The Ultimate Application to Manage your QA Efficient Compliance – Batch Record Module

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.

cResults
Boosting Operating Performance

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Creating A Continuous Improvement Infrastructure for QA organization

A platform to manage all type of QA activities:

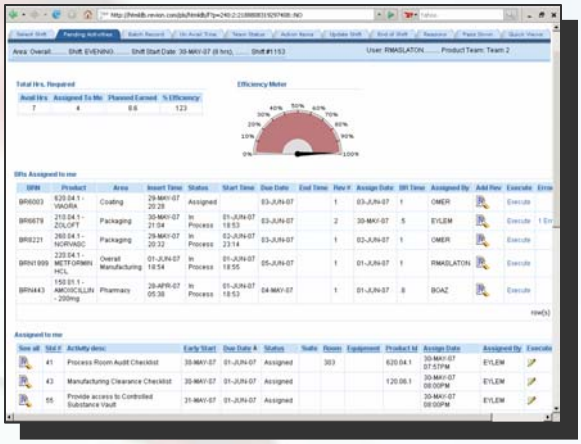
- Audits
- Inspections
- Clearances
- ***Batch Record Release***
- Swabs
- QA Standards Management
- Resource Planning

cME – Key Modules:

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

cME IS THE ANSWER TO ALL THESE QUESTIONS

- **What is the Right First Time (by area / product)?**
- **What is the QA review cycle time?**
- **What is the Mfg./Pkg. response time to correct documentation errors?**
- **What are the main delays / pending issues causing BR delays?**
- **What is the impact of investigations / CAPA closure on the BR release time?**
- **What is my reviewer's efficiency?**
- **What is the RFT by QA tech, and what leads to the variability between QA techs?**
- **What are the causes for time losses for my reviewer's?**
- **What are the value added reviews / stages throughout the release process?**
- **What is the breakdown of the documentation errors?**



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

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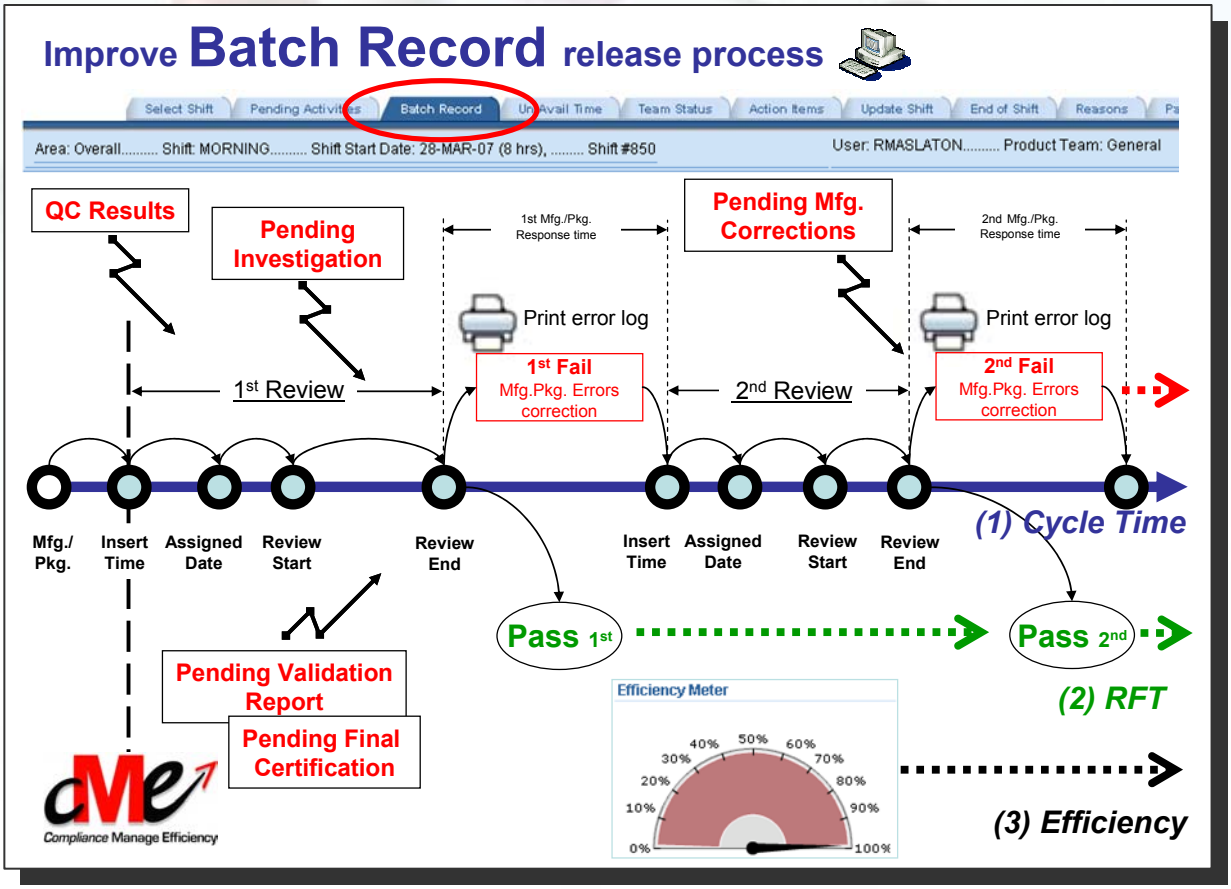
Improve Batch Record Visibility & Efficiency

