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Capacity Planning

In laboratories a significant cost is often incurred due to a mismatch between workload demand and actual capacity.

BSM's structured approach to Capacity Planning addresses and consistently alleviates this mismatch, ensuring efficient and productive management of laboratory resources.

BSM

Capacity Planning

Pharmaceutical production is inherently volatile, with respect to volume of batches produced, the mix of products and the associated testing. Quality Control laboratories are frequently expected to increase productivity to meet demand, whilst being tasked with improving quality and reducing lead times. Therefore, a laboratory's ability to prioritize, work efficiently and react to changes is imperative to its success.

Through the implementation of ‘Real Lean’ techniques, specifically workload leveling, flow and standard work, a lab may recoup up to 30% of its capacity from existing staff and equipment (see blog titled ‘Use Real Lean As Your First Step To Release Capacity’ at https://bsm.ie/blog). However, best practice Lean solutions will still be subject to ongoing volatility if/when future production changes significantly. A genuinely Lean Lab must have a defined process for analyzing forecasted demand and translating it into capacity requirements.

Using a custom built BSM Capacity Planning Tool (CPT), advance notice of ‘pain points’ (capacity shortfalls) can be identified, allowing sufficient time to take remedial action. Similarly, upcoming opportunities (unused capacity) can also be flagged and leveraged.

This briefing will describe BSM’s approach to designing a lab-specific CPT, from gathering comprehensive inputs to valuable insightful outputs.

What we often find in labs

The cost incurred by having a poor understanding of your demand/capacity relationship.

Most QC labs receive samples with a high degree of variability and complexity. This can make accurately calculating capacity a difficult task. Labs often have varying degrees of understanding of lab capacity but rarely a process in place that periodically analyzes upcoming demand and the resulting impact on the lab.

1. Unavoidable volatility

The incoming workload of QC labs is innately volatile with significant peaks and dips in volume (see Figure 1). Little can be done to ease this as pharmaceutical manufacturing is driven by factors such as market fluctuations, pandemic spikes and campaigning. In addition, the mix of products will inevitably change as new drugs are developed/ discontinued. The testing requirements and test 'hands on time' of the samples are also subject to change as testing methods and regulatory requirements evolve. This volatility is unavoidable and can result in poor productivity (during dips) and poor lead time performance (during peaks). Analyzing capacity as a 'snapshot' in time quickly becomes outdated and unusable. Creating a dynamic capacity planning tool, linked to the genuine upcoming demands of the business is the most effective way to capture the resource requirements of a lab.

2. Little visibility of upcoming production demands

There is often a disconnection between supply chain planning and QC labs resulting in the lab having little visibility into upcoming demand. Significant changes in production volume will directly impact a lab and if demand exceeds capacity, the lab will fall behind. Often, this crisis is only identified when KPI's (Key Performance Indicators) begin to decline, at which point the recovery actions will prove arduous and costly. The fire-fighting that ensues is expensive as the lab scrambles to add extra shifts, hire part-time analysts or, even worse, deliver late. The alternative scenario, demand far below the lab capacity, is equally as costly. A lull in production will result in poor productivity and missed opportunities to initiate training, projects or return outsourced testing (see Figure 1).

3. Little understanding of how production outputs translate into lab capacity requirements

Where forecasts are accessible, the full impact of fluctuations in production volume and mix, on the lab, is often poorly understood. For example, a 10% increase in production volume is not necessarily equivalent to a 10% increase in lab workload. Despite having visibility on demand, the lab may not have the information e.g. reliable standard work, optimally modeled test run sizes etc., nor the tools required to convert batches into the various elements of lab capacity.

