



Deliver Paperless Manufacturing that drives Right First Time Production

“Each batch can involve about 1000 manual entries with a human failure rate of one in a hundred.”

‘Paper on Glass’ User Centric Batch Operations - A Productivity Game Changer for Paper Driven Pharmaceutical Production’ - Pharmaceutical Engineering Magazine

To ensure conformance to regulatory requirements, pharmaceutical manufacturers are required to document manual and automated procedures throughout the production process from the receipt of raw materials to the dispatch of finished goods. Managing this documentation takes time, is prone to human error, and may lead to extended review times when releasing finished product to the market.

Implementing Electronic Batch Records (EBR) will optimise your processes through the introduction of electronic work instructions to dramatically reduce production cycle times, and improve accuracy and consistency of the batch record. Implementing an EBR solution will deliver paperless manufacturing by replacing paper batch records, keeping track of the manual and automated batch history, and supporting the batch approval and release process through an online environment. An EBR solution will drive increased compliance, reduce the time to release and deliver right first time production.

What if ...

- You had a system that enforced defined workflows to ensure manual and automated activities are completed in line with your process requirements?
- You had a system that delivered an online batch record which could be integrated with other systems?
- You had a system that detects deviations and provides a dashboard to manage the early review and release of a production batch?

Did you know ...

- Right first time using a paper based system has been recorded as low as 47% with the causes of reworks being errors in documentation (38%) and missing entries (29%).

REGULATORY COMPLIANCE

Manually completed paper batch records can satisfy regulatory requirements; however it is labour intensive to document, review and retrieve paper based production information for compliance and decision making purposes. Reviewing paper batch records to resolve production issues may delay batches from being released from quarantine. The cost of quality associated with a paper based review is significant. The product stored in your warehouse ties up working capital and represents fewer inventory stock turns, and lost profits for your organisation.

RIGHT FIRST TIME

Automated processes ensure repeatable and right first time production, however challenges can arise with manual activities. Executing manual activities according to paper based standard operating procedures can potentially allow variability into your process. Slight variations in a manual production sequences may have an unknown impact on your product quality causing you to quarantine batches until a review can be completed.

REDUCED PRODUCT REVIEW TIMES

Each batch record must be reviewed before a product can be released for sale to the market. Implementing corrective actions or resolving problems associated with the batch record extends the time a batch may be held in quarantine. Collaboration using paper batch records can be difficult as only one physical master copy exists. Non conformances and quality issues must be coordinated and addressed by those working directly with the paper batch record.

OPERATIONS MANAGEMENT: ELECTRONIC BATCH RECORDS SOLUTION

ENSURING COMPLIANCE AND DELIVERING RIGHT FIRST TIME

Emerson's Electronic Batch Record solution provides a single environment to record and document both manual and automated activities. The system will collect data automatically from plant equipment guaranteeing data integrity. Embedding operator guidance within the workflow ensures consistent processes are adhered too. As users interact with the workflow all information is captured and recorded as part of the batch record. The system delivers a real time electronic environment integrated with other business and manufacturing systems and provides real time visibility for all orders.

REVIEW BY EXCEPTION

Emerson's Electronic Batch Record solution allows you to implement review by exception methodologies. All production details are captured in the batch record; this includes any exceptions or deviations which may affect product quality. The electronic batch record can be used to flag any nonconformities and a deviation report can drive your quality review to the remediation steps that will help to reduce the review process significantly.

DELIVER INTEGRATED MES AND DCS ENVIRONMENT TO REDUCE CYCLE TIMES

Emerson's Electronic Batch Record is the only system which provides a truly integrated solution. It is possible to use a single recipe authoring environment with Emerson's DeltaV™ distributed control system. Phases from the DeltaV system can be embedded into the recipe authoring tool and used to build a fully integrated MES-DCS recipe. This provides lower cost of ownership as there is no additional cost associated with testing or maintaining interfaces.

PROVIDE A SINGLE SCREEN FOR PRODUCTION OPERATORS

Emerson's Electronic Batch Record solution provides an integrated environment which pulls together information from ERP, LIMS, QMS, DCS and control systems. Data from the relevant systems is presented to the operator in the correct context providing them with a central location to operate their process. This integrated environment removes the need for data print outs or multiple terminals on the plant floor.

For more information, contact
your local sales office or visit:
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