- **cME** – Compliance Manage Efficiency is the application that enables managing **3** critical elements of batch record release process:
    1. **Cycle Time** – The turn around time for QA to perform various stage / full review and manufacturing to respond to errors / clarifications / issues identified by QA.
    2. **Right First Time** (RFT) Documentation.
    3. **Efficiency** – The ability of the QA reviewers to perform the review in a timely manner.
- **cME** – Compliance and Efficiency module can help improve accountability and ownership by providing root causes and traceability to the error source.
- cME – Manages the complete batch record process from the introduction of a new batch record throughout its statuses (e.g., pending investigation, pending QC, pending Mfg./Pkg. correction) until the disposition is completed as can be seen in the chart below.



cME Provides the Building Blocks to effectively Manage Batch Record Release Process

cME Batch Record Module addresses all aspects of batch record building blocks toward optimized release process:

(1) **c**ME highlights the deficiencies in the batch record layout by pointing out the locations of documentation errors;

(2) **Q**uantify the impact of investigation closure time;

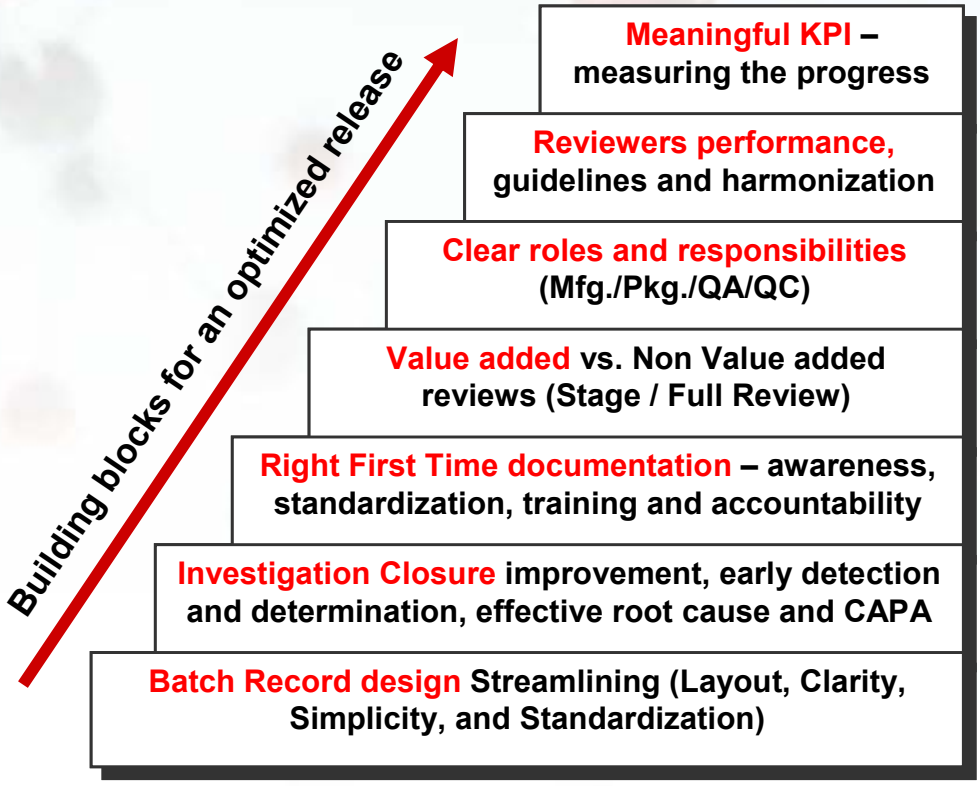
(3) **P**rovide ample out-of-the-box key performance indications on Right First Time Documentation;

