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Making the Move to Electronic Batch Records

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Implementing electronic batch records can offer a means of compliance, reduction in errors, streamlined ability to trace actions, and simultaneous generation of documentation.

An electronic batch record provides proof that an organization properly handles and records all critical steps to produce each batch of a product, whether entered electronically or manually. This record includes data associated with operators, the manufacturing process, equipment, materials, and supplies. It can also include data from laboratory information management systems (LIMS), enterprise resource planning (ERP), process control systems (PCS), and more.

From a compliance standpoint, an electronic batch record solution helps an organization meet 21 *Code of Federal Regulations* (CFR) Part 11, which defines the manner in which FDA accepts electronic records and electronic signatures (1).

By putting electronic batch records in place, an organization sees benefits that relate to improved data integrity and accuracy, streamlined processes, and efficient operations. Optimizing these processes yields improved resource management, improved inventory management, and reduced material losses—all of which positively impact the operation's bottom line.

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But what must an organization consider when beginning the journey to implement an electronic batch record solution? Evaluation of the following areas is crucial:

- People (organization culture)
- Business processes
- Technology.

People and organizational culture

Cultural aspects are significant for an organization to consider when preparing for electronic batch records. The changes required for the successful implementation of an electronic batch record affect personnel throughout a company and include how people work with each other, how data are used, how data integrity is maintained, and how processes are implemented. Operators, engineers, and maintenance personnel must be trained to complete the right activities and access the right data at the right time.

Management must communicate the overall organizational direction and why this change is important.

Before training can begin, managing cultural change must be well planned and include communications across all areas of an organization. Input should be solicited from stakeholders and business direction should be given to multiple audiences.

Management must communicate the overall organizational direction and why this change is important. Plant-floor personnel will therefore understand why changes are occurring,

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and they will recognize the value of the changes in their daily responsibilities. Ultimately, the cultural shift needs to be management driven and accepted across the enterprise.

At the same time, plant-floor personnel have deep process expertise that management likely does not possess. Therefore, although management must drive the electronic batch record initiative and the accompanying changes, plant-floor experts need to help set the requirements that ensure a smooth transition. Plant-floor personnel must provide input to assess how changes will affect work processes; they will also help craft a workable and well-accepted electronic batch record solution.

Managing organizational culture change is most successful when personnel from many areas of expertise are involved in making decisions and in building an implementation plan. A good start to the initiative is found in a participatory workshop environment that encourages team members to see their personal stake in the changes and recognize the benefits to them and to the organization. The workshop can bring value when the participants:

- Map the changes to organizational key performance indicators and the inherent values
- Discuss organizational change, best practice business processes, technology, and regulations
- Gather information to build a consensus about the overall concept, boundaries, and expectations for the overall concept
- Align the organization and promote teamwork.

Business processes for electronic batch records

A true electronic batch record captures—in digital form—all information entered electronically or manually. Manually entered data that are critical to the process need to be verified by a second person if it is not readily available for verification inherently by the system. All systems in an enterprise must enforce data integrity so that the data in the electronic batch record can be considered accurate and dependable. Data integrity is about ensuring that data are taken from the right place and recorded in the right way. It means data are attributable, legible, contemporaneously recorded, an original or true copy, and accurate (ALCOA).

To maintain an environment of digital integrity and support electronic batch record accuracy, all personnel—new or experienced, management or plant-floor—must follow procedures consistently as directed per the procedure. To ensure that data cannot be tampered with or manipulated, an organization must build a data-integrity strategy into each of these business processes:

- **Equipment management:** So that all device information is available electronically, it is essential to select instruments that securely deliver data to be used in higher levels of the International Society of Automation (ISA) S95 architecture.
- **Material management:** The manufacturing execution system (MES) can be integrated with ERP systems to allow tracking of materials, manufacturing orders, inventory transactions, and more. This ability eliminates manual, error-prone data transactions to resolve inventory and production discrepancies.
- **Batch record process flow and recipe management:** An MES solution can be used to minimize common paper-based errors with electronic verification of equipment and recipes to reduce variability and deviations. When properly integrated with the process control and computerized maintenance management systems, the MES provides access so that all production records can be easily produced, stored, and approved with electronic signatures.
- **Exception management:** All production details must be captured in the batch record, including associated exceptions or deviations that may affect product quality. The electronic batch record can be used to flag nonconformities and be used to create an exception-based batch report for easier quality review.

