we have 80 in the lab, so this means we were perhaps too aggressive or we missed some of the activities that are performed in the lab. Once we establish within +/-10% that the model reflects the AS IS, this could be our baseline for the lab model. As mentioned at the beginning, if the lab would like to perform a time study, once the grouping is completed and the forecast is entered, then time study could focus on the biggest hits, the highest contributing tests to the overall staffing / instrument requirements. Without these steps listed before, any time study may be focused on insignificant test methods and the value as a result will be limited.

When we look at the complexity and the significant effort required for building a resource model tool we may ask ourselves what are the benefits from such a model other than telling us the number of analysts and instruments we need. Although it is important enough as it stands by itself, there are many other benefits that are part of this effort and help identify opportunities for improvements and help refine some of the operating model we have accustomed to use:

- Identify tests methods that contribute most of the HOT / FTE and work on improving these.
- Identify desired campaign size method / product and work with the supply chain and manufacturing on alignment / synergy to improve the lab efficiency. (for example allow the lab to hold a sample for 3 days before starting with the testing so other samples could arrive to enhance the campaign size.)
- Establish campaign size target for the analyst based on the data collected. (Figure-4)
- Project work load for a given period and re-prioritize projects / initiatives

in the lab to meet the desired service level for the expected demand.

- Leverage the collected standards for scheduling, costing and efficiency calculation.
- Identify ROI for projects leveraging the standards that were collected as part of the resource modeling.
- Define training road map based on Hands On Time (HOT) requirements for each method.
- Limit vacations during a specific period where demand exceeds capacity.
- In case of multiple sites, the application of resource modeling could branch into lab consolidation (i.e., centralized stability), enhanced redundancies and more, yet it requires the relevant and accurate information to make these significant decisions.

These are some examples where detailed resource model can be used and adds significant value to the QC laboratories and easily justify the level of effort required to establish such a model. Needless to say that any costing analysis, scheduling tool, and operational excellence initiative will need the same data as the resource modeling does. This is the foundation for any improvement program that involves the laboratories operation and should be carefully and methodically performed.

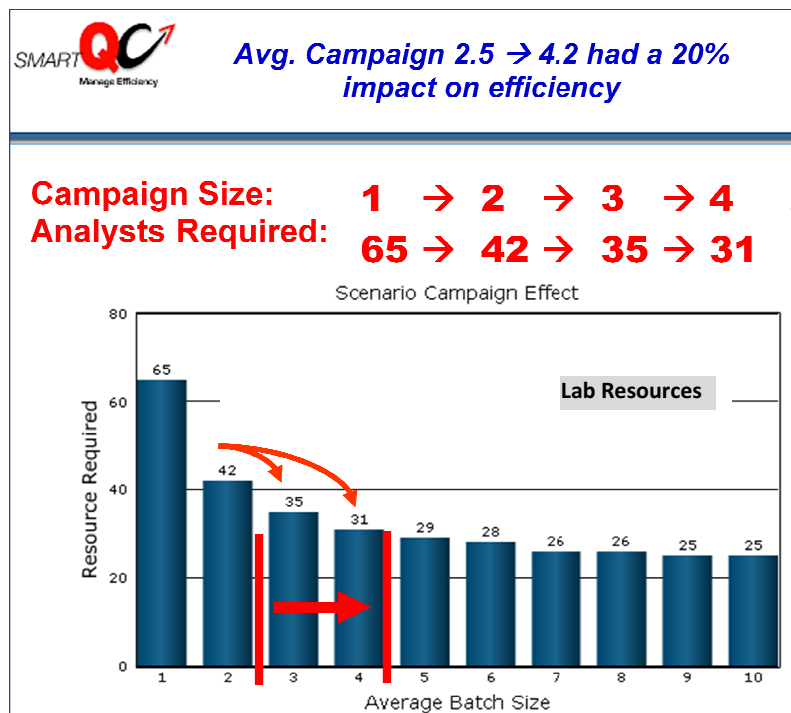
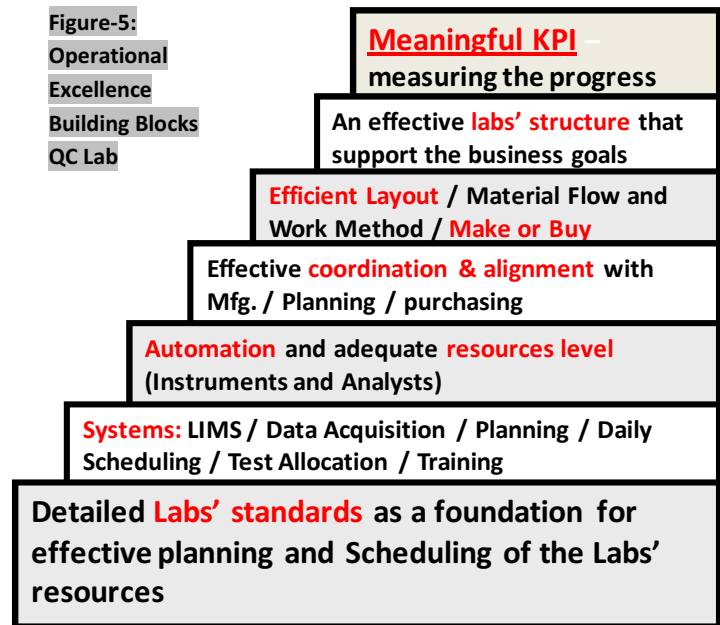


