Efficiency Management in Quality Operation
cME Newsletter

August 2008 , Issue 8

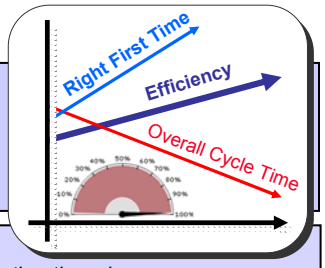
Dear Colleague,

Welcome to cResults Newsletter, designed to offer you insights, news, information about Quality Operation Efficiency Management, Software solutions: cME (www.cmanageefficiency.com) to manage batch record release and overall QA efficiency, and 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*

In this Newsletter we have dedicated a section for our QC Laboratories Resource and Planning web based software tool and related tips regarding QC.



Tips of the Month

Some of our Key Performance Indicators (KPI), which are metrics used to help an organization define and measure progress toward organizational goals, need to be dynamic. A certain KPI should always be monitored while other should be more dynamic to enable the operation excellence team measure specific progress related to a project / initiative.

Key Performance Indicator – QA Tech Efficiency Measure

In order to address cycle time, we can leverage the batch record to capture most of the critical milestones affecting the release process – delaying the product from reaching its final destination => Patient.
Here are some of the main components that can be measured by leveraging the batch record:
Batch Record Review Time (Time the batch record spent in QA from the time it was received, assigned, reviewed and a decision was made); Batch Record Delays: Once the QA completed their review, the usage decision may not take place as a result of issues such as: pending Investigation / CAPA; Pending QC Sample Release; Pending validation and more. Other delays can be attributed to Mfg. Turn Around Time once errors were found in the batch record.
As can be seen, the overall release time could be comprised of several different components and not necessarily caused by the actual review duration. So it is in our best interest to capture these milestones so we can address the true root cause of the cycle time delays rather than blame it all on QA when the measure only captures the time from its arrival to QA and the time the usage decision was made.

News and Events

Upcoming Events:

- Upcoming Webinar dates: **August 29th and September 1st."Managing Batch Record and Overall QA Efficiency"**
- Please visit our web site **www.cmanageefficiency.com** or **www.cresultsconsulting.com** for the latest events

News:

- Read about Managing Efficiency in Quality Operation by cResults and Par Pharmaceutical. This article describes the journey toward operation excellence in quality operation. (both laboratories and quality assurance operations)
- The article link is available at www.cmanageefficiency.com or www.cresultsconsulting.com

QC Section

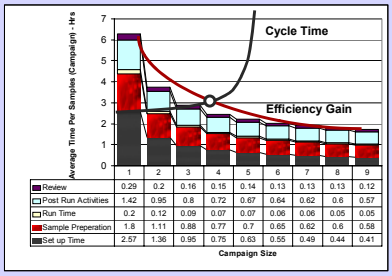
More About Smart QC – Resource Planning and Scheduling for QC Laboratories

- Why is it a complex problem to schedule and manage the lab: A simple example will illustrate the QC complexity often ignored: If we will use an average of 40 samples a day (all labs) and 6 tests per sample with 10 day turnaround time than the number of tasks that need to be scheduled and managed are 2,400 !!! (40*6*10).

How To Optimize Campaign Size in the Lab?

- Often, the Lean Sigma / operation Excellence team is challenging the QC lab to reduce its campaign size up to one sample in order to reduce the overall cycle time. This typically results in efficiency losses of up to 30% which are actually causing the opposite effect as the lab becomes busier and their queue is getting higher. So both extremes are not desired. Not a long campaign (i.e., 7-8 samples) and not ONE. It is suggested to develop a chart as illustrated on the right that shows the diminishing return of campaigning once the main efficiency gain is achieved (this could be after 2-4 samples).
- By balancing between high campaign and efficiency we could better serve our overall supply chain. This is not to say that we should not make a constant effort in reducing sample prep., and instrument set up yet we should try to optimize between cycle time and efficiency.
- For more information about smart-QC please visit us: www.smart-QC.com

SMART QC
Manage Efficiency



	1	2	3	4	5	6	7	8	9
Review	0.29	0.2	0.16	0.15	0.14	0.13	0.13	0.13	0.12
Post Run Activities	1.42	0.95	0.8	0.72	0.67	0.64	0.62	0.6	0.57
Run Time	0.2	0.12	0.09	0.07	0.07	0.06	0.06	0.05	0.05
Sample Preperation	1.8	1.11	0.88	0.77	0.7	0.65	0.62	0.6	0.58
Set up Time	2.57	1.36	0.95	0.75	0.63	0.55	0.49	0.44	0.41

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