4. Reacting to a mismatch in demand and capacity with the wrong solution

Due to the lack of an effective process and tool, the true capacity constraints of a lab can often be hidden. This results in even further costs for the lab as the most appropriate solution may be overlooked. For example: the lab's 'on-time delivery' metric has started to decline and they are at risk of releasing samples late. The obvious solution is to add headcount and/or overtime or extra shifts. However, multiple capacity constraints could be the cause of the backlog but not immediately apparent. Perhaps the volume and/or mix has changed so that the testing profile:

a) Includes more tests that are poorly covered in terms of cross-training i.e. there is a sufficient complement of personnel but training levels on the newly critical/ bottleneck tests are low.

b) Includes more tests with arduous reviews i.e. there is an adequate number of testing analysts but not enough individuals trained and assigned to review workload.

c) Includes increased demand on certain instruments i.e. there is sufficient human resourcing but a shortfall with regards to equipment availability.

d) Includes more tests that have high failure/re-test rates i.e. there is no deficit with respect to staffing and equipment but Right First Time (RFT) rates are causing a release delay.

Each of these bottlenecks require a very different solution and mis-identifying the problem can be an expensive mistake.

The BSM Capacity Planning Tool allows the lab to align demand and capacity in advance, avoiding the above dilemma. It provides the lab with the ability to make data-driven decisions and address the actual capacity limitations before they become a constraint. It also gives advance notice of upcoming opportunities and provides sufficient time to leverage that opportunity (see Figure 1).

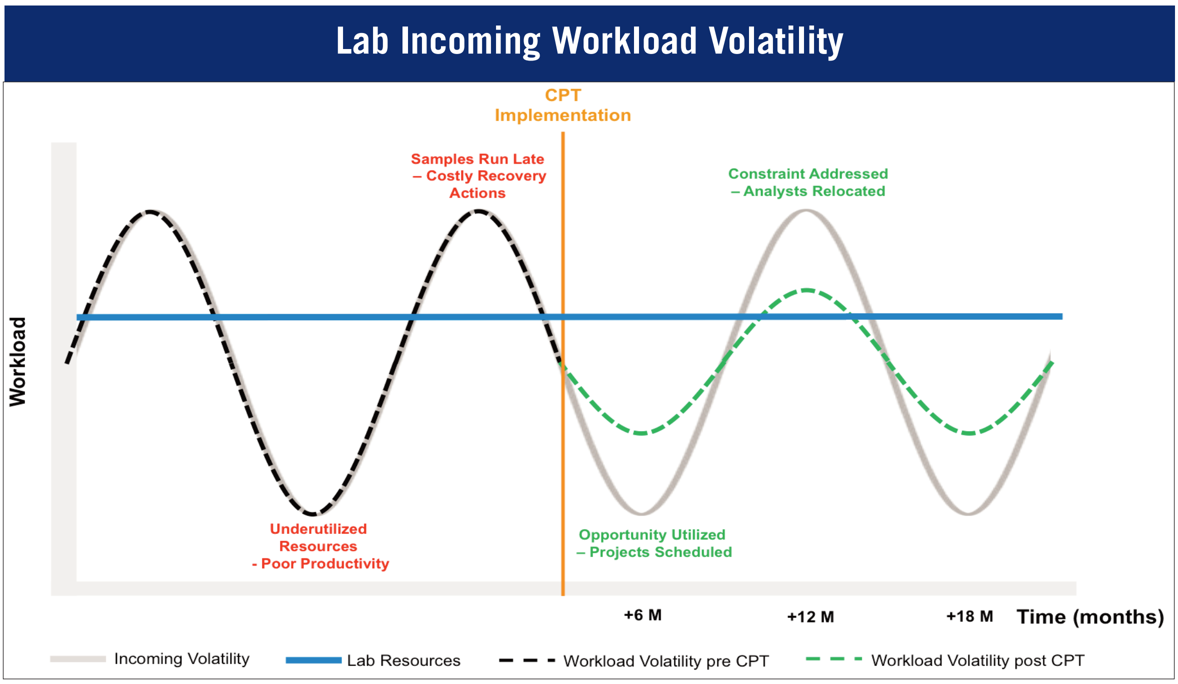

Figure 1: Lab Workload Volatility before and after CPT implementation.

