

Efficiency Management in Quality Operation cME & Smart-QC Newsletter

JUNE/JULY 2009 , Issue 18/19 - The Effect of ALL Functions on the overall batch record release

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*

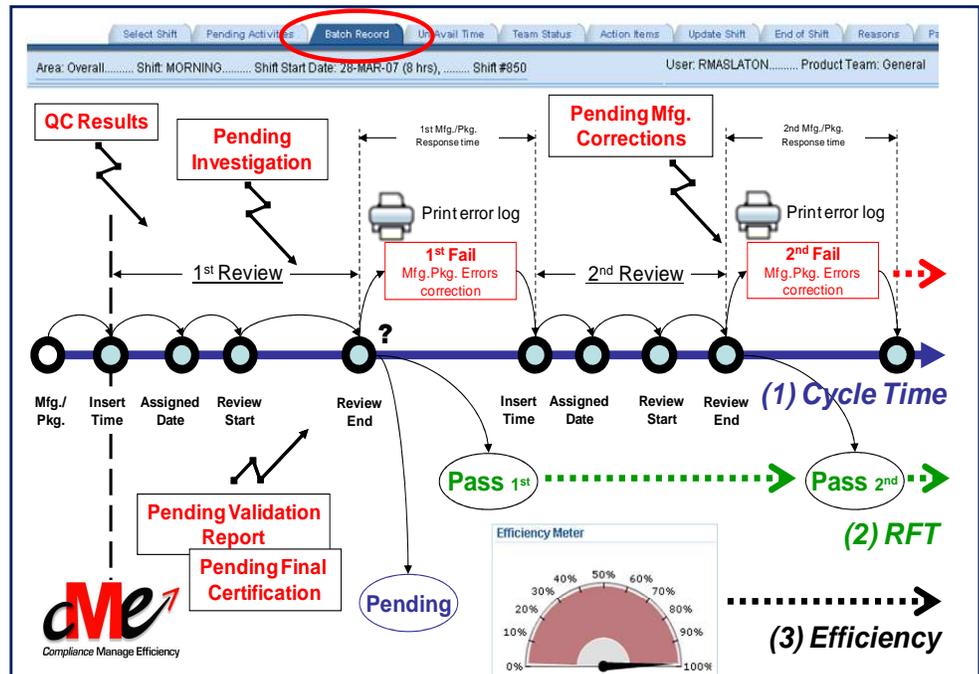
Please be sure to register for our upcoming Webinars: *Documentation Errors Reduction Methodology and Overall QA Efficiency, KPI in Quality Operation and Resource Planning, Scheduling and COQ for QC Labs.*

This Newsletter is dedicated to **The Affect of ALL functions on the overall batch record release**

Introduction: In today's economy, the 2 primary goals for most of the brand and generic companies are compressing their cycle time and reducing cost. Shorter cycle time provides many benefits:

- Reduce risk of exposed WIP when quality event is detected and due to a lengthier cycle time many other batches were exposed to the same equipment / issue hence may need to be rejected
- Lower cycle time is enabler to reduce overall inventory
- It reduces the sensitivity to demand fluctuation, reduce space congestion, improve span of control and more.

The cost reduction is a result of the new business environment and overall economy. In this newsletter, our focus is the holistic dependencies and relations between the various functions and events in the supply chain that affect the overall batch record release process.



Key Points: The chart above, outlines the overall mapping of a typical batch record flow from one area to another and the various events that can cause delays. The ultimate goal is to eliminate delays that are due to communication issues, recurrence of events that effective CAPA could eliminate and more. The common theme is transparency and the access to information and then to allow the key decision makers to quickly act on specific new information and enable the batch record to continue its flow to the next step.

Let's identify some of the critical elements that typically could delay the batch record release process:

- 1. Investigations:** This typically has the most significant impact on the batch record release in terms of time delay and it in many cases lacking the clear understanding that it delays a batch record. In other words, some investigations occur early in the process and are not in the critical path of releasing the batch record while many others are in the critical path and there needs to be transparency to understand which affect the overall release cycle time.
- 2. QC:** In most cases QC does not have the visibility when a sample release is at a point of delaying the overall BR release. The use of both Smart-QC and cME provides this link and enables the QC to know which BR is pending the release of the sample while others may still be in review, pending error correction or in investigation.
- 3. Manufacturing Errors:** Although our goal of using cME is to eliminate errors by addressing the root cause and improving visibility and accountability, we will still see some errors occur. The key is visibility and making the mfg. accountable for the cycle time impact by the time they take to resolve a BR error.
- 4.** There are other delays relates to validation and additional information requirements. These are less frequent as compared to the above.

Upcoming Events:

- June 19th 2009 & June 26th on **Planning and Scheduling in QC Laboratories** www.smart-qc.com.
- Will be announced on **KPI In Quality Operation**.
- June 22nd 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