

Paper on Glass

Sustainable production with Electronic Batch Records (EBR)

People provide flexibility in production processes. It is through them that complexities and abnormalities are easily mastered. But what drives the operator? In Life-science industries paper-based operation procedures and reporting is frequently used. As production becomes increasingly complex, Right First Time for 'paper-based' batch production is declining.



BATCH CONTROL DRIVING THE OPERATOR

Bringing together three key elements: Multi-Touch tablet operation, Batch Control and Dynamic Reporting. The operator works with user friendly tablets to execute tasks and record process data. The automated reporting then provides the batch record and analysis.

Reworks and rejects in paper-based production arise from two major contributors: i) Incorrect entries, where recorded data is written in the wrong place. ii) Missing data, where the recording step is conveniently missed.

With 'Paper on Glass' the operator is required to follow the procedure strictly. Without exception clearly marked data must be entered in the correct sequence, checks and limits can be applied, and the batch cannot continue without populating the requested fields, thus overcoming the missing entries and incorrect data. Thanks to zenon on portable devices 'Right First Time' just got a whole lot better!

AUTOMATED ANALYSIS AND REPORTING

Post batch analysis is expensive, difficult and time consuming. The piecing together of process data into a batch report is a

regulatory must for each executed batch. With zenon's 'Paper on Glass' application, the piecing together of information and analysis is completed automatically, and ready immediately once the last pill has left the production table. But zenon goes further: Automated reporting is not limited to batch reports: RBE (Report By Exception) reports are easy to implement, alarm analysis for QA or engineering is instantly viewed in a easy to read graphic format. Events can be viewed in real-time, where in the occurrence of a critical violation stop/go decisions can be made directly, not post batch. This package significantly minimizes costs and maximizes equipment availability.

PAPER MANAGEMENT A THING OF THE PAST

'When the QA documentation paper weighs as much as the production line, the batch is ready for release!' Paper management is a significant process to handle in Life-Science industries. From the Master batch record and its development through QA into production, individual operation procedures (SOP's) and the associated manual batch record need to be stored long term in secure environments, all this takes a significant slice of the revenue.

Digital storage is certainly easier to manage, consumes little space, and has significantly more possibilities to use the data. zenon Redundancy secures the archived information, and at separate locations if desired. The same production data can be used for a multitude of purposes, for example OEE (Overall Equipment Effectiveness) KPI's use the same information as the batch report.

FAST FACTS

- ▶ No change to equipment or process
- ▶ Validation efficiency
- ▶ Reduce cycle times
- ▶ Increase accuracy
- ▶ Cost avoidance; Right First Time
- ▶ Continuous improvement, new process flows
- ▶ Increase speed of new product introduction

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Validation efficiency	<ul style="list-style-type: none">▶ No change to equipment or process
Reduce cycle times	<ul style="list-style-type: none">▶ Enforce production execution sequence▶ Real-Time view of process status
Increase accuracy	<ul style="list-style-type: none">▶ Overcome missing data and incorrect entries▶ Time-stamping & confirmation of executed stages▶ Digital storage & archiving of production data
Cost of compliance	<ul style="list-style-type: none">▶ Production is executed consistently▶ Mandatory comments on deviations and exceptions▶ Analyze as a process not individual machines▶ Automated batch reporting, analysis, RBE
Cost Avoidance	<ul style="list-style-type: none">▶ No large volume paper storage▶ Eliminate paper production & paper Master batch records▶ Expand data usage, e.g. for OEE, energy efficiency
Continuous improvement	<ul style="list-style-type: none">▶ New process flows▶ Increase speed of new product introduction▶ Minimum Risk Model