This graph represents a labs volatile incoming workload over time (grey line) and the level of resourcing (blue line). Pre CPT implementation the lab is reacting to the volatility resulting in poor productivity during workload dips and samples running late during workload peaks (black dashed line). Post CPT implementation the workload (green dashed line) dip is lessened (projects are scheduled) and workload peaks are addressed (analysts relocated to assist).

Capacity Planning Tool – Inputs

Every lab is different with a unique combination of tests, equipment, resources, sample types, lead-time requirements, workload volume and volatility. BSM gathers comprehensive CPT inputs, based on the key principles of Lean and creates outputs tailored to the specific needs of the lab. The general principles are detailed below.

1. People

Availability and Competences

Frequent management of lab resourcing levels is required to ensure the unit is sufficiently staffed for periods of peak demand. Staff must also be adequately trained to cover all necessary testing, ensuring a flexibility of workforce and enabling a swift exchange of resources if required. In short, to determine overall available capacity, management would ideally track and have a detailed knowledge of (see Figure 2a):

- Availability: How many available FTE's does the lab have? Factors such as training, meetings, holidays, extended leave etc. should all be accounted for.
- Role: How many FTE's are involved in testing vs support functions?
- Competence: What is the cross-training coverage on all of the most critical tests and where do key vulnerabilities lie?

Often, little thought is given to cross-training and resources can be dedicated to particular tests or sample types. If the volume of samples for their designated test is volatile, this will be directly imported into their daily workload, resulting in a productivity loss. Considering the group as a whole, individual analysts may be overloaded whilst others are underutilized, resulting in overall poor group productivity (see blog titled 'The Trouble with Dedicated Resources: Leveling the Workload' https://bsm.ie/blog). BSM design and implement aggressive cross-training plans based on appropriate coverage for all critical testing avoiding these productivity pitfalls.

NET AVAIL FTE'S	x	AVAIL HOURS PER MONTH	=	AVAIL CAPACITY (AVAIL FTE HOURS)

Figure 2a: Capacity Tool Calculations – Available Capacity.

2. Testing and Efficiency

Product-Test Table

Labs perform a variety of tests for multiple demand channels. The Product-Test Table acts as the 'engine' of the CPT and is the master list of all testing required for each product and sample type. In order to translate the forecasted demand into workload one also needs to determine the following:

- Test method standard work
- Optimum test session sizes
- Instrument capabilities and utilization

The accuracy of the CPT outputs and a lab's ability to effectively execute future workloads is dependent on the accuracy of these key Lean inputs (see Figure 2b).

Standard Work

Gathering timing information is notoriously difficult in labs and requires a sensitive and systematic approach. Standard work is a key Lean principle which aims to define the ideal work sequence in order to decrease variability in task performance, reduce errors and ultimately establish the ideal testing times. BSM have developed a method of collecting standard work that is accurate and easily adaptable should batch sizes change. The method involves mapping the combination and sequencing of tasks based on analysts that are good time task managers, thereby creating the 'standard' for each test method. For further details, see blog titled 'Time Studies, Work Measurements and Standards – How Not to Alienate You Team' https://bsm.ie/blog,

Optimized Test Sessions

In many labs, samples are simply tested in order of arrival to the lab. This imports production volatility directly into lab operations, allowing the daily workload and mix of samples to vary. Unsurprisingly, if this happens, the number of samples in individual test runs will also vary. This lack of 'standard run sizes' allows fluctuations in testing session times potentially impacting lead-time and productivity performance. Even where samples are not immediately tested, the number of samples that accumulate can vary to a large degree, often times depending on how comfortable the analyst/lab is with 'holding' samples. Best Lean practice creates data-driven rules in which samples are tested at the levelled demand (the rate at which the samples need to be tested to meet customer requirements) in as few testing sessions as possible. BSM uses standard work and historical data to determine the optimum test session sizes to meet the levelled demand within the defined lead time. This avoids sub-optimal test sessions, maximizes productivity and results in on-time delivery to the customer.

