

Efficiency Management in Quality Operation

cME & Smart-QC Newsletter

Q3 2010 , Issue 24/25 - Theory of Constraint (TOC) in Quality Operation

Dear Colleague,

Welcome to cResults Newsletter, designed to offer you insights, news, information about Quality Operation Efficiency Management, Software solution: cME (www.cmanageefficiency.com) to manage batch record release and overall QA efficiency, Smart-QC (www.smart-qc.com) for QC Laboratories Planning and Scheduling, events and quality related efficiency improvement ideas.

We hope this issue of cResults Newsletter will spark new ideas to help you better manage your quality operation, and improve your customer service level. At the end of the day, we are not successful unless you are.

Sincerely,

Rafi Maslaton *President, cResults*

*This Newsletter is dedicated to **Effective Management of Lab's Resources, removal of Non Value Add (NVA) Activities and Maximizing Campaigning while maintaining customer service level***



Introduction: In our current economy environment and overall industry state of mind, we ought to focus on efficiency and overall cost. This leads us to constantly review our staffing level and seek efficiency improvements that could potentially result in reducing our overall cost of quality when it comes to quality operation.

Most of you are familiar with the book *The Goal* by Eliyahu M. Goldratt, that discusses the operations management approach with a focus geared towards the Theory of Constraints, bottlenecks and how to alleviate them. When it comes to the QC Laboratories the key constraint in terms of cost and capacity limiter are the analysts. (**A constraint is anything that prevents the system from achieving more of its goal**)

Theory of Constraint (TOC) in Quality Operation: Although QC has relatively limited control of incoming samples (FG/IP) and arrivals of raw material (RM), there are several types of internal constraints that the labs can control and manage: Instrument: The way instrument is currently used limits the ability of the system to test more samples in a compressed and timely manner.

People: Lack of skilled / qualified people limits the lab's throughput. Mental models held by people can cause behavior that becomes a constraint (Culture).

Policy: A written or unwritten policy prevents the system from making more.

These internal constraints affect the QC ability to meet customer demand and targeted COQ while could be enhanced internally. The TOC by focusing on the key constraint (People) support the optimization concept with its approach while a robust lab management platform as Smart-QC could help with facilitate this approach.

The five focusing steps to enhance the current bottleneck throughput are (based on TOC)

Theory of Constraints is based on the premise that the rate of goal achievement is limited by at least one constraining process (Primarily People in the QC Lab). Only by increasing flow through the constraint can overall throughput be increased.¹

Assuming the goal of the organization has been articulated (e.g., "Make money now and in the future") the steps are:

1. Identify the constraint (the resource or policy that prevents the organization from obtaining more of the goal)
2. Decide how to exploit the constraint (get the most capacity out of the constrained process)
3. Subordinate all other processes to above decision (align the whole system or organization to support the decision made above)
4. Elevate the constraint (make other major changes needed to break the constraint)
5. If, as a result of these steps, the constraint has moved, return to Step 1. Don't let habits become the constraint. ²

The five focusing steps aim to ensure ongoing improvement efforts are centered around the organization's constraints. In the TOC literature, this is referred to as the "Process of Ongoing Improvement" (POOGI).



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How we can address the 5 steps when it comes to QC Laboratories:

