

The Ultimate Application to Manage your QA Efficient Compliance

cME - Compliance Manage Efficiency: Key Points

Executive Summary

- cME** is a web-based application that creates a **continuous improvement platform** for QA organizations. It was developed to help pharmaceutical companies improve their **QA efficiency, improve visibility, increase value-added compliance, and increase accountability and ownership.**
- cME** supports the QA team in improving managerial capabilities and **efficiency management** in areas such as: Overall **Batch Record** life cycle, **Audits, Clearances, Swabs, Inspections**, Time spent on SOP / Deviation / Monitoring and more.
- cME** provides few simple steps to improve shift and **efficiency management, pass down, shiftly reports** and has a **real time electronic whiteboard.**
- cME** provides **robust reporting** and trending capabilities and reduce reporting time and data collection time.
- cME** provides accurate and **factual** quantification for all QA activities and sets **clear expectations** and standards for each of the QA activities to ensure adequate time is being spent where needed
- cME** assists **Lean / Six Sigma teams** in **identifying opportunities** for operation excellence projects by **measuring deviation from standard** and trends / root causes / variability in actual performance. cME enables a **continuous measurement** of the impact of ongoing lean / six sigma projects, so benefits can be measured corrective actions taken.
- cME** is **easy to implement (within 2 weeks)**, and simple to use,

- ↑ Improve Efficiency ↑ Improve Value-Added Compliance
- ↑ Improve Visibility ↓ Reduce Cost
- ↑ Increase Accountability ↑ Increase Ownership



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Value Add – Key Points

The following section outlines the various benefits and value add cME delivers to a typical organization:

-  QA Executives and Managers can use the Executive Dashboard which outlines Quality operation performance. Key Performance Indicators (KPI) and includes Compliance, Batch Record, Efficiency, and Pass-down.
-  Managers will be able to track and manage any QA Action items derived from audits, clearances, general activities or manually entered with observation types and details, owners and due dates.
-  QA Managers will easily manage workload and assign tasks to team members at the click of a button through cME which is single web based platform instead of multiple disconnected applications. QA Techs and Managers can use this information to manage, assign and re-assign tasks to better distribute and balance the workload for the QA team.
-  QA Managers will be able to manage and measure efficiency for various activities such as Batch Records, Audits, Clearances, Inspections, Swabs, General Activities, and identify Non-Value Added activities for improvement.
-  Your team will be able to reduce batch record release cycle time and help lead documentation errors reduction with improved visibility through cME. QA Techs will execute batch record reviews for multiple stages, record errors, track cycle time with easy access to status, history, past errors and monitor number of revisions to release the batch.
-  Users can view the frequency of events and error rates for various activities and compare them to compliance standards and department procedures. Also, observations/action item types from activities and error types from batch record reviews are tracked and trended by area, type, time period, and owner so systematic improvements can be initiated.
-  QA Techs can use the cME's whiteboard to effectively map out their day. User's whiteboard allows them to see their assigned tasks, add and execute new tasks, observations, action items, and provides feedback on planned, actual, and real time workload and efficiency.
-  Your team will be able to utilize the Pass-down module which provides a collaboration page for different shifts for comments / highlights, overall completed tasks during a given shift by all QA members, and any pending activities or action items.
-  Users can define desired search criteria for reporting and can glance at data by selecting a date range and topic (i.e., compliance, efficiency, batch record), and choose from over 30 built-in templates designed for presentations. You will be able to reduce time spent on reports/metrics/KPI.
-  With cME, cycle time for each task and batch record review is tracked and analyzed from the task creation to task execution and wrap up which also helps reduce response time to issues. Current in process activities are also provided for team collaboration.
-  And finally, cME comes with structured approach to manage QA operation that will help you make the right decision related to project selection, organization budget, and provide your production partner with the focused information to improve efficiency and compliance.

