# Efficiency Management in Quality Operation
# cME & Smart-QC Newsletter

## *Q2 2011 , Issue 26 - H1 2011, Balancing Cycle Time and Efficiency in QC Laboratories*

**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.

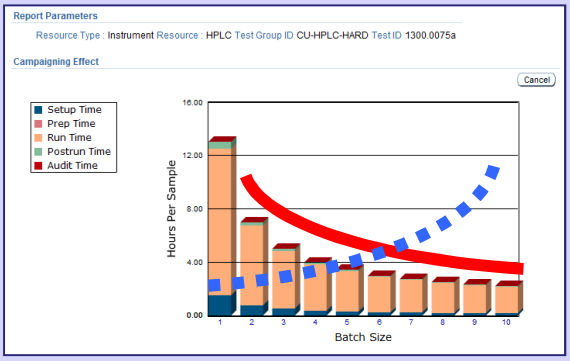
Sincerely,
Rafi Maslaton *President, cResults*

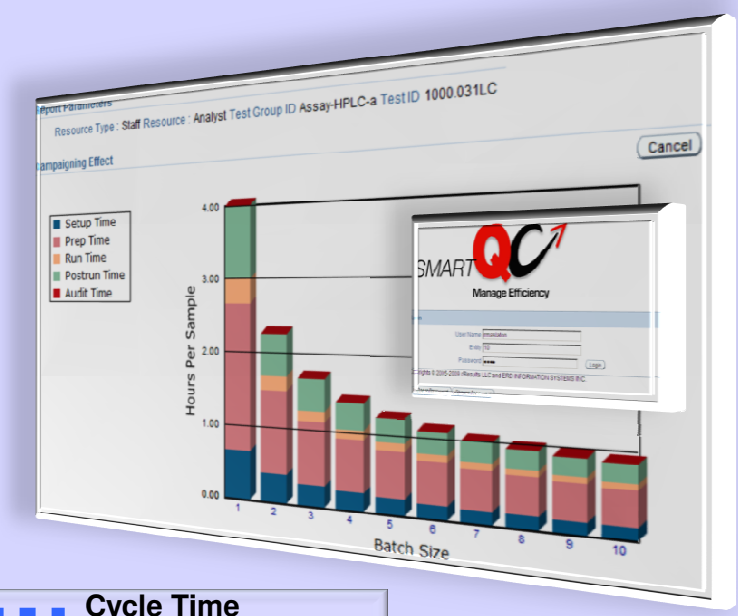
*This Newsletter is dedicated to* ***Balancing Cycle Time and Efficiency in QC Laboratories while managing backlog.***

***Introduction***: The current economic environment, increased completion by generics, government pressure and overall industry state of mind, we ought to focus on reducing inventory, improving our service level and at the same time reduce the overall cost. These key goals are contradicting and create a huge challenge for our operation. We all know that lab cycle time reduction could be achieved by utilizing faster instruments and reducing cleaning time, yet this is usually not the key challenge. What we are seeing over and over throughout the industry is the supply chain group trying to push the lab to test and release the samples as these arrive.
This sounds LEAN and great in terms of cycle time but there is a catch and this will be the main focus of our newsletter this time.`

***Balancing Cycle Time and Efficiency in QC Laboratories while managing backlog:*** So what is wrong with this picture? The key issue is that by testing ONE sample at a time, we lose approximately 30-40% efficiency. This is due to the fact that we are performing the sample preparation, setting up the instrument, running the instrument and analyzing the results for one sample / test while this takes the majority of the time if we test ONE or multiple samples. Adding more samples to the first one will have a relatively small increment of time (for most tests) added for both the analyst and the instrument (i.e., HPLC). Let's see an example for average hands on time (touch time to perform the test) as a function of campaign size (Batch of few samples that the tests are performed together).

