Managing Batch Record Releases & Overall QA Efficiency

ROI – Areas of Improvements

Creating A Continuous Improvement Infrastructure for QA organization by affecting the following KPI

1. Cycle Time

- ✓ Reduce cycle time.
- ✓ Measure cycle time milestones as a mean to improve the overall cycle time performance which includes:
- ✓ Measure Pending Status (QC, Customer, Deviation, Validation effect on the overall cycle time)
- ✓ Release Cycle time
- ✓ Mfg. cycle time breakdown

2. Service Level

- ✓ Provide the ability to respond quickly to customer/sales inquiry regarding status of Batch / Product. (Reduce time to search for a batch record / location of the BR.)
- ✓ Help prioritizing QC samples, that delay release of the BR by leveraging out-of the box reports and query tools/filters in cME.

3. Improved Overall Visibility and Span of control

- ✓ View a complete Tree of batch record with all the associated sub batches to be able to identify status, cycle time, owner, expected release. This could improve the ability to expedite where applicable BR that are gating us from meeting monthly / quarterly shipments.

4. Reduced Documentation Errors

- ✓ Measure and Improve RFT (Right First Time) by leveraging the structure approach offered by cME
- ✓ Leverage the system to improve the following
- ✓ Improve information availability and provide a more real time feedback on developing trends and issues related to BR (i.e., new product, new BR design, individual errors that could be corrected sooner, etc.)
- ✓ Increase manufacturing / packaging involvement by providing the information in timely manner
- ✓ Improve accountability and ownership
- ✓ Improve data structure, and visibility to error type / and operator involved to better identify the root causes for the error, hence eliminate these errors from reoccurring.
- ✓ Reduce the overall response time to correct BR errors.
- ✓ Measure the RFT on the overall site cycle time and customer service level.

5. Expected Efficiency Gain

- ✓ Reduce time involved in generating key performance indicators.
- ✓ Reduce Non-Value-Added (NVA) activities as it relates to reports, chasing information, expediting, communicating, and more.
- ✓ Identify other potential NVA activities that are being performed by the QA operation group and should be eliminated or delegated to Mfg./Pkg.
- ✓ Increase management span of control, and decrease response time to QA issues, hence improve overall cycle time and service level.
- ✓ Improve QA review consistency by providing metrics and information by each individual.

cME Compliance Manage Efficiency

cResults

cME is affordable, enhances value added compliance, and implementation takes **ONLY 2 weeks**.

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Be ahead of the curve with cME

Desired Improvement Areas - by leveraging cME

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6. Systems Consolidation & Standardization

- ✓ Reduce number of various local manual / MS excel applications by implementing ONE platform to manage all business related quality operation information.
- ✓ Improve standardization within value stream, and between value streams / groups / sites by leveraging ONE robust platform.

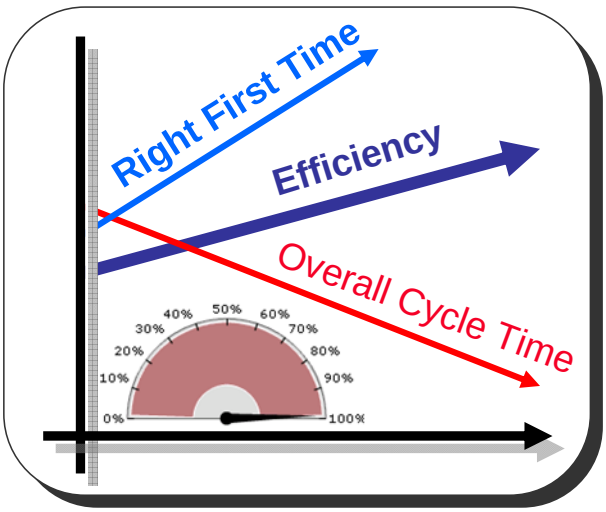
7. Standardization

- ✓ Provide a standard platform, and methodology to track batch record, manage efficiency and reports in quality operation.

8. Other and future usages of the cME platform

- ✓ Tracking time spent in various Quality operation projects / activities (i.e., RM Sampling, Swabs, Validation, Compliance initiatives)
- ✓ Cycle time by manufacturing steps and packaging in addition to batch record release, deviation etc.
- ✓ Efficiency management throughput the quality operation

cME is configurable solution designed to help Quality Operation Meet and Exceed Their Goals



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