FORECAST PRODUCT VOLUME > PROJECT TEST TABLE > SAMPLE VOLUME BY TEST X STANDARD TIMES = ROUTINE TEST WORKLOAD (REQD FTE HOURS)

Figure 2b: Capacity Tool Calculations – Determine Routine Testing Workload.

Equipment (and Consumables)

Asset utilization monitoring delivers significant Lean benefits. It ensures that a lab possesses the correct number of each piece of equipment as defined by the forecasted demand of testing sessions.

BSM's CPT provides labs with knowledge of how instruments are used throughout the laboratory and can significantly help labs optimize operations and drive cost savings.

3. Demand

Workload Categories

Capturing demand can involve numerous inputs from many sources (see Figure 2c). BSM consolidates all important sources of workload for the lab including:

- Routine Testing e.g. in-process, release, stability, raw materials and environmental testing
- Non Test Tasks e.g. meetings, 5S activates, media preparation
- Project Test Workload e.g. additional non-routine samples for testing, validation lot testing
- Project Non-Test Workload e.g. CAPAs, Transfers etc.

Often production and stability based inputs involve a simple transpose of data from validated systems (e.g. LIMS systems or SAP) into the CPT. Other data, not managed in such systems require manual entry into the CPT e.g. project workload and test error rates and are updated when necessary.

While production forecasts can be somewhat unreliable, the CPT has an accuracy function that monitors the ongoing %Error between predicted and received batches.

ROUTINE TEST WORKLOAD + PROJECT TEST WORKLOAD + ROUTINE NON TEST TASK WORKLOAD + NON TEST PROJECT WORKLOAD = TOTAL WORKLOAD (REQD FTE HOURS)

Figure 2c: Capacity Tool Calculations – Demand Categories.

Capacity Planning Tool – Output Analysis

The outputs of the CPT are tailored to the specific needs of the lab and can be readily amended if and when priorities change. There are typically two variations of each chart, one looking at the short-medium term future (e.g. 0-6 months) that is routinely used and one detailing the capacity requirements for a longer term (e.g. 12-18 months) that is intended to predict the long-term resourcing requirements and support the annual budget process.

1. People

Projected Utilization

Using the forecasted workload of the lab, the CPT calculates the percentage utilization of current analysts (see Figure 2d).

By setting a utilization target, usually 80-85%, the lab can assess if monthly demand will exceed current staffing levels and make pro-active decisions before the constraint impacts the labs timely delivery of samples. Potential excess resources (where capacity exceeds demand) may also be identified allowing sufficient time to take advantage of the opportunity to reassign/redeploy some individuals to activities other than routine testing (see Figure 3a). Various iterations of this chart can be produced which display the staffing requirements based on individual labs, workload category etc.

TOTAL WORKLOAD (REQD FTE HOURS) / **AVAIL CAPACITY (AVAIL FTE HOURS)** = **PROJECTED CAPACITY UTILIZATION %**

Figure 2d: Capacity Tool Calculations - Projected Utilization.

