MasterControl™

MasterControl EBR™

Many pharmaceutical manufacturers and other process manufacturing companies continue to rely on manual, paper-based systems to maintain their batch records. Such systems often fall short, exposing these organizations to inefficient production record processes, poor data tracking, and inaccurate or missing information. MasterControl's electronic batch record (EBR) solution can help make this inefficient and cumbersome manual process more efficient while significantly reducing risk.

How Can MasterControl Help You?

If you are using a paper-based or hybrid system, maintaining complete and orderly master batch records and batch production records according to FDA 21 CFR Part 211 requirements can be an inefficient, error-prone, and costly process. Unnecessary risks common with manual, paper systems during the batch record process – illegible documentation, incomplete data, outdated training, and poor visibility and traceability – can result in product quality issues, recalls, warning letters, and even consent decrees.

MasterControl EBR™ contains all the tools that pharmaceutical and process manufacturers need to gain control of their manufacturing data and documentation. The EBR offering is a fully connected production records solution, connecting standard operating processes (SOPs), training, inputs, specifications, change control, quality events, and traceability. It empowers manufacturers to create and deliver an easy-to-audit record of proper handling for every major step in producing a drug or product.

Here's how the MasterControl EBR solution addresses some of the major challenges that companies face with their current systems managing batch records.

Challenges and Solutions

Challenges	MasterControl Solution
Inefficient processes: Batch record processes conducted manually are inherently slow, cumbersome, and prone to errors. As batch records grow greater in both size and complexity, they require more time to prepare and review and often cause delays in product shipment.	**Efficient processes:** Automating the batch record process makes an inefficient and cumbersome manual process more efficient. MasterControl's EBR solution error-proofs processes and eliminates common production mistakes such as missing or incomplete documentation. Plus, manufacturers can better maintain centralized, electronic records of proper handling for each significant step in the production, packaging, and holding of every drug product batch.
Insufficient tracking: A manual batch process makes tracking logs, test results, and other records from different departments extremely time-consuming. Insufficient tracking significantly increases the occurrence of bottlenecks, a critical problem if defective batches need to be identified.	**Automatic tracking:** The EBR solution provides real-time visibility and traceability into manufacturing operations and processes, including employee training and quality events. Real-time deviation tracking lets companies integrate deviation handling throughout the manufacturing process. And by automatically capturing real-time data across manufacturing and sounding a warning if a quality event occurs, the affected process or product is quickly contained.
Disconnected systems: In a paper-based or partially electronic system, data is often kept in disconnected repositories, which makes reporting, trending, and analysis difficult. And because most manual systems don't connect other quality processes, continuous improvement is almost impossible.	**Connected processes:** The EBR solution allows connectivity with other applications that control different processes, ultimately connecting critical manufacturing and quality processes to one another. For example, production data can be correlated to deviations, material nonconformances, and customer complaints. Robust collaboration tools and capabilities also facilitate better communication and collaboration among users and across departments.

Features and Benefits of MasterControl's EBR

MasterControl EBR is the preferred solution for automating and optimizing management of manufacturing/ production processes and documentation.

- **Complete Data Capture:** All user entries are captured, electronically stored, and available for reporting. This includes loading of external files, making them part of the batch record. Integrate with other systems (e.g., QEM) to ensure no more disconnected quality data or events.

- **Data Integrity Checks:** Each field can run automatic checks to ensure the data entered is complete and in the correct format. Missing or incomplete data, illegible documentation, incorrect date formats, or incorrect units of measure will never be a problem.

- **Real-Time Deviation Tracking:** Seamlessly integrate the recording, assessment, and approval of planned or unplanned deviations into the overall manufacturing process, with in-process corrections published on a completed record and an FDA-compliant audit trail.

- **Proper Employee Training:** Automatically track and enforce worker training prior to performing activities in production. Ensure training records are current by capturing all data and recording all signatures as operators complete their daily activities.

- **Robust Collaboration:** Easily and securely let many users collaborate, and even allow trusted third-parties to participate, in batch record processes, with parallel and sequential processing as well as FDA-compliant electronic signatures on records and approval routes.

- **Audit-Readiness:** Automatically track and store all relevant production data in a central location, retain records with a comprehensive and compliant audit trail, and quickly deliver complete, error-free forms that meet FDA auditors' requirements.

- **Compliant System:** As with all MasterControl software, the EBR solution is fully compliant with 21 CFR Part 11 regulations, providing time-stamped audit trails, reporting, and e-signature capabilities, as well as robust security features.

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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