Pharmaceutical Operations Strategy – the QC Perspective

By Dan Barzily

Introduction

The pharmaceutical industry is constantly growing. Even in times of economic recessions, many companies experience increasing customer demands, which require increased throughput of all steps in the product value stream.

In the life sciences sector, the QC organization is a key factor in delivering products on-time to the market. While most operations managers take into account manufacturing capacity, QC is often the bottleneck when meeting greater demand.

Pharmaceutical QC

Quality is one of the most significant constraints in a pharmaceutical organization. The industry is heavily regulated by the FDA and Pharmacopoeia, and required to meet GMP and GLP standards. Similar to the manufacturing process, some QC assays will take up to two weeks until results are available. This situation leads to various challenges, including:

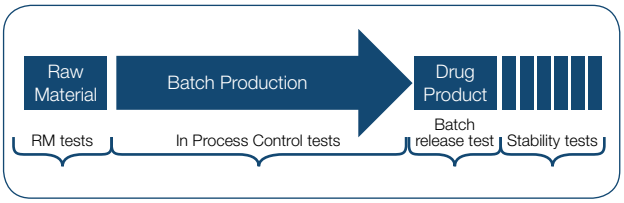
- Batches could be rejected post production, which means the organization has invested vast resources (time and money) in a non-conforming product
- The service level of the QC department is crucial for delivery

How can the QC department meet manufacturing requirements and achieve best practices, without over-investing in equipment, facilities and personnel?

Capacity modeling – bottom-up approach

In order to assess the true needs of the QC organization, the first step is to understand the workload – as a function of production volume.

1. Mapping the quality operation



The main product of the mapping phase includes:

- List of all the assays performed per product
- Frequency and quantity of samples taken for each assay per batch
- Equipment needed to perform each assay, including the constraints for each instrument. e.g. max samples per run, set-up time, validation durations and frequencies, etc.

2. Time studies

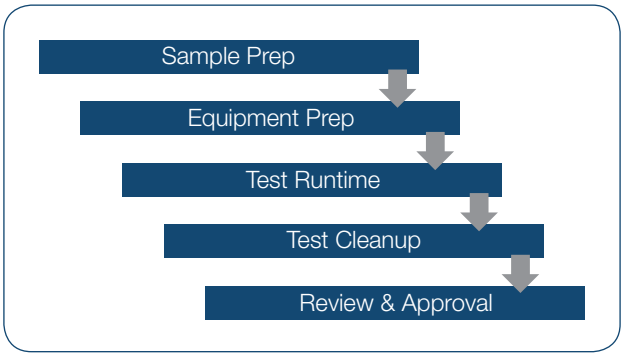
The second stage of understanding the workload is to perform time studies. These time studies are the core of the capacity model, and require a high level of accuracy. Depending on the total number of assays performed, we usually divide the assays into 'test groups' which are similar in methods, instruments and consumables used.

a. Variable vs. fixed time

The fixed component is the time it takes to do all the 'one-off' activities related to the test: bringing the samples; calibrating the equipment, wiping the desk afterwards, filing the SOP, etc. The fixed component is always the same, irrespective of the quantity of samples in the run. The variable component is the time it takes to do all the activities that have to be repeated for each sample in the run: weighing a sample, pipetting a sample into a test tube, writing a result, etc. The variable component is repeated in line with the number of samples in the run.

The separation of fixed and variable time per test enables us to analyze the impact of campaign size on capacity. In other words, campaigning plays a significant role in assessing the resources required (FTE, instruments, and footprint) to meet QC demands.

To ensure that all the events of an assay are captured, the study must observe the following stage gates:



All these stage gates must be observed, before the time study is complete.

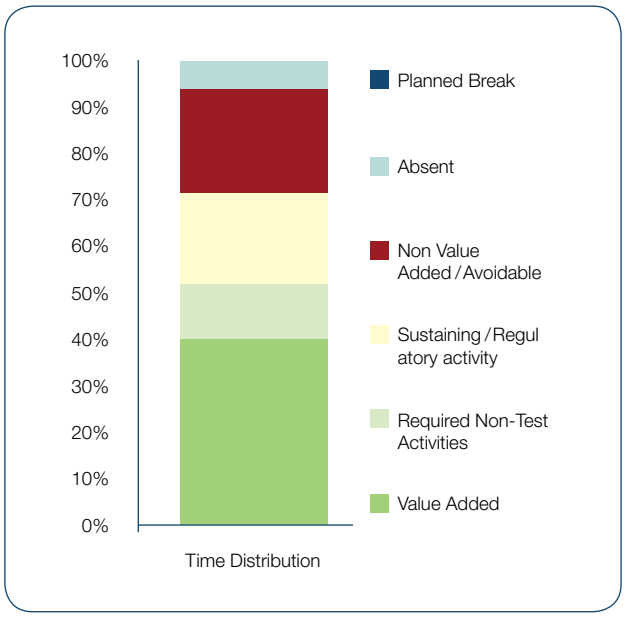
3. MOS – multi observation studies

An additional component of the capacity model is the analyst's availability to perform tests. Apart from taking into consideration availability losses, such as weekends, public holidays and days ill, we use the MOS methodology to assess the time on-site analysts spend on test-related activities.