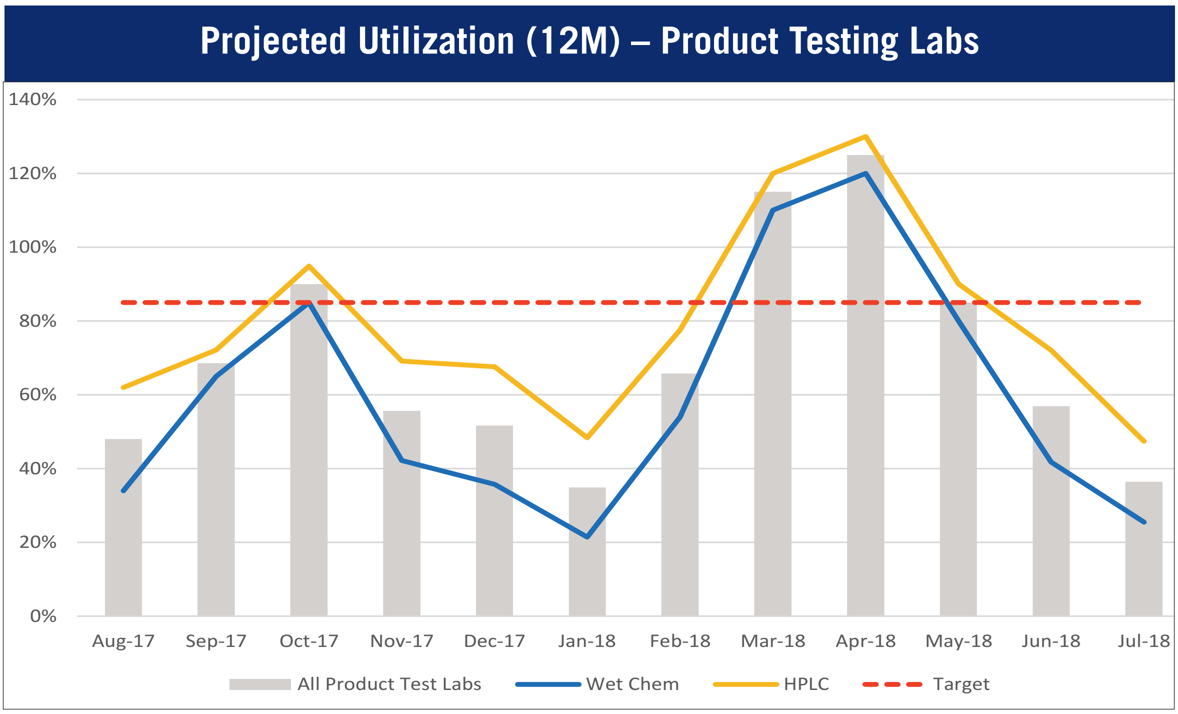

Figure 3a: Projected Utilization Graph.

The graph represents the forecasted utilization for all labs (grey bars). Also shown is the utilization for only the Wet Chem team (blue line) and HPLC team (yellow line). The target in this example is set at 85% (red dashed line). November to February represents a period where capacity exceeds demand (an opportunity), while March and April highlight a period where demand exceeds capacity (a constraint).

Cross-Training Coverage

As the testing profile of the lab changes over time so too will the most critical and most common test methods. The CPT will flag tests where coverage is insufficient, allowing cross-training priority schedules to evolve as the business changes (see Figure 3b). This pre-emptively avoids testing being held up by the lack of competent analysts.

Test Name	% All Testing (6 months)	Cross Training Cover
Test A	9.4%	60%
Test B	7.1%	80%
Test C	5.9%	35%
Test D	4.8%	45%
Test E	3.6%	20%
Test G	3.4%	89%
Test F	3.3%	44%

Figure 3b: Cross Training Table Output.

2. Testing and Efficiency

Workload Breakdown

The CPT provides multiple other reporting outputs which help a lab understand the forecast demand on many levels. While these will depend on site preference, some standard useful outputs include a breakdown of:

- Workload by Product (see Figure 4a)
- Workload by Sample Type (see Figure 4b)
- Workload by Test Method
- Project Workload by Category

Other outputs may be incorporated to address specific 'pain points' of a lab.

For example, perhaps a lab is not meeting its lead time target and they suspect the possible reasons are:

1. Review backlog
2. High rates of re-testing

The CPT can be used to convert incoming workload into number of hours (and FTE's) required for testing, review and re-testing. This visibility allows one to dedicate the appropriate resources to review and testing and may prompt further review or test training. These outputs are also a powerful representation of hours lost to re-testing and should spur RFT route cause analysis.

