Efficiency Management in Quality Operation
cME & Smart-QC Newsletter

January 2009 , Issue 13 - Focused on Efficiency Gains 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.

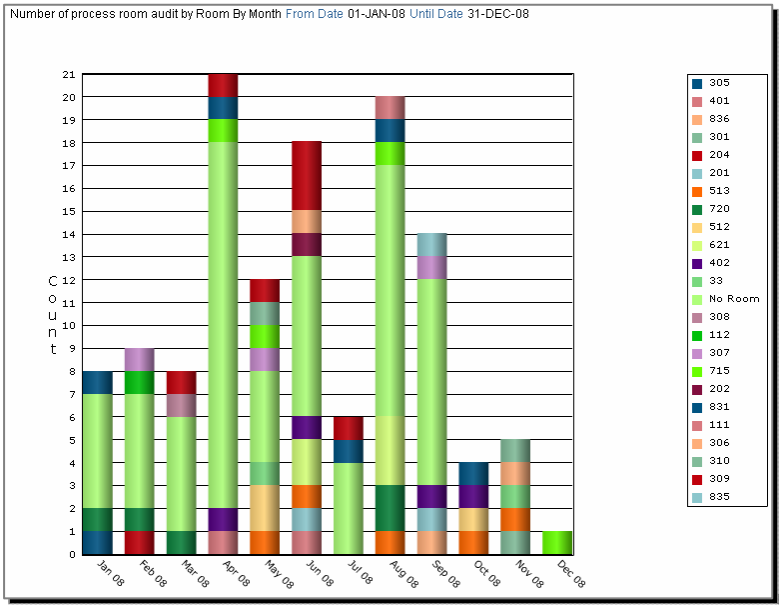
We hope this issue of cResults Newsletter will spark new ideas to help you better manage your quality operation, and improve your customer service level. At the end of the day we are not successful unless you are.

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 Efficiency Improvements – Internal Audits & Campaigning Effect in QC.

QA: Typically in our industry, audits are performed and, in many cases, the issues found are not recorded in an electronic system and very infrequently a regular root cause analysis takes place. It is often found that audit findings are minimal yet the audit form, content, and frequency remain the same. By leveraging a data collection platform such as cME, we can see trends, and audits that are not generating observations which can suggest, either we are not auditing the correct topics, or the manufacturing staff has matured and are performing an adequate job, and hence the audit frequency can be reduced. These are questions that we should ask constantly and by using a risk based approach, we can effectively reduce frequency of non-value added audits, enhance audit content, and increase the overall value added compliance QA could deliver to the business. Furthermore, most organizations do not track audit findings and perform trend analyses by room, product, and shift to help identify the root cause and support the manufacturing team in continuous improvement. The tracking of the audit findings in most cases is not done effectively as many of the observations are not qualified to become a quality incident and therefore do not get the attention they deserve. This is one of cME's strong points as it provides the needed platform to collect the audit results, associate observations to a specific audit and provide the query engine to analyze the observations as can be seen in the chart on the right. This chart shows an example of a specific audit procedure and the quantity performed by room, product, equipment and users then can view the observations and discuss root causes, remediation plan, prevention and ultimately the elimination of non-value added activities and waste. This will re-focus the QA team toward more critical GMP value added activities as the previous audits could be eliminated or at least their frequency reduced via effective root cause analysis and guidance and clear some of the QA technician time for other prioritized initiatives.



The chart above outlines Audit activities performed by room and failures can be added to the same view. Leveraging this information can lead us to the source of audit failure e.g., a specific room that is poorly maintained, or product that is "sticky" and leads to cleaning issues, 2nd shift that is not sufficiently trained, etc. The QA team provides the information to the Manufacturing team and identifies where observations took place, the Pareto of observation types and the details associated with these observations. With this approach implemented, the organization will achieve the desired outcome including remediation of issues, elimination of non-value added audits and overall improvement of the state of compliance.