Figure-4: Campaigning effect: Describes the affect of campaigning (batching) on overall resource requirements. In case of testing one sample at the time, the required resources will be 65 to accommodate the overall work required while campaigning 3 samples at the time could drop the overall resource level to 35 analysts.

Now we know how to model the QC lab resources and when reviewing the key building blocks (Figure-5 (2)) of QC operational excellence, we could clearly see the important of resource modeling effort. From the top bottom, the essential piece of meaningful Key Performance Indicators (KPI) is good standards, in order to determine the lab structure we need to know the staffing requirements by function, by value stream, by team, by technology, by center of excellence; Furthermore, key output of a resource model that could affect our lab structure is the ability to match the current Lab's personnel skill set (qualifications) vs. future needs. We may have the right number of analysts yet we may not have them qualified on the right methods / techniques. The modeling tool can outlines the required analysts by methods and we could compare these results to the current lab skill set and establish a road map for training to close the identified gaps. Make or buy decision should be based on factual data in case there is an alternative to test in house vs. using outside lab services. Coordination with planning should be based on modeled capabilities vs. opinion as it affects lab's service level as on-time delivery and turnaround time; these KPI are highly affected by having the right size lab in terms of analysts and instruments; automation decision should be once again based on factual data that will help determining the Return of Investment (ROI) of these projects. Any scheduling system will require the lab standards that are the foundation for effective planning model.

Summary: QC Laboratories are one of the most complicated environments to model especially in labs that have high product mix, diversified products that are tested with large number of analysts and instruments. In order to manage that complexity, a robust approach is required to simplify the lab complexity and also minimize the level of effort while maintaining accuracy of the model's inputs so



decisions can be made based on that analysis. Resource analysis should be done on a regular basis i.e., every month, quarter based on the dynamics of the forecast. At this point, the Lab should determine if there is a major change in required analysts or whether the incoming demand can be managed with the current resources. The criticality of modeling tool in today's economy is high since we are trying to balance between cost and service level. Not having the correct information could lead to the wrong decision affecting either the cost of quality or if we did not hire sufficient resources, the service level, and potential delays to launch new products as it takes several months to hire and train new analysts or to purchase, install and validate new instruments. **The last key driver for having resource modeling tool comes from an unexpected are that is compliance; lack of adequate resources due to poor planning, could lead to increase in employees' stress, increase in overtime and eventually lead to human errors and compliance risk.**

About the Author: Mr. Rafi Maslaton, President, cResults an IPS affiliate, has over 19 years of diversified experience in operations, manufacturing engineering, information systems, and business management issues for fortune 500 firms. Prior to joining cResults, he served as COO of Sparta Systems, the maker of TrackWise, overseeing the complete project life cycle for clients. Rafi has managed operational excellence projects for over 100 QC Laboratories, and work with Fortune 500 clients such as: Abbott, Amgen, Baxter, Bausch and Lomb, Bayer, Centocor/OBI, C.R. Bard, Eli Lilly, Fort Dodge, Genentech, J&J, Merck, Novartis, Par, Pfizer, Pharmacia, Roche, Sandoz, Shire, Schering-Plough, Teva and Wyeth, Agere Systems, HADCO, IBM, Intel, Lucent, Motorola, Nortel Network, Philips, Raytheon, and Siemens. Mr. Maslaton developed the first resource planning, scheduling and cost of quality software for the QC laboratories Smart-QC and the first Batch Record and Efficiency Management software solution for QA cME. rmaslaton@cresultsconsulting.com



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