(4) **c**ME allows the lean / six sigma improvement teams the quantification of value added vs. non-value added reviews to define the review model;

(5) **c**ME structured approach enforces a clear roles and responsibilities for all participants in the review process;

(6) **T**he efficiency management module provides the reviewer efficiency KPI, and finally

(7) **c**ME is equipped with powerful queries and reports templates to oversee trends, performance metrics and monitor daily / weekly / monthly reports



cME – Batch Record Release Management: General Flow

cME Batch Record Module provides an effective platform to manage the overall batch record release process:

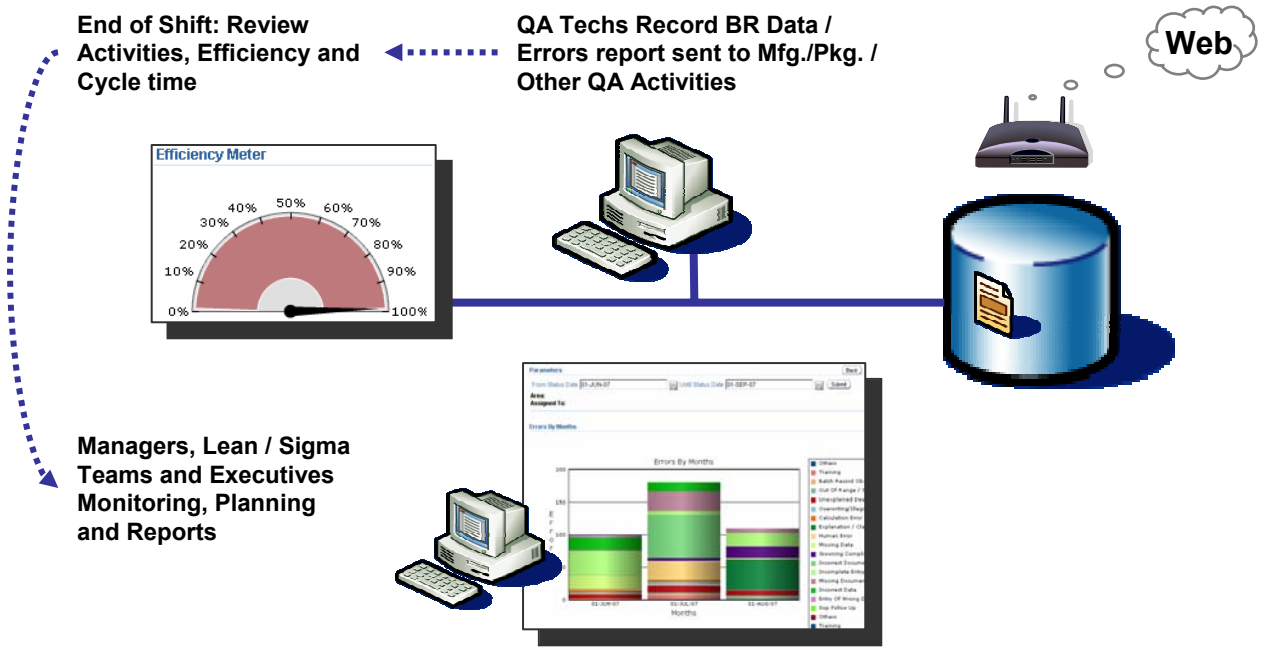
(1) **A**t the beginning of the shift QA Techs log in and review pending batch records assignments

(2) **E**nters expected in-direct activities (i.e., meeting, training) Then,

(3) **T**he QA techs review the BR and update cME with the applicable information

