Efficiency Management in Quality Operation
cME (QA) & Smart-QC (QC) Newsletter

October 2008 , Issue 10

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 documentation Errors Reduction Methodology and Overall QA Efficiency in October 10th and October 13th. Also Register for our Resource Planning and Scheduling Webinar for QC Labs on October 31th.
This Newsletter is dedicated to the methodology of reducing batch record documentation errors. STEP by STEP Approach.

Batch Record Improvement Methodology:

Step-1: cME provides an overview on error reasons breakdown for all areas. This gives us the first indication of where the issues could be found

Step-2: Takes us a step further to find out by month which of the error codes are the dominant ones.

Step-3: Identify if the errors are contributed by a specific area. In this example, Pharmacy was the lead area in terms of errors generation, which greatly helps the team to focus on this area to get a quick win.

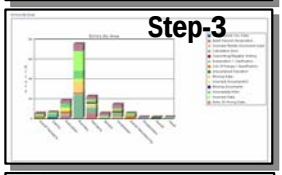
Step-4: Focus on a pareto – find out which of the errors are the most dominant in a specific month. As in step-1 we were focusing on the overall errors, in step-4 we are looking if a trend is detected for month specific details. This is another step in identifying if the errors are related to a specific area or/and a few specific error codes.

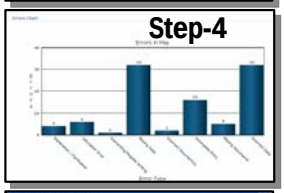
Step-5: Provide the right first time metric by each individual QA reviewer. Once a substantial difference is detected, it can guide the team to improve the standardization process among the reviewers.

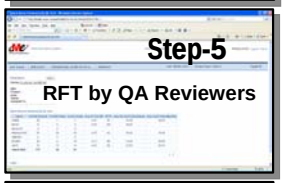
Step-6: In this step we will look closer on the types of errors made. While in previous steps, the main focus was on the types of errors, in this step, we are focusing on the details level which can lead us to a specific page that may cause issues, a specific information that is often missed, etc. This can lead to changes of the actual batch record design along with some targeted training for the production team.

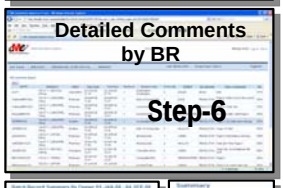
Step-7: cME provides the view of the same data previously analyzed from the production ownership. In other words, once an error is recorded, in addition to the area, the error code, the QA check that are being recorded, the production owner that could be a group leader, or a supervisor is recorded as well. This allows the team to identify some specific issues related to an individual that may need additional training or some clarifications.

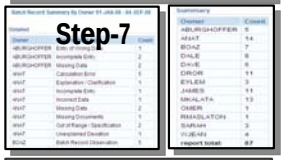
Step-8: Finally, cME provides robust cycle time and efficiency data that could show us not just the errors but also the impact of QC samples, investigation, pending for errors response, etc. so the team could once again focus on the most critical area / individual / events that lead to cycle time losses and overall deficiencies.

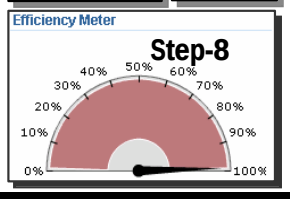












News and Events

Upcoming Events:

- Upcoming cME Webinar dates: **October 10th and 13th ." Batch Record Documentation Errors Reduction Methodology & QA Efficiency"**
- Upcoming **Smart-QC** Webinar dates: **October 31th." Planning and Scheduling in QC Laboratories"**
- Please visit our web site **www.cmanageefficiency.com, www.cresultsconsulting.com, and** www.smart-qc.com for the latest events

QC Section – SMART-QC: Resource Planning and Scheduling for QC Laboratories

3 major steps in managing QC laboratories:

- **Do I Have Sufficient Resources?** Using Smart-QC, we can determine if we have sufficient number of analysts, at the right locations (labs) with the right training. We can also check if we have adequate number of instruments to support a given forecast. In case that there are issues / gaps, Smart-QC can be leveraged to run "What-if" analysis to determine what Additional Resources maybe be needed, Shift Structure, Analyst Allocation (internal / external), Cross Training, Special Projects that could be rescheduled, Campaign Optimization etc. Once a detailed plan is established, the lab team will focus on execution.
- **Execution:** As a routine operation, once the samples arrive, Smart-QC will support the managers and supervisors in allocating the various tests required to release the samples to various analysts, based on work-load, due date, critical path, training, and other configured parameters.
- **Monitoring:** This step is aimed at identifying trends, short-falls, and opportunities for improvement as part of the management review. Smart-QC provides a robust reporting tool to help manage the daily, weekly, monthly and longer term planning and trending as part of the DMAIC CONTROL step.