BIOVIA ELECTRONIC BATCH RECORDS

ELECTRONIC EXECUTION AND DOCUMENTATION ENVIRONMENT INCREASES PRODUCTIVITY AND ENSURES REGULATORY COMPLIANCE

DATASHEET

Manufacturers in GMP-regulated industries have traditionally relied on paper-based manual processes and/or hybrid IT systems to document execution of production batch records. These documentation practices are prone to transcription and calculation errors; they also create delays in batch releases resulting from inefficient review and approval processes compounded by the use of paper. The result can be larger inventories, shorter shelf lives, longer time to market and possibly erroneous release of defective products. Failure to follow a paper process that results in deviations can have expensive and potentially devastating consequences. These issues can result in a regulatory investigation, warning letters or recalls resulting in huge costs to the company.

Automating the execution and review of batch records can bring significant compliance and cost saving benefits to any manufacturer in regulated industries. By automating documentation and data review activities, BIOVIA EBR enables manufacturing operators and managers as well as QA data reviewers to:

- Save time in day-to-day work
- Reduce inventories
- Improve product release quality
- Guarantee that the SOP/recipe was executed exactly to the process outlined
- Reduce product release cycle times
- Realize over 50% time savings in data capture, document preparation, and QA data review

Reduce non-compliance risks

BIOVIA EBR assures proper initiation of a procedure/SOP/recipe, preventing usage of outdated documents. Only trained and approved operators are authorized to use approved supplies and equipment and are alerted, in real-time, if any non approved components are used. Ensuring that all collected data values are within approved and validated reduces downstream deviations and investigations.

Increase productivity

BIOVIA EBR automates batch and continuous process administration, making standard operating procedures electronically available, so there is no need for paper printouts, logbooks, or binders. With validated calculations built into the procedures, manual calculations and other manual tasks are eliminated. Routines and all data elements are followed by operators and are electronically transferred to the BIOVIA EBR, reducing review cycle times by 75% and enabling the transfer of data to integrated corporate systems such as MES, SAP and BIOVIA LIMS.

Data Security & Access Control

All data is maintained on a secure, 21CFR Part11 compliant server. Access controls allow rights and permissions to be set for performing process or laboratory tasks and accessing existing data.

Procedure Management

Procedures/SOPs are retrieved from existing document management systems, assuring the correct procedure and version are assigned or retrieved for each task.

Figure 1: Dashboard widget for EM.

Equipment & Instrument Management

Instrument and System libraries are provided to facilitate installing and validating common at-line instruments equipment, laboratory instruments and systems. Central administration facilitates implementation and increases compliance.

Test & Session Management

BIOVIA EBR's Session Manager allows batch administration for operators and technicians in the plant. Easily create work orders for individual tests or process steps, which can be forwarded to managers for assignment and/or approvals.

Data Acquisition

Data is automatically transferred from validated devices/ equipment to the operator's hand-held clipboard, eliminating transcription errors and increasing productivity through direct data capture and no need for secondary verification processes.

Data Review

Reduce time for data reviews by 50-80% with our on-board dashboard "reviews at a glance" and a series of step-by-step compliance flags indicating any issues, deviations or notations that need review.

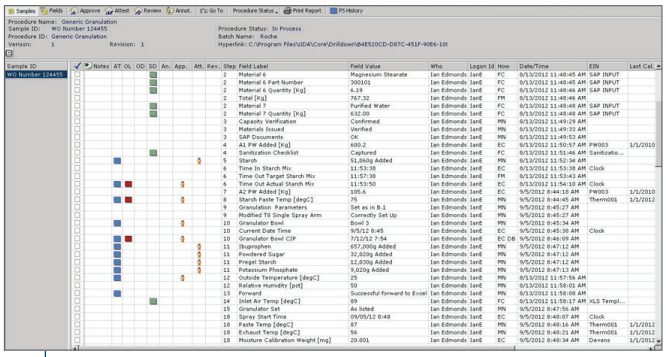

Figure 2: Dashboard widget for IM.

Data Reporting & Trending

BIOVIA EBR allows use of standard report writers to create configurable reports with trending information including number and types of samples each analyst has completed, people and instrument performance, vendor and materials tracking metrics as well as compliance to procedures by monitoring and displaying the number of unplanned deviations as well as successful processes.

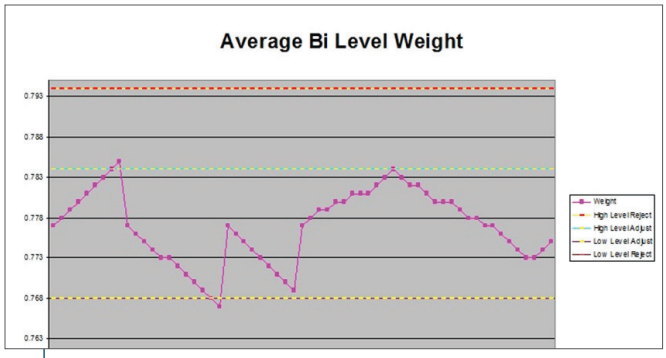

Figure 3: Data Review and Trending Report.

Data Exchange

The Data Exchange Manager provides bi-directional communication with other enterprise IT systems such as BIOVIA LIMS, ERP, MES and document management systems, supporting a range of communication formats including XML and ASCI and enables configuration of process input information, work lists, and output information.

BIOVIA Electronic Batch Records is included in the BIOVIA Process Management and Compliance Suite, a comprehensive informatics platform for capturing, managing, and analyzing development and process data for operational excellence in new product development and commercial quality operations.

To learn more about BIOVIA Electronic Batch Records, go to **accelrys.com/electronic-batch-records**

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