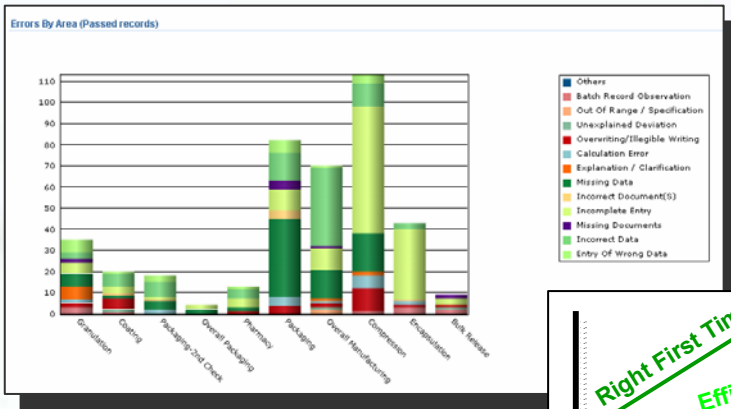
(4) **A**t the end of the shift each the QA tech review the shift performance and update pass-down notes and provide loss of efficiency reasons and receive an efficiency score.

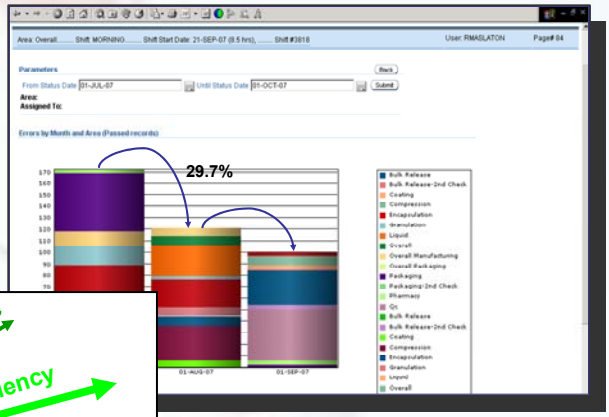
(5) **M**anagers review current batch records status, efficiency results and compliance trends via the cME dashboard and initiate ***Operations Excellence/Lean/Sigma initiatives accordingly.***

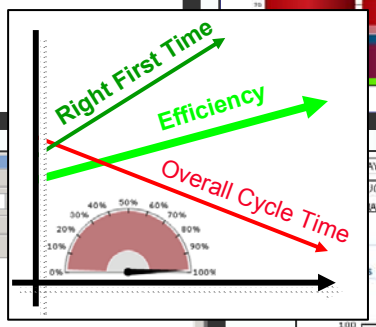


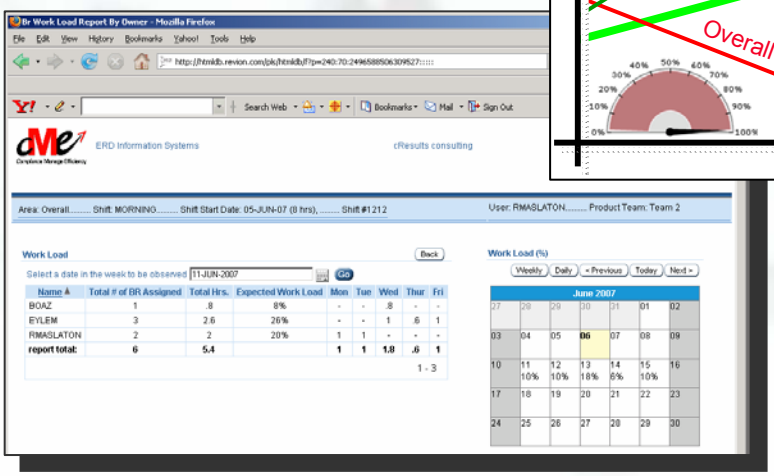
Batch Record Management Reports

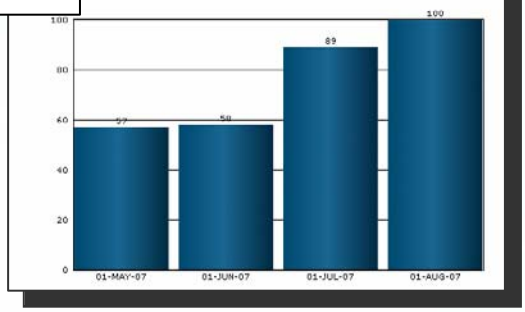
Metrics includes: Efficiency by QA Tech, Right first time (RFT), Avg. review time by Mfg., Avg. review by QA, Avg., Avg. cycle time for general QA activities, Errors found per BR, work load expected based on queue and backlog and more











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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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