

Efficiency Management in Quality Operation

cME & Smart-QC Newsletter

MAY 2009 , Issue 17 - QC Analyst & QA Reviewer Availability: Tracking and Benchmark

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*

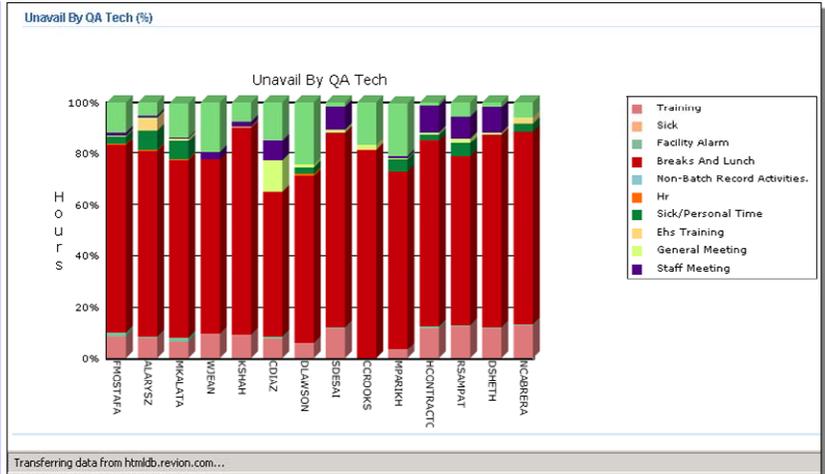
Please be sure to register for our upcoming Webinars: Documentation Errors Reduction Methodology and Overall QA Efficiency, KPI in Quality Operation and Resource Planning, Scheduling and COQ for QC Labs.

This Newsletter is dedicated to Tracking QA/QC professionals' Availability for cost, planning and scheduling

Introduction: Our previous newsletter was dedicated to Efficiency Management business processes as part of the overall attempt to reduce Cost of Quality and better compete in current economic conditions and off-shore low cost manufacturing. A key part of managing efficiency is the resource availability and how to account for activities that are not directly related to sample / batch. Previously, we discussed how to convert the throughput / activities performed into earned hours based on pre-defined standards and compared these to the available hrs. This ratio can be used as a Workload Meter for planned activities and Efficiency Meter for performed activities. Available hrs. is defined as the remaining hrs to perform activities such as tests / audits (QC), batch record review, inspection / audit (QA) and more out of the total weekly shift. For example if a shift is 40 hrs./week, once we deduct training, meetings, etc. we end up with 30 hrs. which then could be used for the more direct activities.

In most cases, companies who are collecting this type of data are realizing that what they get from a FTE is 40-60% test related activities in a lab, and slightly higher in the QA. The following charts illustrate the types of activities that are captured in Smart-QC and cME that help the management team to see where the unavailable time keeping staff from performing direct QA/QC activities is spent and take action as needed. This in most cases is where a lot of waste is generated in participating in ineffective meetings, excessive NVA projects, and more.

In order to obtain control of these activities, a company must establish well defined activity types and list of activities, institute policies regarding what should be the balance between direct activities vs. indirect activities and enforce that via a weekly review meeting. Policies could include (in QC for example) how many hrs per week should be focused on test/audit related activities vs. other, and set expectations to what we would expect from an efficient and effective analyst (i.e., 30-35 hrs of test related activities). Similarly in QA, for the release group, the expectation should be 30-35 hours of batch record related activities. Once the data is collected on a regular basis, the Process Excellence team could leverage the information to initiate projects that eliminate non-value added activities, streamline processes that generate waste and track improvements over time by leveraging this platform. Having the visibility on where time is spent in the lab or in QA is a critical element in achieving Efficiency and reducing Cost of Quality. In the end better knowledge of the various non-test / non-BR activities is critical for planning and also, due to lack of visibility, we may over / under estimate resource needs and get into overtime and backlog situations.



Rows Test Detailed Activity Summary

Activity	No. Of Occurrences	Avg. Actual Hrs	Avg. Plan Hrs	Avg. Actual / Plan
Change Control	7	3	5.7	53
Controlled Documents and Records	3	3	4.3	69
Customer Requests	3	2.3	4	58
Data Monitoring	1	4	1	4
Equipment Validation	5	2.8	4	7
General Cleaning / House Keeping	4	4.5	4.0	90
General Maintenance	2	3.0	4.3	69
Glassware Washing / Autoclave	1	0	10	0
IT - CDS	3	8.3	7.7	109
Inventory Supplies / Purchasing	2	4	6.5	62
LIMS - Create Query	2	0	3	0
LIMS- Preassessed Change Control	2	5	4.5	111
LIMS- User Accounts	1	2	4	5
Method Validation L24 (Develop Prod/ Methods	2	4	6.5	62
Notebook Archiving / Logbook Review/ Gen data review	1	0	0	0

Unavailability Distribution Summary

Unavail Type	No Of Occurrences	Avg. Duration Hrs	Total
Special Project	12	7	84
Training	27	4	108
Vacation	8	8	64
off-site	2	8	16

Summary

Training	115
Special Project	81
Vacation	60
off-site	16
Sum - 272	

Upcoming Events:

- May 11th, 18th on **Planning and Scheduling in QC Laboratories** www.smart-qc.com.
- May 15th on **KPI In Quality Operation**.
- May 8th 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