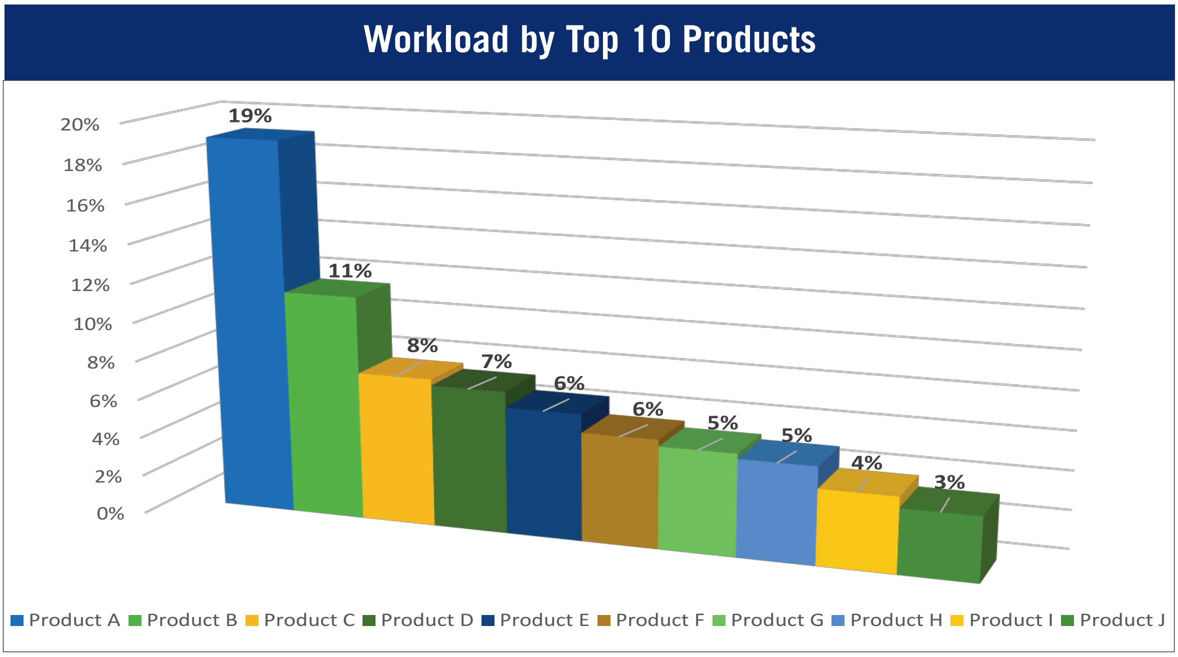

Figure 4: (a) Workload (% of total) Breakdown by Product

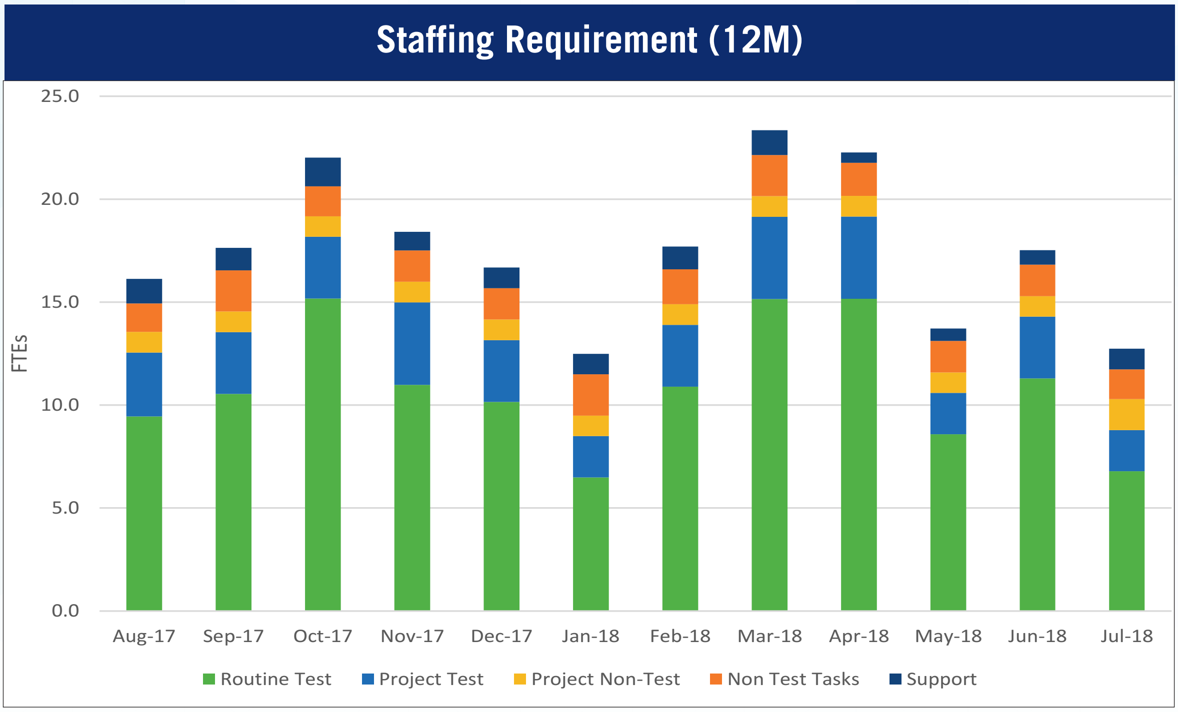

Figure 4: (b) Workload (FTEs required) Breakdown by Sample Type

Testing Efficiencies

Another function of the CPT is the ability to monitor how efficiently samples are being tested. Following best Lean practice, historical data is used to determine the 'standard run sizes' of test sessions to ensure maximum productivity. As volume/mix changes, so too will optimum run sizes. The CPT will automatically calculate the number of runs of each test method that will be completed by the lab. By comparing future levelled demand to historical levelled demand, one can flag tests where run sizes may need be to be amended. For example, if the volume of samples for Test A is projected to be 180% of current and historical volumes the lab will be prompted to reconsider test session sizes for this method and if possible increase the session size so as to minimize the number of required test sessions (see Figure 5).

Test Name	Projected vs Historic Volume
Test A	150%
Test B	81%
Test C	91%
Test D	80%
Test E	110%
Test G	60%
Test F	50%

Figure 5: Testing Efficiencies Table.

Equipment Utilization

Based on the predicted number of test runs, the CPT will calculate a projected utilization of each instrument. Equipment that may become a constraint will be flagged allowing for redeployment of equipment from areas of low utilization or the need to purchase additional equipment. If on the other hand, the long-term view predicts an excess of equipment, the lab may consider decommissioning some older equipment and thus avoid costly preventative maintenance and calibrations etc. This output enables labs to make strategic decisions to optimize return on current investments and eliminate unnecessary future capital expenditures.

3. Demand

Accuracy Monitoring

When analyzing capacity, a common concern among labs is the accuracy of production forecasts. BSM liaise with supply chain planning to source the most reliable data for input. The CPT will then calculate the %Error between the forecasted workload and the number of batches actually received each month. If a particular forecast is consistently above/below the received workload, this can be taken into account when estimating future capacity.

Sustainability and ‘What If’ Scenarios

BSM provides extensive training to lab analysts and/or management in CPT inputs, outputs and future amendments. As an important element of Lean Lab sustainability and to ensure the full benefits of the CPT are realized, a quarterly review process is routinely established. A qualified team will update the tool, evaluate the outputs, propose actions, communicate to the relevant stakeholders and escalate any potential concerns to upper management.

