Efficiency Management in Quality Operation
cME & Smart-QC Newsletter

OCT/NOV 2009 , Issue 22/23 - Scheduling Complexity and Approach 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*

Please be sure to register for our upcoming Webinars: Documentation Errors Reduction Methodology and Overall QA Efficiency, KPI in Quality Operation and Resource Planning, Scheduling and COQ for QC Labs.
This Newsletter is dedicated to ***Scheduling Complexity and Approach in Quality Operation.***

Introduction: In today's environment, there is growing pressure on Quality operations to reduce their overall cycle time as part of an overall supply chain streamlining. The real challenge in cycle time compression initiative is the availability of the information to enable the quality Operation to make the right decisions to support the business needs. Balancing the quality resources availability vs. the priority set by the business and to balance it with cost / overtime and efficiency improvements to meet the desired schedule are key. Quality operation is a complex environment to schedule and often time does not have the tools / systems in place. The complexity in many cases can be attributed to the significant number of tasks that need to be managed and balanced as well as the access to the information as in some cases the quality operation is operated in an isolated environment and taken for granted when it comes to receiving updates about changes in priority. This newsletter we will touch on some of the key attributes leading to the complexity in quality operation management.

QA Complexity & Directions: QA by design is on the critical path to release the batch as it is the final step. Furthermore, in complex and diverse operations, the amount of batch records that need to be released is significant and can become a major impact on the cycle time. The main complexity in QA, as indicated in the introduction part, relates to the availability of information. Few examples could help; pending investigation that was not communicated to the release team, this may waste QA release resource time focus on reviewing a batch record that is not needed at this stage vs. focus on more critical items. Having Out of Spec event in QC will cause the same effect. QA is relying on Manufacturing and Packaging to correct the errors found in the batch record before they could complete their approval process. Changes in priority, raw material expiration and more have similar impact if the information is not readily available for QA. Also, QA is involved in many investigations, change control, audit activities, inspection and more that need to be scheduled and managed along with batch records release. The above complexity as similarly discussed below in QC, requires a constant communication with the Supply Chain regarding RM and Priority and Mfg. and Pkg. as well. The amount of information and changes need to be managed in a computerized platform so it is not dropped or hidden and hence full transparency is available for the overall team to make the right decision and focus on the most critical items first. This was the premise of cME – Compliance Manage Efficiency solution to host all of the above information and provide an accurate picture of the QA activities in a real time.

QC Complexity & Directions: QC is probably the most complex area to schedule and manage at the site. A simple example will illustrate the QC complexity often ignored: If we will use an average of 20 samples a day (all labs) and 5 tests per sample with 10 day turnaround time, then the number of tasks that need to be scheduled and managed are 1,000!!! (20*5*10). In addition, we have to prioritize the activities with consideration of the shift structure, the compliance aspect as it relates to stability, work balance between analyst and their qualifications as well as their methods proficiency. Furthermore, the assignments need to be aligned with the workload / availability of the analysts which means we have good standards that tell us what an assignment represents in terms of level of effort (Hands on time). As we know, in QC, we need to optimize our campaign size to enhance efficiency as well as not to exceed the cycle time expectations. While we have all of this complexity, priorities often change, sometimes daily, and not always communicated to the QC staff members so we may spent resources time focus on the wrong tasks. The above complexity definitely enforces the need for more automation in the scheduling process; enhanced communication between QC, QA and the supply chain and better transparency in the lab. Smart-QC performs the above in a couple of clicks and provides clear prioritized schedule **(R/Y/G)** and expectations (Standard) for the users, a real time dashboard and highlights the critical samples. Many of the mid-size labs founds that a manual whiteboard is too difficult to maintain and ends up as a message board vs. a scheduling board.

Conclusion: While in Mfg. a scheduling board in many cases may seem adequate. The QC complexity, multiple tasks requires a computerized scheduling system to manage the information and present it to the team members in a meaningful way aligned with the supply chain goals. The QA even though it could use a scheduling board, will quickly find itself making constant changes like QC and soon enough the board will be out of sync with the ERP / Supply chain priority. Hence the key for success is a computerized platform that will host the information and leverage a set of rules and robust algorithm and use that as the primary scheduling tool. Enhancements will be made if applicable by the supervisor / manager based on new / experience based information. This will allow us to manage the exceptions and focus on the more challenging scheduling events.

Upcoming Events:

- October 23rd on **Planning and Scheduling in QC Laboratories** www.smart-qc.com.
- October 16th on **KPI In Quality Operation.**
- October 30th on **Batch Record Documentation Errors Reduction Methodology & QA Efficiency.**

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

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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.