GMP ASPECTS OF ELECTRONIC BATCH RECORDING - PART 1

Helping to meet ALCOA+ requirements

BATCHLINE

This article is the first part of a series based on applying the ISPE GAMP GPG Data Integrity - Manufacturing Records

Electronic Batch Record (EBR) systems collect information about the process operation as the manufacturing progresses. Regulations require Batch Record data to be managed under the ALCOA+ principles, see the table below for a summary on how EBR ensures these principles and the typical improvement over paper record controls:

Attribute	How it is achieved using BatchLine EBR
Attributable	The EBR provides a secure software platform with necessary access controls, audit trails, and time stamps to automatically capture who, what, and when metadata for all activities and records.
Legible	Data is written on screen in a clear easy to read font and is accessible at all times to authorized users.
Contemporaneous	The EBR records actions at the time of the data entry and all entries are automatically time stamped (this functionality also provides the additional benefit of typically removing over 20% of manual data entries in an equivalent paper record).
Original	Entry of data into an EBR may be by several methods, this is discussed in more detail below. The system acts as a 'second person' verification for all automatically entered actions such as calculations and integrated data from other systems.
Accurate	The EBR solution itself is qualified to ensure the data collected is accurate according to the specifications expected set points and limits. Critical instruments that are integrated must be checked for calibration and effective change control ensures changes that may impact data are managed correctly.
Complete	All the data entries in EBR that are specified are enforced, it is not possible to 'forget' to fill out an expected value or to miss a comment on an exception.
Consistent	Data in the EBR is entered following the correct order according to the defined workflow and sequencing.
Enduring	EBR provides a robust electronic storage medium for the duration of the record, BatchLine's uses leading cloud service providers to maintain high standards for data security and reliability, and backs up to additional cloud and local storage automatically in both machine and human readable (pdf) format.
Available	BatchLine maintains secure backup and retrieval of all data for the duration of the service provision, it is possible to extract the batch record and specific data for own local storage as part of a DR plan as required.

Original Data: entry of process values into BatchLine

As above for Data Integrity there is a requirement that the Original Data is ensured. In EBR, data can be entered manually such as for equipment set up where machine parameters can be entered and BatchLine checks the entries against the specified pre-set values. The following examples highlight where

manually entered data collected in EBR are an improvement over typical paper batch record controls:

- Data is entered and Batchline automatically checks the entry against specification values, formats and the right sequence of the processing
  - » All changes to data are audit trailed
  - » Exceptions are generated automatically in case of being outside the specification limits
- Data on printouts from standalone equipment can be scanned into the EBR with the corresponding meta data; who, what and when the record occurred so that the data is collected at the right time
- Photos of the process can also be used in a similar manner with their associated meta data to verify that the image is collected at the right time (NOTE: printouts and photos have to be verified as true copies, this verification is managed in the EBR)

> **Case studies show that standalone EBR typically reduces the overall number of manual data entries in a batch record by 50%.**

It is also possible to integrate data directly from equipment to the EBR, this adds a level of complexity and cost for the technical interfacing, however can further reduce the need to transcribe data into an EBR, especially those values that are classed as a Critical Process Parameter may be considered.

- Data such as raw material weights can be captured from a weigh scale which is interfaced directly with the system and checked directly against the BOM specification.
  - » This also removes the need for second person verifier for BOM quantities as the system is qualified and validated to be accurate
- In specific cases if a continuous measurement of a CPP is required (an example might be pH measurement in a bio-reactor) the instrument can be connected via IoT gateway and the data collected in the EBR

When starting an EBR deployment we recommend that you perform and document a risk assessment of the data flow to justify the way the data is collected. The assessment should also consider the alarm, summary records, and audit trails. Critical alarms and any changes to critical settings have to be recorded. Simply put, EBR can manage these important data recording tasks without paper, and brings many ALCOA improvements simply by using its basic functionality.

About BatchLine

BatchLine is a first of its kind cloud Electronic Batch Record (EBR) designed specifically for pharmaceutical, supplements, herbal medicines, food, and cosmetics manufacturers. It brings the tools and benefits of a traditional EBR system at a fraction of the cost, using the latest technology and simplified web native design.

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