

The Ultimate Application to Manage your QA Efficient Compliance

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

cME – Compliance Manage Efficiency is a fully web-based application that creates a continuous improvement infrastructure for QA organizations.

ERD Information Systems cResults consulting

cMe

Compliance Manage Efficiency

The Ultimate Platform to Manage your Efficiency

cMe Login

Licensed To ERD Information Systems

User Name

Password


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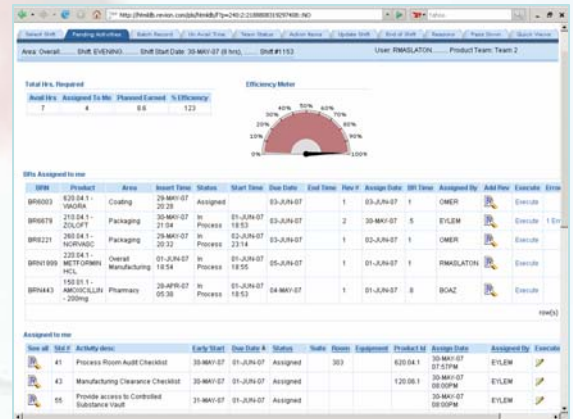
Creating A Continuous Improvement Infrastructure for QA organization

A platform to manage all type of QA activities:

-  Audits
-  Inspections
-  Clearances
-  Batch Record Release
-  Swabs
-  QA Standards Management
-  Resource Planning

cME – Key Modules:

-  Efficiency Management
-  Batch Record Release
-  Standards and Resource Planning



cME - Key Benefits

- Visibility for QA efficiency losses, value-added compliance, observations, and root causes
- Immediate feedback on shift status and performance
- Improve Batch Record release time visibility and Right First Time documentation
- Better trending and tracking of observations, failures and action items
- Comprehensive and configurable compliance and efficiency management dashboard
- Provides the infrastructure for continuous improvement.
- Offers meaningful key performance indicators

Features and Functionality

- Tablet PC data collection
- Wireless Link-up
- Flexible form generation
- Configurable to meet your QA structure
- Easy to use and provides security level that aligns with your structure
- Robust reporting tools with multiple, pre-defined templates

WHAT ARE THE ANSWERS TO ALL THESE QUESTIONS?



Improve Value-Added compliance

In today's business environment, **operational challenges** such as **cost reduction**, **cycle time reduction**, improved **efficiency**, **Right First Time**, and **schedule adherence** are recognized as imperative issues. QA is often viewed as a **non value-added function** that is inefficient and unable to add value to the business. *cME can help change that paradigm.*

cME – Compliance Manage Efficiency is a **web-based application that creates a continuous improvement infrastructure for QA organizations**. It was developed to help biotech and pharmaceutical companies improve their QA efficiency, improve visibility, increase value-added compliance, and increase accountability and ownership. cME is easy to implement, simple to use, and **provides 5 Simple Steps to Improve Shift Management**.

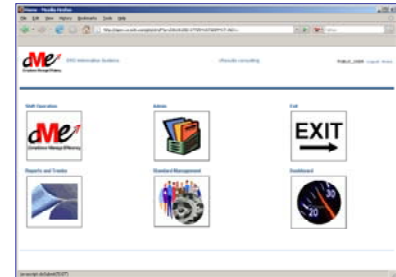
cME - Efficiency and Compliance Management System also aims to provide robust reporting and trending capabilities and reduce reporting time and data collection time:

- Allows shift data and audit data to be collected using handheld devices
- Provides robust reports of compliance and efficiency trends and KPIs

cME - efficiency management application assists **Lean / Six Sigma** teams by enabling the following:

- Identification of opportunities for lean / six sigma projects by measuring deviation from standard and trends / differences / variability in actual performance
- Continuous measurement of the impact of ongoing lean / six sigma projects, so benefits can be measured corrective actions taken

cME General Flow



- 1 Record shift data / audit information via Tablet PC / Hand held devices



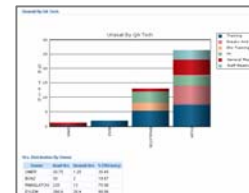
- 2 On-Line / Off Line data download / sync – end of shift



- 3 Print Reports: Compliance and Efficiency measures



- 4 Manager and Executive Dashboard



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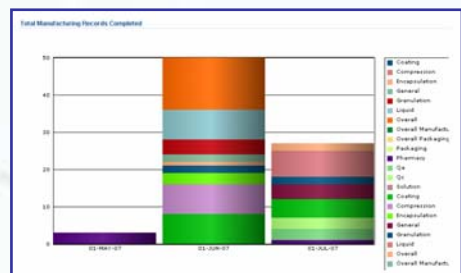
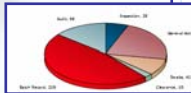
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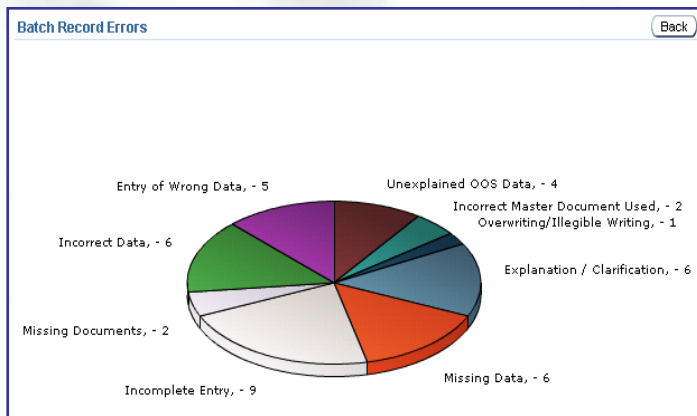
Simple Steps To Improve QA Shift Management

At the beginning of the shift QA Techs log in and review pending activities / batch records assignments enters expected in-direct activities (i.e., meeting, training) Then, the techs perform & record activities using Tablet PC (i.e., Audits, Inspections, Swabs etc.) or their desktop for Batch Record review. While performing their assigned activities, they record observations / action items related to the above. At the end of the shift each tech updates completions, pass-down notes and provide loss of efficiency reasons and receive an efficiency score. Managers review current activity status, efficiency results and compliance trends via the cME dashboard and initiate Operations Excellence/Lean/Sigma initiatives accordingly.

Activity List Summary			
Activity Description	Total Count	Avg. Cycle Time	# Of Observations
Inspection	28	249.71	9
General Activity	101	113.90	1
Swabs	41	122.20	1
Clearance	10	68.54	4
Batch Record	219	621.99	58
Audit	66	285.93	18



Metrics includes: Efficiency by QA Tech, Right first time (RFT), Avg. review time by Mfg., Avg. review by QA, Avg., Avg. cycle time for general QA activities, Errors found per BR and more



cResults, an affiliate of IPS, provides consulting services to improve the overall operational performance of its clients by reducing costs, increasing productivity and improving overall organization efficiency. cResults is the leader in Operations Consulting specializing in the Life Science and Microelectronics Industries. Founded in 2005, cResults is owned and managed by industry trained and experienced professionals.

ERD Information Systems is a leader in providing software solutions for diversified industries. The company was founded in 1998 in Israel and started its US operation in 2002. ERD information systems mission is to provide state-of-the-art enterprise-wide software management tools that help streamlining operations, improve efficiency, lower costs and reduce cycle time. The company's flagship product, Smart-QC was developed with some of the industry leaders to address a broad operational complexities of the manufacturing and laboratories.



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