MOS – multi observation study is a technique used to assess the time distribution of analysts in their working area:

- Sample multiple analysts (5-10) in constant time intervals (usually 5 minutes) during a whole shift, documenting each sample by categorizing the task performed. Task categories are pre-defined.
- MOS is used for various purposes:
  - Understanding the portion of the non-test-related activities of the analysts. The model core calculates the workload based on the tests performed in the lab. On top of that the non-test-related activity portion is added to calculate the final FTE requirement
  - Identifying potential improvements in the lab by categorizing the time distribution to value-added and non-value-added activities

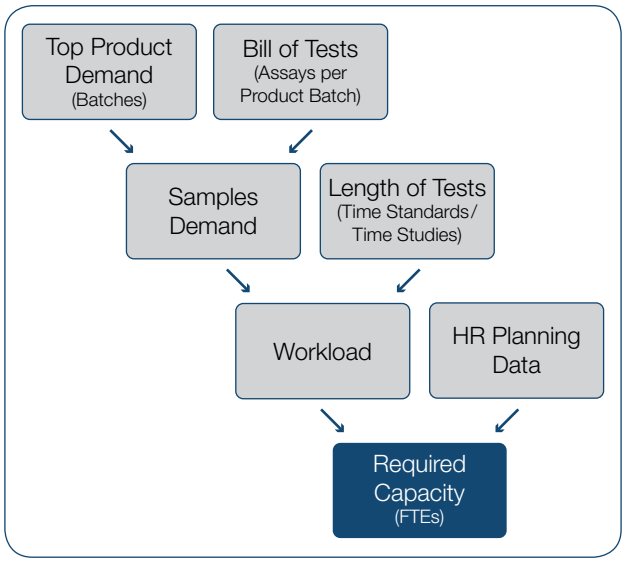
MOS results (example):



4. Demand profiles for top products

The last piece in the puzzle of QC demand is the forecast for top product batches. We encourage our clients to provide a few scenarios for each product so the analysis can address different strategies for each. Not only commercial batches are included, as clinical batches and stability samples (commercial and clinical) can represent over 50% of the workload.

Capacity model algorithm summary:



Analyzing results

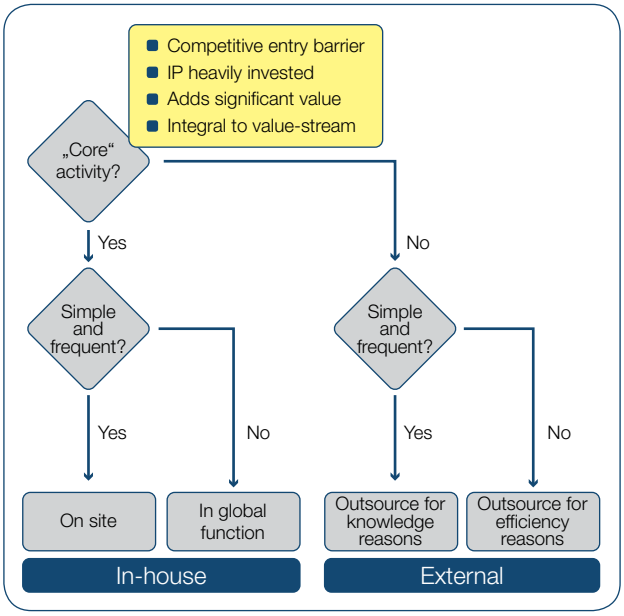
After formulating the model for all sites in the network, it is time to zoom out and analyze the results, while taking into account the following considerations:

- Test at source vs. test at central laboratory
- In-house vs. outsource
- Shifts and overtime policy
- QC service level
- Campaigning

While deciding on the right strategy, it is important to acknowledge the trade-offs between each factor. Obviously, increasing campaign sizes (batch size) will reduce the number of FTE required but, on the other hand, will increase lead times and could theoretically affect compliance. Testing at source (where manufacturing takes place) will improve lead times, while establishing a COE (center of excellence) will realize savings by consolidating facilities.

The art of formulating the right strategy requires that you find the evasive balance point for each trade-off while bearing in mind the long-term goals of the company. Each component is addressed in a structured approach while formulating different strategies.

Outsourcing decision tree:



Strategic capacity-modeling benefits

Preventing overinvestment:
In many cases, sizing the QC operation in terms of FTE, footprint and instruments is undertaken by the QC department managers. This situation, where major capital and operational expenses are allocated on the basis of past experience and managerial common sense, often results in excessive investments in underutilized equipment, facilities and personnel.

A well-built strategic capacity model enables the organization to size the QC operation, based on an analytical scientific tool which supports data-driven decision making. Tefen's experience shows that ~15% of total QC expenses can be avoided by more accurate long-term sizing according to different customer demand scenarios.

QC network optimization:
The global pharmaceuticals market is dynamic, with brands constantly increasing their global reach and experience fluctuating customer demands. As a result, the QC network is becoming even more complex to design and often plays a critical link in the product value stream, affecting on-time delivery of final products.

A strategic capacity model enables you to analyze the pros and cons of different network designs, and provides management with a clear view of the trade-offs between lead time/flexibility/cost and risk. This model helps management to answers difficult questions, such as:

- How many labs do we need?
- Where should we locate our labs?
- How can we prepare our QC network for new market penetration or new product introductions?

Considering the benefits above, the model results have proven to be invaluable while establishing a 3-5 year growth plan for pharmaceutical QC operations. Case studies performed by Tefen over the past few years have shown that savings can reach six figure USD amounts on an annual basis.

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