Outside of the periodic review, the lab may refer to the CPT to create scenarios and assess the associated impacts on resources.

What are the implications of increasing/reducing product X by Y% volume?

What if we move Test A from lab 1 to lab 2?

What are the consequences of reducing available analysts by Z%?

How can we best balance workload across labs 3, 4 and 5?

The risks, opportunities and subsequent return on investments of the different solutions can then be evaluated to facilitate informed decision making (see Figure 6).

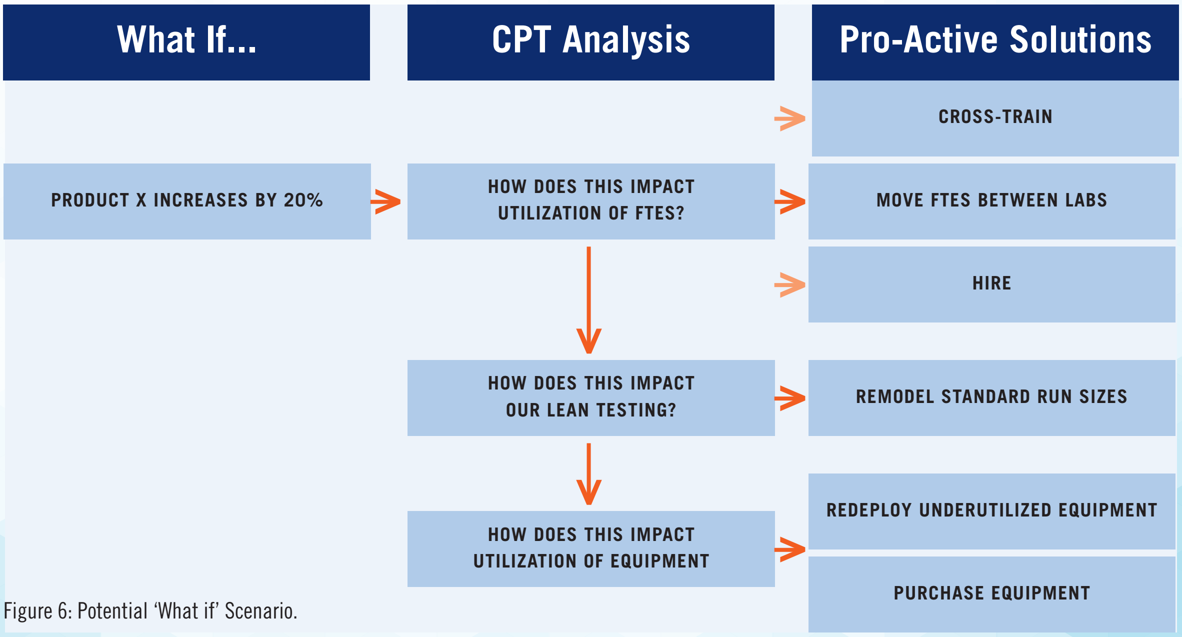

Figure 6: Potential ‘What if’ Scenario.

Conclusion

The process steps outlined here give an overview of Capacity Planning as part of a Lean Lab project and highlights the numerous benefits a greater understanding of capacity and resource utilization can provide.

By uncovering the true capacity capabilities of a lab and future capacity requirements an organization can move away from the costly chaotic responses to changes in demand. As global leaders in Real Lean transformations, BSM is uniquely qualified to deliver a comprehensive Capacity Planning process that will encourage a culture of pro-active performance management and continuous improvement.

BSM is the global leader in the provision of Real Lean transformation services to life science companies. We support companies to deliver significant measurable improvement within their QC, QA, R&D and Regulatory Affairs processes.

We develop innovative solutions via the application of best practice lean, re-engineering and change management techniques, and we have an extensive track record of successful implementations.

To discuss any aspect of this briefing

or how BSM can benefit your organisation please contact:

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