White Paper on
Electronic Batch Records
for Pharma & Biotech
Introduction

Many people within Pharmaceutical and Biotech manufacturing believe that a manufacturing execution system (MES) equates solely to an electronic batch record (eBR) system. This is an over-simplification because MES covers all manufacturing operations: production, inventory, quality and maintenance. The reason for this over-simplification is often due to the relationship between the value drivers associated with MES and the alignment with business objectives.

The value drivers for MES can be summarised as follows:

- Reduce working capital
- Reduce direct costs
- Improve reliability
- Improve operating efficiencies
- Reduce manufacturing operation and supply chain risk

Manufacturing business objectives for a plant or site are often related to these value drivers. Business objectives are broken down into more specific details for roles and individuals within a manufacturing company, but business objectives should invariably align with value drivers. The primary objective of electronic batch records is to reduce the direct cost of quality by allowing a review of manufacturing records by exception rather than reviewing all records. Reviewing what went wrong on a validated process saves a huge amount of time and cost because reviews can be carried out during production. This review by exception can also be tied into the release of a batch to the supply chain which helps reduce work in progress (WIP) and inventory which reduces working capital. Having electronic batch record sequences also helps improve reliability and efficiency, albeit harder to quantify and measure. For our product, Shopfloor-Online, we have mapped our software modules to business benefit enablers and real benefits which roll up to the value drivers listed above. This ensures that Shopfloor-Online drives value into your business. Shopfloor-Online is 21 CFR Part 11 compliant.

The Details

An electronic batch record (eBR) is an instance of a master manufacturing batch record (MBR) for a product. MBRs and eBRs are electronic replacements for the paper based systems that many manufacturers have had in place for decades. Removing paper records from the plant floor and replacing them with an electronic and sequenced way of gathering the right data for the right product from the right authority at the right time allows the manufacturing records to be reviewed in parallel with production. The term paper-on-glass refers to a simple conversion of the paper based batch record to an electronic equivalent. However, the maximum benefit of an EBR is
delivered when the sequence has a means of creating events that were not-as-expected as it executes. Reviewing what went wrong as soon as possible after it has happened, allows deviations to be raised and linked to the event in a more efficient way. An electronic review and approval work flow for the completed electronic batch record allows the document to be electronically routed to the required groups and specific users efficiently without the transfer or paper records or batch books around the plant. As a result of having an electronic system for batch records, batch record reviews and approvals, the system should be able to give manufacturing the visibility to all batch records and their status. KPIs and metrics can be created around the reviewed, approved and released batches in order to drive down the direct cost associated with this business process.

**Master Batch Records**

An MBR is essentially a template for the sequenced collation of batch record data for a particular product’s manufacturing process. For batch manufacturing, the alignment between the S95 standard for MES with S88 for batch control systems is essential in order to deliver a best in class batch record solution. Batch processing can be complex, so MES sequence templates need to align with S88 for maximum configuration flexibility. Shopfloor-Online uses sequence templates and template type to differentiate between MBR and other sequence types (e.g. pre-manufacturing setup record, post-manufacturing clean-up etc.).

Shopfloor-Online uses a step-and-transition sequence model with action, phase, operation and procedure layers to align perfectly with S88. Shopfloor-Online contains an entity model with embedded application programming interface (API) calls (small blocks of code). These APIs are the action layer building blocks which can be used to build phases. The API input arguments and output(s) are parameterised. Input parameters for APIs can be deferred to the phase layer above. Phases are then used to build operations and operations to build procedures. Parameters can be deferred from each layer to the level immediately above. Shopfloor-Online has 3 library layers: phase, operation and procedure.

For multi-site implementations, close attention to master data such as process unit types is required to facilitate the strategic re-use of library elements. It is envisaged that phases and operations would be transferrable between installations using import/export functionality as long as the associated master data and application versions are the same. Library components can be designed using a drag-and-drop web browser based configuration screen. Full version control applies to each layer of the library. Editing an exported library component is possible for advanced users using Notepad for example.

- **Sequence Template Type = MBR**
- **Sequence Template = Product Name with version control**
API = Parameterised actions
Phase = a combination of one or more APIs with parameters
Operation = a combination of one or more phases with parameters that is associated with a unit type
Procedure = a combination of one or more operations with parameters that represent the collection of data required for the products master batch record.

The totality of an MBR can include materials, hazardous classification data, calculations, required standard operating procedures, equipment types, workflow events, workflow actions, data collection, specifications and limits, barcode label printing and electronic signatures.

