Efficiency Management in Quality Operation
cME Newsletter

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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*

Tips of the Month

A simple way to establish efficiency measure to the review process can be achieved as follows: Set up expectations / standards related to review time (i.e., 1 Hr., 2 Hrs) for each area / product or a combination of both; record the number of reviews made by each reviewer times the standards and compare with the actual shift duration excluding breaks / non-batch record related activities. The calculated Hrs. earned vs. the actual shift duration * 100% provides a good starting point for efficiency measure. There are more elements that need to be considered – stay tuned for the next newsletter.

cME *Compliance* Manage Efficiency

Key Performance Indicator – RFT (Right First Time

While most companies record the minimal data to calculate the right first time, it is critical to connect that measure to our previous newsletter KPI that was cycle time. Focusing on RFT as the main metric may lead to prolonging the cycle time when manufacturing or packaging may spend more time and numerous reviews to ensure ALL errors were found. However, this, in many cases, adds several days sometime to the cycle time that at the end although improves the RFT as a single metric, hurts the overall service level by adding several days to the overall cycle time.

Efficiency Improvement

One of the most dominant causes for batch record release delays is attributed to deviation / investigation / CAPA. Most companies, even with transition to electronic QMS to enhance their ability to track and automate the investigation/CAPA process, were not able to quantify the impact on the release process. Hence, in most cases, the cycle time related to resolving an investigation is typically counted against QA. It is critical to provide the breakdown of cycle time loss due various causes such as pending for investigation resolution, pending for QC results, pending for validation reports vs. pure review time.
Here are some of the key items that could help reduce the overall Investigation Closure time:

- Early detection that there is a quality event and determination if this event should be documented as a full investigation
- Effective root cause analysis
- Facilitate resolution and management decision when applicable
- Effective CAPA should be put in place not only to satisfy the required closure, but to truly prevent reoccurrences.
- Institute a culture of discipline, accountability, and teamwork

Events

Upcoming Events

Upcoming Webinar dates: **June 27th and June 30th**.
Please visit our web site www.cmanageefficiency.com or www.cresultsconsulting.com for the latest events

New cME Features

Audit trail was introduced recently as mentioned on our previous newsletter, since than we have enhanced our capabilities to associate batch records to intermediates or common blends to enable our users to have an accurate cycle time measure for a finish good product by seeing all the other associated batch records that were used to create the final product. Also cME provides the ability to see, in a tree like format, all the associated batch records and there statuses to facilitate a fast resolution to meet aggressive and demanding cycle time and supply chain visibility

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 includes substantially more reports and our test allocation algorithm was enhanced to better manage cycle time, efficiency, and on time delivery in QC laboratories. Please visit us: www.smart-QC.com

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