The chart on the right, illustrates the decrease in hands on time per sample as a function of batch size / campaign size. Going from 4 hrs average HOT for a single sample to 1.5 hrs per sample when campaigning 4 samples. This is a 62.5% reduction in HOT per each sample. When applying this ratio across multiple tests the impact on the lab's efficiency could be substantial. Similar effect applies on instruments such as HPLC as can be seen in the chart below. 69% Drop in run time per sample when comparing a run with SINGLE sample vs. 4 samples




**Cycle Time**

**Avg. HOT per Sample**

# Efficiency Management in Quality Operation
# cME & Smart-QC Newsletter

***Q2 2011 , Issue 26 - H1 2011, Balancing Cycle Time and Efficiency in QC Laboratories***

As we can see the desired campaign size ranges from 3-5 samples depending on the ratio between the increment time for each additional sample vs. the fixed "COST" time related to the initial set-up.
Here is a real case study: Company-A got into a major backlog in the QC Laboratories. A daily meeting is established by the supply chain team including functions such as QC, Production, QA, and Purchasing to discuss the daily priorities. The current QC backlog is 2 weeks using the current operation, test methods, staffing level and campaigning strategy. The volume is steady with a slight increase expected over the next few weeks based on the current sales forecast. The supply chain team comes to the meeting with a **daily list for QC** of which samples need to be tested for both Raw Material (RM) as we may have manufacturing suites idle due to NO RM available/released and we cannot ship to our DC as the QC samples were not released and therefore the usage decision cannot be made. Similar list is handed to the QA for Batch Record review. The lab is trying to fight back and asked for testing at least 2 samples vs. a single ONE, but no mercy on the other side. The lab is processing the samples as instructed by the supply chain team, and see their backlog increased, overtime is exceeding any budget plan, and each day the list of URGENTLY needed samples is growing. Actually, when the lab has a backlog, the only way in the short term to reduce the backlog is increasing campaigning size, using overtime, and obviously pushing any project / vacations to a later date. The increased campaigning helps increase the lab capacity for the short term and help them manage the backlog on one hand and handle the steady stream of samples in the regular production. This may seem contrary to tradition RUSH RUSH RUSH approach, however, it is the only approach that could work in this scenario. Of course, having a resource planning and scheduling tool like Smart-QC would help to see in advance that the lab is under capacity and we should expect a backlog in 3 or 6 months based on the current forecast and we should act accordingly when this information is available. The whole purpose of resource capacity planning is avoiding these cases both over/under capacity and put a plan together to help the organization manage these fluctuations affectively.
Lesson Learned: (1) Plan in advance by performing a monthly workload analysis for 6-12 months ahead and make sure you are staffed accordingly; if backlog situation occurs, (2) daily meeting should be conducted, (3) campaign size should not be ONE unless it is a major business risk of losing a customer, and goal should be to (4) maximize your campaign with stability samples, while making sure stability samples are not suffering. In addition, (5) manage the other non-test related activities more carefully so you will not find out that some of your team members were involved in 40 hours of archiving effort. Other projects such as method transfer, method validation should also be prioritized accordingly.

***In summary:*** QC is affected by campaign size probably more than we realized. Backlog contrary to intuition may be better managed if supply chain will allow as much as possible for the lab to campaign vs. run ONE sample from a list of priority. Better planning using capacity and staffing modeling could prevent us getting into this situation and allow the business more time to prepare and get organized. Reaction is many time very costly and resulted in major deficiency in terms of labor and instrument efficiency. While instruments are not a bottlenecks in most of the labs the ANALYSTS are and campaigning should be encourage while keeping the focus on cycle time and on-time delivery. Smart-QC provides the planning part and the algorithm to schedule the work and help with the balancing of the campaigning and efficiency.

## *Upcoming Events:*

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

***What's New in Smart-QC and cME*** The new release of cME is now fully integrated with Smart-QC as well as with ERP / Quality Management System as TrackWise and LIMS. This provides the QA reviewer with the ability to see ALL batch record related information in ONE place and make the usage decision more effectively. Smart-QC new functionality is supporting tests dependencies for cases when a specific test needed before other could start.

# Efficiency Management in Quality Operation
# cME & Smart-QC Newsletter

*Q2 2011 , Issue 26 - H1 2011, Balancing Cycle Time and Efficiency in QC Laboratories*


## *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.