Efficiency Management in Quality Operation
cME Newsletter

July 2008 , Issue 7

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.

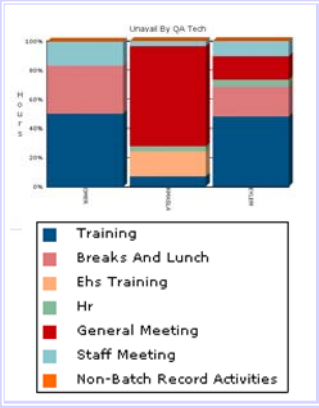
We hope this issue of cResults Newsletter will spark new ideas to help you better manage your quality operation, and improve your customer service level. At the end of the day, your success is our success.

Sincerely,
Rafi Maslaton *President, cResults*

Tips of the Month – *Communicate Errors via Structured Form to your Production Partners*

In order to improve the ownership and accountability of the Mfg. and Packaging response to documentation errors, provide them with a formal document for correction that includes, the time it was reviewed, the QA reviewer in case there is a clarification needed, the reason code for failure, the description of the failure, the page / section it occurred. This can lead to 15-20% improvement in response time for corrections.
The example on the right shows the standard forms coming out of cME that is used as an attachment to the batch record and then returned to the error owner for corrections.

Key Performance Indicator – QA Tech Efficiency Measure



In our previous newsletter we briefly discussed the QA Techs efficiency measure. Here is a more detailed description on this method *(how to calculate efficiency)*. One of the most challenging key performance indicator in quality operation is efficiency of the QA techs. We have worked with several clients and refined the method of measuring QA Efficiency as it relates to the QA effort.
The QA efficiency calculation is done by establishing standards for QA activities and measuring the earned hours during the shift based on activities completed vs. the overall hours in a given shift as follows:
- Earned Hours = Σ All Activities Performed * Standard time to perform these activities
- Available Hours = Available direct staffing hrs – Σ All the planned unavailable activities (i.e., meetings, training)
QA Efficiency = (Earned Hours / Available Hours) * 100%
The available hrs. should exclude NON Direct QA Activities such as training on company policy and procedures, meetings etc., however these need to be collected as well in order to assess the overall activities performed by QA professionals.
The method of establishing standards, the level of detail required for these standards, how to deal with activities for which standards could not be established, are some of the challenges need to be addressed when attempting to measure efficiency.

News and Events

Upcoming Events

Upcoming Webinar dates: **July 25th and July 28th.**”**Key Performance Indicators in Quality Operation**”

Please visit our web site www.cmanageefficiency.com or www.cresultsconsulting.com for the latest events

News

cResults and Par Pharmaceutical will be featured in Pharmaceutical Processing in the upcoming July Magazine, the article discusses the journey to efficiency in quality operation (both laboratories and quality assurance operations)

New cME Features

cME is now providing its clients with Robust cycle time reporting tool. These reports can capture the overall cycle time both review and production as it is reflected in the batch record tracking milestones. Although QA is not directly involved in the Mfg. and Pkg. processes, the batch record is reflection of all the supply chain delays / issues such as: Pending investigation/CAPA, pending for QC results, pending validation, pending QA review. The batch record can also be used to better identify these delays and provide the lean / sigma team a clear focus in order to reduce the overall cycle time.

What's New?

Our **Smart-QC**, a web based resource planning and scheduling software as well a platform to manage efficiency in quality control laboratories is now being offered as a service via the WEB. This provide small and large companies the ability to implement smart-qc on day-1, while the IT is being set up to host the application internally. **Please visit us:** www.smart-QC.com

cResults | 3 Executive Drive 2nd Fl. | Somerset | NJ | 08873

Efficiency Management in Quality Operation
cME Newsletter

July 2008 , Issue 7

ERD Information Systems

cResults consulting

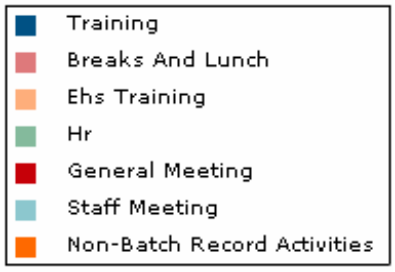
Title: Errors / Clarifications Report

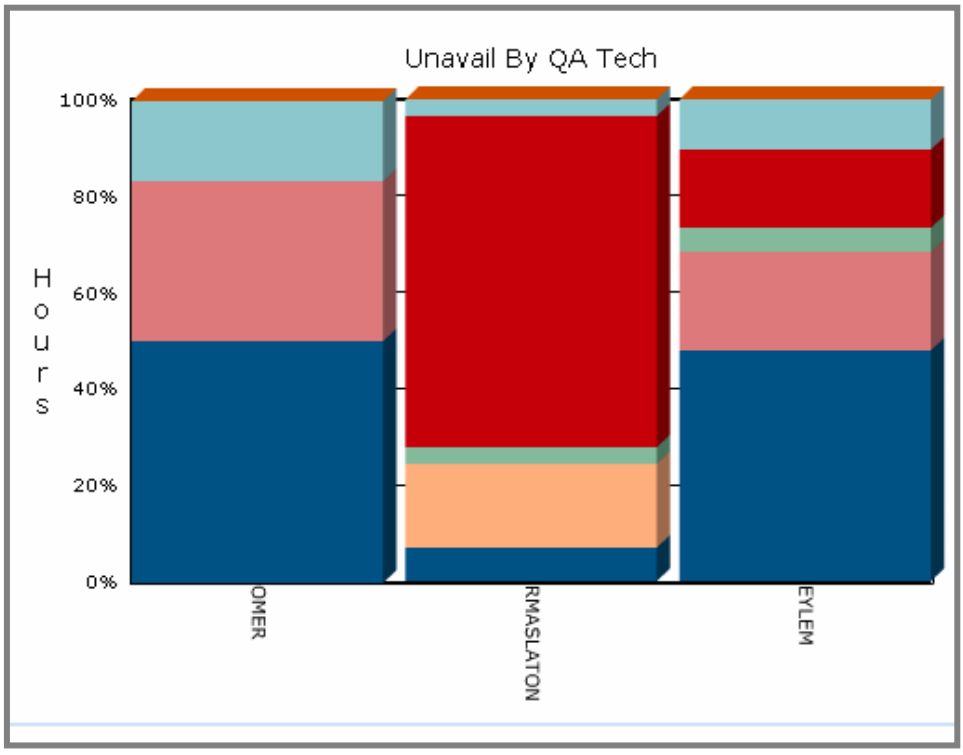
Product: 593.10.1 - ENALAPRIL MALEATE TAB 10 M PAR
Area: Packaging
Batch Record Number: 18506403
Date Received: 14-JUN-2007 17:24
Date Reviewed: 14-JUN-2007 17:44
QA Reviewer: KSHAH

Communicate Errors via Structured Form to your Production Partners

Errors / Clarifications List

Reason Code	Number of Errors	Owner	QA that Check	Desc \ Comments
Incorrect Data	1	BYOGESH	KSHAH	Ips filler and Elevator number is documented but used for slat counter
Missing Data	1	BYOGESH	KSHAH	Equipment list -Vision system number is missing





Compliance Manage Efficiency