1. **Identify the constraint:** QC efficiency is driven by internal and external factors. Some of the common external factors that could be streamlined and improved are: poor planning where workload throughout the year is not balanced, lack of communication that leads to focusing on the wrong samples, lack of campaigning, poor planning and execution in manufacturing that leads to rushing samples through QC that leads to once again lack of campaigning that resulted in efficiency losses. Other external factors such as high number of re-test requests due to lack of understanding of the deviation / compliant and first reaction is additional tests (which may not always be required), End of the month / End of the Quarter / Year effect, when many of the manufacturing batches are produced and QC has very limited time to release before the end of the period is due. These and more are all typical external factors impacting QC that could be improved by a more robust planning system, improved communication and reduced overall turnaround time at the Lab to enable a faster response time.
2. **How to gain more capacity:** depends on several functions / systems / practices. We will mention several key ones: Campaigning – as indicated previously, is not completely at the control (internal) of QC as Supply chain may insist to get certain samples released first which means MAJOR INEFFICIENCY. However, campaigning between finished good and stability is a Lab decision. Having a robust scheduling system can help to make sure stability samples are not being pushed to the last minute as typically commercial samples receive priority. Negotiating service level with supply chain for turnaround time could significantly increase the opportunities for campaigning. Improved consistency of the lab release turnaround time could help increase the confidence and the allowable flexibility of the Lab and more.
3. **Align the whole system or organization to support the decision made above:** This is primarily related to supply chain setting up priority, turnaround time as detailed in the previous steps.
4. **Elevate the constraint:** In addition to improved campaigning and further managing the resource efficiency (this was covered in previous newsletter and shows reports, metrics and approach on how to measure and measure efficiency in QC Labs), we can control the analyst time outside the direct bench time. It is commonly known that the average lab analyst time to perform test ranges between 55%-70%. This is due to other activities such as cleaning, calibration, material preparation, OOS / Investigations, training, meetings, and more. What we found once we have Smart-QC (one of the cResults clients) included how much non-testing activities we performed in the lab and that not all of these activities should be either performed at all or could be easily pushed to the next quarter or the time table negotiated. In other words, many of the activities that are tasked by the lab should not always take priority over testing, backorder, etc. and due to the lack of a management tool and awareness this consumes significant time of our constraint – THE ANALYST. Several suggestions in this area: Once you are using a system such as Smart-QC, quantify the Non-Test activities and set up a policy to limit these on a weekly basis. Provide the supply chain members with choices and cost, so it will be clear that these are not for free and there is a trade-off. Schedule the Non-test for times that the workload is not at its peak. Outsource or In source to other groups activities that do not require the same level of science as you need from a chemist and most importantly have your supervisor monitor these carefully.
5. **If, as a result of these steps, the constraint has moved, return to Step 1. Don't let habits become the constraint.** [3]

In summary: QC is affected by external contributors but has several internal policies and opportunities to enhance its own efficiency. The TOC provides the approach to manage the most critical constraint in the labs, PEOPLE, and by leveraging a platform such as Smart-QC that supports efficiency and cost drivers like campaigning, transparency, ownership and accountability can truly enhance the management of the number one constraint in the QC Lab, its PEOPLE. The QA is very similar and in many cases we find that the key constraint and rate limiting factor is PEOPLE. Although various quality systems could be streamlined, it always results in people making the decisions and in most cases this leads to prolonging the overall turnaround time.

References

[^] ^a ^b Cox, Jeff; Goldratt, Eliyahu M. (1986). *The goal: a process of ongoing improvement*. [Croton-on-Hudson, NY]: North River Press. ISBN 0-88427-061-0.

[^] Goldratt, Eliyahu M.. *Essays on the Theory of Constraints*. [Great Barrington, MA]: North River Press. ISBN 0-88427-159-5.

[^] Dettmer, H William. 1997. *Goldratt's theory of constraints: a systems approach to continuous improvement*, ISBN 0-87389-370-0, p 14, 15.

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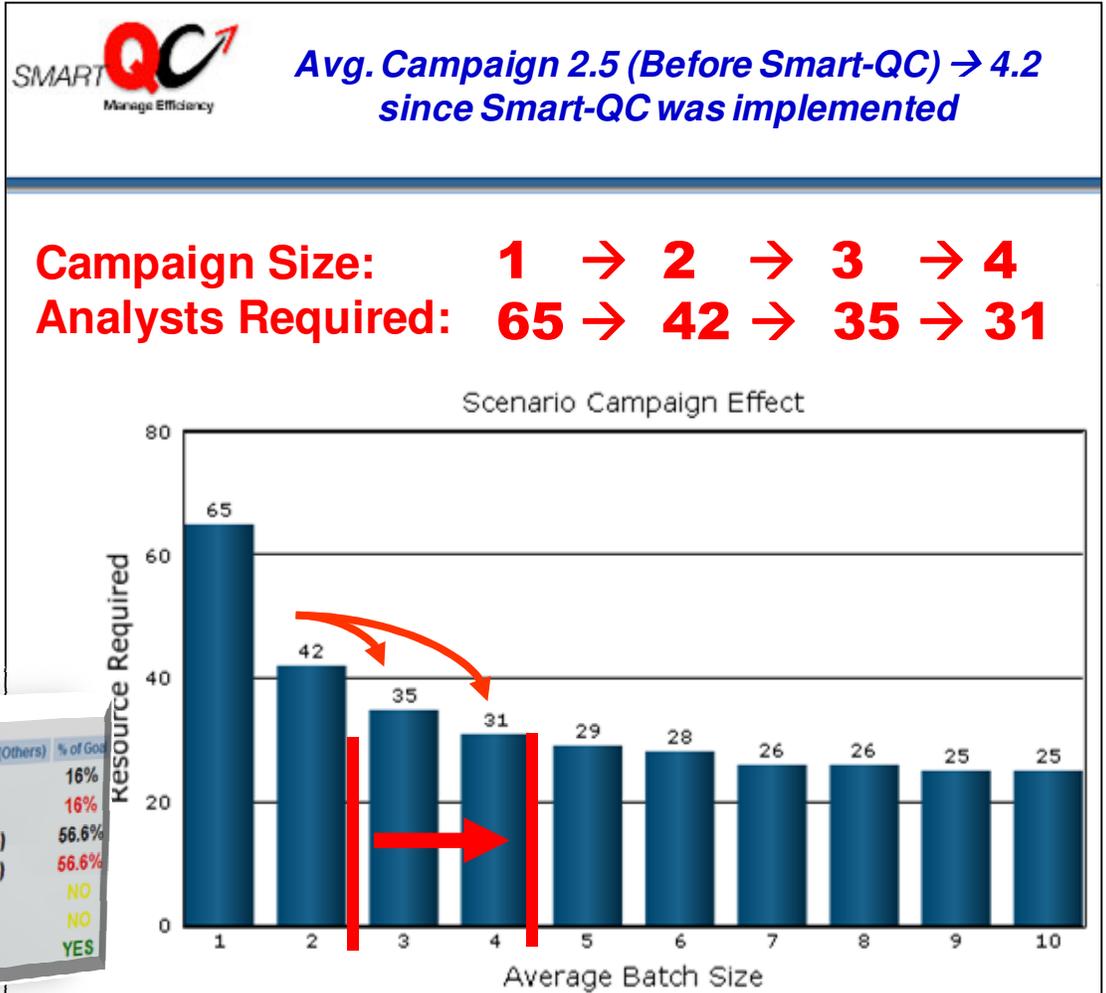
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What's New in Smart-QC and cME Smart-QC has recently come out with a new release that significantly enhanced its integration with LIMS enhanced existing functionality with Overtime management, Right First Time Documentation related to Lab Audit, Campaigning hold time, additional reports and Key Performance Indicators and enhancements to the scheduling algorithm. We are currently working on a new version for cME and will provide an update in our next newsletter.