News and Events

Upcoming Events:

- January 12th on **KPI In Quality Operation.**
- January 9th and January 30th on **Planning and Scheduling in QC Laboratories www.smart-qc.com.**
- January 16th 2009 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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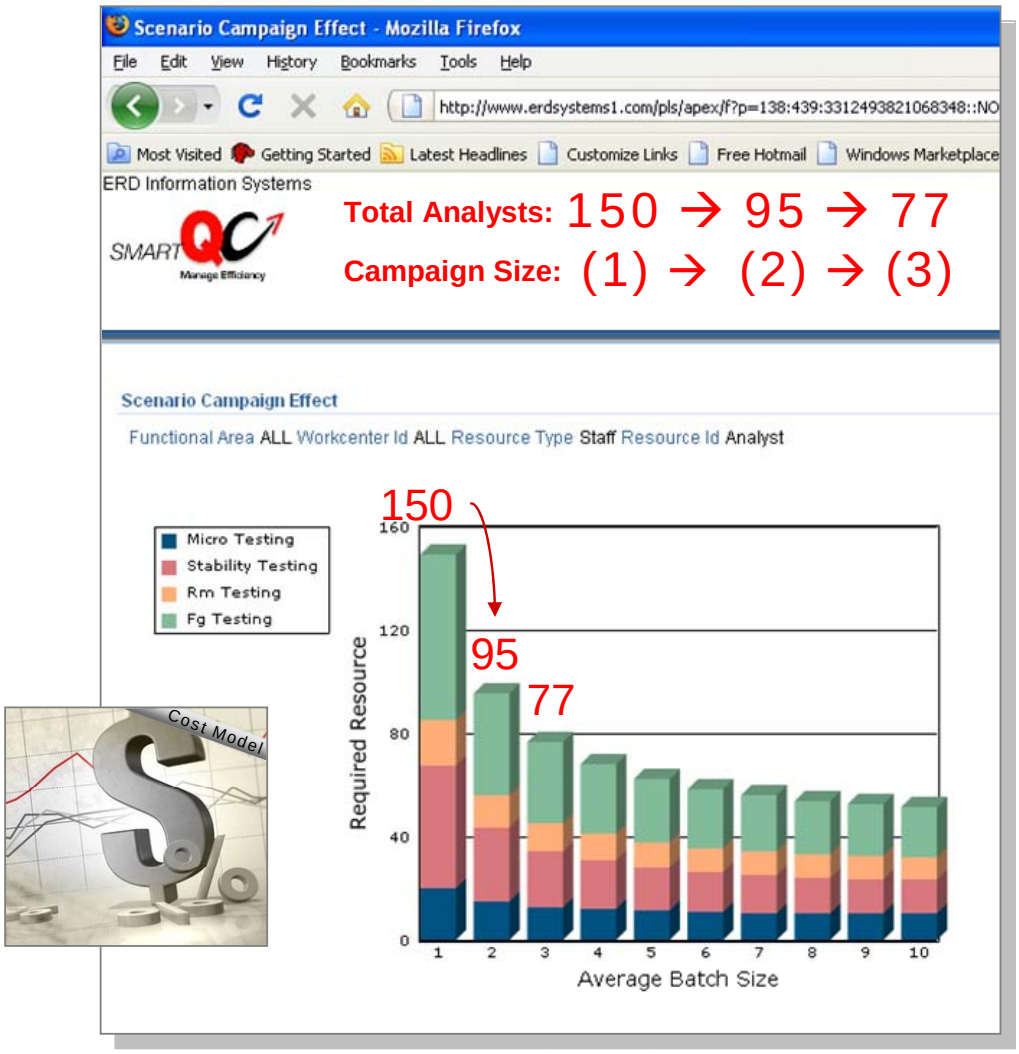
QC Laboratories: It is common knowledge in the QC laboratories that campaigning is desired for efficiency gains. Most QC labs are making an effort to campaign for example between Stability and Finished Goods. However, when both labs are managed separately, (i.e., Stability Lab and Finished Goods lab) campaigning is more difficult to achieve as a result of issues with visibility, communication, ownership and accountability. In some cases, the Stability and Finished Good Labs are separated for compliance reasons, which obviously eliminates the opportunity to then campaign. In order to balance between efficiency and compliance, Smart-QC provides the visibility and the needed prioritization to balance between these competing goals. The chart below illustrates the impact of campaigning and demonstrates the reward for perfecting this complex challenge. In the example, by campaigning at least 2 samples, the total required analysts reduces from 150 to about 95. Although this presents a major improvement, going to 3 samples can improve efficiency to the level of reducing additional 18 analysts. By the 4th sample the efficiency gains are less significant although other measures such as equipment efficiency, chemical consumption are improving as well. In summary, without a robust information system and effective business processes, campaigning can become a major challenge and can potentially lead to compliance issues when it relates to Stability. However, the expected benefit is so significant that the effort is worthwhile. In a separate structure where Stability and Finished Goods are managed by separate Managers / Supervisors, the likelihood of achieving effective campaigning maybe at best 50% of the total opportunity, and truly blame can't be on the Managers since it is extremely complex to maintain your duties while trying to increase the overall laboratories efficiency and effectiveness.



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