**Electronic Batch Records**

An EBR is an executed instance of a version of the MBR for a specific batch of a product. The EBR sequences for each batch need to be scheduled and controlled in some way on any MES. Shopfloor-Online has a batch (work order) scheduler. Work orders can be scheduled either manually or using an automatic interface to ERP which detects new work orders released to production and then adds an EBR instance for that batch to the Shopfloor-Online scheduler. The status of the EBR can be controlled by users similar to a batch control system recipe. The EBR sequence can be put into a hold state. Each configuration layer for the EBR procedural sequence has steps and transitions. Transitions can be disabled to prevent the sequence from moving forward in the event of physical equipment failures or other interruptions. The scheduler and sequence controls have a full security modelling capability so only those with the correct access rights can interact with the sequence.

Interaction with an executing EBR in Shopfloor-Online entails a split screen interface in a web browser (i.e. Internet Explorer). The sequence steps and transitions are graphically represented in one part of the web page and a grid (table) containing the active actions, phase and operations in the other part of the screen. Users can interact with the next actions that require an input from a user. Double-clicking an action will display a form for the user to complete and/or click OK on. The sequence moves on when actions are completed with any not-as-expected results flagged as events that need reviewing.

The EBR sequence execution has status colour coding so that it is evident to users what the active step(s) in the sequence are. Users can browse around the sequence layers to get to the any step or transition within the sequence.

**Review by Exception**

In many plants with paper records, the batch book might be reviewed at the beginning or towards the end of every day for issues, however many issues are only caught after the shift has changed and the errors, omissions or missing initials and date-time entries may have to wait several days before being rectified.
In Shopfloor-Online, phases can be designed to create events for steps with results that were not-as-expected. This allows users to configure a solution that matches the criteria for when a deviation is required during the production of individual products at a batch level at least. The sequence can force the required entries to be made before moving on. This review-by-exception functionality enables departments within the manufacturing organisation to start reviewing the events in real-time. Review-by-exception functionality saves time and reduces direct costs as the review can be completed in parallel with production.

**Electronic Release**

When a batch book has been reviewed by each department and gone around the review cycle at least once, but possibly more times than people would like to admit, the batch book is signed by the relevant approvers and the qualified person (QP) has the ultimate responsibility for the release of the product batch to the supply chain and market. The status on the ERP system is usually manually updated once the batch book and all associated checks (including deviations) are completed.

In Shopfloor-Online, once the review by exception functionality is complete, the work order (batch) state is changed to “reviewed”. An in-built but configurable workflow for the approval by either personnel groups or specific individuals can be executed for the EBR. The completion of the approval workflow can be used to change the overall quality status of the work order (batch) to “released” in the MES and ERP systems.

**The Benefits**

Electronic batch records for batch manufacturing improves operating efficiency and reduces costs by:

- Providing real-time visibility to not-as-expected events in parallel with batch manufacturing to reduce the manufacturing lead time.
- Ensuring Right First Time manufacturing by avoiding missing entries and initials/signatures.
- Reducing the batch review effort by only reviewing things that went wrong, events that were not-as-expected rather than many pages of instructions with manual initial and date time entries.
- Reducing manufacturing investigation time and effort.
- Reducing the review cycle time by having an electronic approval workflow to signoff the EBR.
- Reducing the product release time from days to minutes or even seconds by automatically updating the work order and its quality status in MES and ERP.
- Reducing the net data entry effort for production.
- Reducing the cost of paper, paper processing, filing & safe storage for up to 11 years as per your record retention policy.
- Centralising all data related to the batch record business process to facilitate real-time metric measurement.
• Attracting more manufacturing business by showing that your process plant is in good shape - global metrics are coming, adopt KPIs early, but report when ready

The Conclusion

Shopfloor-Online MBR & EBR functionality can deliver huge efficiency and cost benefits to your batch manufacturing facility. The competitive advantages offered by the use of Shopfloor-Online EBR are too compelling to ignore.

Shopfloor-Online is a browser based application which allows users to configure a true library of phases, operations and procedures. With drag and drop configuration in a browser environment, Shopfloor-Online is designed to provide affordable and easy to configure EBR solutions to batch manufacturers with the terminology that customers want to use.

Don’t forget, there are many factors to successful Electronic Batch Record implementations – start by choosing LZ Lifescience and Shopfloor-Online.

Have a look at our sectors page for more relevant functionality for your life science manufacturing operations: http://www.lzlifescience.com/sectors

Please contact us for more information about Shopfloor-Online:

Email: info@lzlifescience.com or sales@lzlifescience.com
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