Case Study

- Prior to the implementation of Smart-QC, the average campaign size was: 2.5 tests per campaign
- Since the deployment of Smart-QC began, campaign size is averaging: 4.2 tests
- This represents about 20% efficiency gain

STEP #2: HOW TO GAIN MORE CAPACITY



Activities Summary

Weekly Performance	Goal	Goal Completed (Others)	% of Goal
Samples This Week	188	30(31)	16%
Daily Progress - Samples	188	30(31)	16%
Tests This Week	265	150(506)	56.6%
Daily Progress - Tests	265	150(506)	56.6%
Number of Investigations	1	12	NO
Re-Tests	1	17	NO
Rejects	0	0	YES

Upcoming Events:

Please visit our web site www.cmanageefficiency.com, www.cresultsconsulting.com, and www.smart-qc.com for the latest events

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OCT/NOV 2009 , Issue 22/23 - Scheduling Complexity and Approach in Quality Operation



Smart-QC Key Value Add & Deliverables:

- **Capacity Planning** for both analysts and instruments (*per site(s) / network*)
- A fully **integrated QC lab budget** with Resource Planning leveraging advanced allocation methodology.
- Detailed work centers / labs, **products and tests cost**
- **Automated Test Allocation** and **work load balancing** for analysts across various labs to **maximize campaigning opportunities** and **improve service level**
- **Manage lab / analyst weekly efficiency**
- **Productivity losses** tracking for **Lean / Six Sigma** process improvement initiatives
- Manage the **Cost of quality (COQ)** and identify cost enhancement opportunities (**Make or Buy analysis**)
- **Robust Reporting** tool with powerful **What If Analysis** capabilities
- Upgrade your **lab visibility** and **overall span of control**
- A robust **benchmarking tool** for the overall network (once deployed across multiple sites)

cME Key Value Add & Deliverables:

- Improving managerial capabilities and **efficiency management** in areas such as: Overall **Batch Record** life cycle, **Audit, Clearances, Swabs, Inspection**, Time spent on SOP / Deviation / Monitoring and more
- **Robust reporting** and trending capabilities and **reduce reporting time and data collection time.**
- **Accurate and factual** quantification for all QA activities and provides **clear expectations** and standards for each of the QA activities.
- Reduce **batch record release cycle time** and help lead **documentation errors reduction** through improved visibility, structure, ownership and accountability via cME
- Assists **Lean / Six Sigma teams** in **identifying opportunities** for improvement and **continuous measurement** of the impact until **demonstrated.**
- Provides **Key Performance Indicators (KPI)** and real time status board in areas such as Compliance, Batch Record, and Efficiency.
- Provide the production team with the focused information to improve efficiency and compliance.