The following topics should be well understood and processes should be set in place to maintain data integrity. Each topic is a subset of the four business processes mentioned previously and must be in place to support electronic batch record processes:

- **User and workstation management:** Each instance where the data or process are affected must be recorded. Individual users must have unique IDs and passwords. If logon sharing is unavoidable, the situation should be documented, justified, and managed by a procedure to periodically review audit trails for suspicious activities.
- **Electronic signatures:** For any case where an electronic signature is required—in specific activities related to the quality of the product—a two-token (ID and password) or biometric reading should be used. Other acknowledgements may be single token, but individual user IDs should still be used. Often active directory integration is used as the tool to manage this at a corporate-wide level for many systems.
- **Disaster recovery:** A disaster recovery plan must be established and tested for system and data back-up and recovery. This procedure should include how to back up and recover portions of the system and to test the whole system.

Technology

An electronic batch record solution resides in layer three of the ISA-95 model; the layer includes production dispatching, detailed production scheduling, reliability assurance, and other manufacturing execution functions. Electronic batch record solutions can provide an integrated environment that pulls together information from ERP, LIMS, quality management systems (QMS), distributed control system (DCS), and other control systems. Data from the relevant systems are presented to the operator in the correct context providing them with a central location to

capture their electronic batch records. Technology infrastructure should provide all the security and personnel management tools required to meet the established business process goals.

To prepare the organization for electronic batch records, technology solutions must be evaluated to fit the situation. Process set up and process control scenarios as well as integration to higher level systems should be considered. The technology must be applied per the practical needs of various operating scenarios. Often, several solution scenarios will be used for various types of operating plants and even within a plant.

As such, a set of guidelines should be established to cover how to apply the technology, and the integration should match the needs of the facility. These guidelines should cover practices associated with the level of shop-floor automation, workflow philosophies, and workflow integration. For example, consider the following different needs of manual or automated processes:

- **Manual processes:** A process that requires significant manual steps might not require much shop-floor automation. In this situation, the integration between the electronic batch record and the shop floor relies heavily on instructions to the operator. Common steps should be analyzed to ensure consistency across the operation and to ensure that parallel and serial steps are managed appropriately with the electronic batch record workflow.
- **Automated processes:** In the case of an automated process, integration with the shop-floor automation system can be handled in several ways. The PCS could start the batch and launch the associated electronic batch record, or the electronic batch record solution could launch the workflow and start the PCS batch. Recipe and workflow integration between the PCS and electronic batch record solution could be accomplished using a combination of several different strategies. One method is to have one system manage both the PCS and electronic batch record workflow steps. Another method is to use read-and-write actions to ensure that the systems are working in tandem. A third method is to employ more of a listening capability within the electronic batch record solution to stay in step with the PCS. When to apply these capabilities should be covered in a project guideline.

Any technology solution should be able to validate that the data adhere to the ALCOA principles. Utilizing systems and devices that send data digitally to the electronic batch record solution with requisite checking capabilities is helpful so that manual data entry and verification is not required.

Benefits and effort repaid

Many people must be involved in preparing the culture, the processes, and the technology for an electronic batch record solution. Although the associated considerations and implementation activities are not trivial, the risks and expenses of not implementing an electronic batch record solution far outweigh the costs of implementing it.

Without an electronic batch record solution in place, the short- and long-term effects can include rising costs of business operations and potential product quality issues that could have otherwise been prevented. Without the batch record solution, an organization pays for manual compliance, manual documentation, manually dealing with errors, manually tracing actions, and manually gathering/reviewing all information about deviations.

Instead, with an electronic batch record solution in place, an organization can look forward to an easier means of compliance, reduction in errors, streamlined ability to trace actions, and simultaneous generation of documentation with product. All of these benefits add to a swift return on investment.

Reference

1. FDA, 21 *CFR* Part 11, Electronic Batch Records, 62 *Federal Register* 13464, Mar. 20, 1997. **PT**