Advanced Electronic Batch Record (EBR) Implementation Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The pharmaceutical and biotech industries are undergoing a massive Digital Transformation revolution, driven by the imperative of Data Integrity and the pursuit of Operational Excellence. Manual, paper-based batch records are increasingly obsolete, posing significant risks of transcription error, prolonged Batch Release Cycle Times, and compliance exposure under strict regulations like FDA 21 CFR Part 11 and EudraLex Annex 11. This advanced course moves beyond the fundamentals of simply "going paperless" to focus on the strategic implementation of sophisticated EBR solutions within an integrated Manufacturing Execution System ecosystem. Advanced Electronic Batch Record (EBR) Implementation Training Course addresses the complexities of a multi-site rollout, advanced System Validation, and leveraging EBR data for real-time Process Optimization and Continuous Improvement across the entire supply chain.

This program is essential for leaders and project teams tasked with orchestrating a successful, enterprise-wide shift to Advanced EBR systems. Participants will master the critical pillars of implementation, including Master Batch Record Design and Configuration, Review-by-Exception strategies, and rigorous GxP Compliance adherence. By focusing on both the technology and the necessary Change Management and Cross-Functional Alignment, the course ensures that the digitalization effort delivers tangible Return on Investment, enhances Audit Readiness, and secures a competitive advantage in the age of Smart Manufacturing and Industry 4.0.

Programme Curriculum

Advanced Electronic Batch Record (EBR) Implementation Training Course

Introduction

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Course Objectives

1. Strategize and champion an enterprise-wide Digital Transformation roadmap centered on EBR/MES integration.
2. Master the principles of ALCOA+ Data Integrity and ensure their technical enforcement within the EBR system architecture.
3. Develop a robust, end-to-end EBR Validation Lifecycle strategy compliant with global GxP standards.
4. Design and configure highly flexible, dynamic Master Batch Records for complex, multi-product processes.
5. Implement Review-by-Exception methodologies to reduce Batch Release Cycle Times by up to 50%.
6. Evaluate and select appropriate EBR Vendor Solutions and calculate the comprehensive Total Cost of Ownership.
7. Integrate the EBR solution seamlessly with critical enterprise systems for a unified data flow.
8. Lead the Change Management initiatives required for high user adoption across production, quality, and IT departments.
9. Configure advanced features such as Electronic Signatures, automated equipment integration, and real-time alerts.
10. Utilize EBR data for Real-Time Quality Metrics, Process Analytical Technology, and Predictive Analytics.
11. Prepare the organization for a "paperless" Regulatory Audit and manage electronic record submission and archival.
12. Design a sustainable System Governance and long-term maintenance strategy for continuous compliance.
13. Apply EBR principles to specialized manufacturing, such as Cell and Gene Therapy and High-Volume Sterile Production.

Target Audience

1. Quality Assurance & Compliance Professionals.
2. Manufacturing & Production Managers/Supervisors.

3. Validation & IT Specialists.
4. Process/Automation Engineers.
5. Master Batch Record Authors & Configurers.
6. Program/Project Managers.
7. Senior Directors/Executives.
8. Biotech & Cell/Gene Therapy Specialists.

Course Modules

Module 1: Strategic Alignment & Business Case for Advanced EBR

- Mapping EBR to Industry 4.0 and Smart Manufacturing goals.
- Quantifying the ROI and TCO for a comprehensive MES/EBR rollout.
- Developing an enterprise-level Digital Maturity Assessment
- Case Study: Justifying a multi-million-dollar EBR investment by predicting Batch Release Cycle Time reduction.
- Digital Transformation, ROI, TCO, Strategic Alignment, Industry 4.0.

Module 2: GxP and Advanced Data Integrity

- Deep dive into 21 CFR Part 11 and EudraLex Annex 11 technical controls.
- Implementing ALCOA+ principles via system design.
- Advanced Electronic Signature and audit trail configuration best practices.
- Case Study: Rectifying systemic Data Integrity gaps identified during an FDA warning letter review.
- 21 CFR Part 11, ALCOA+, Electronic Signatures, Data Governance, Audit Trail.

Module 3: Master Batch Record (MBR) Configuration & Design

- Principles of a dynamic, flexible MBR for multi-product, Quality by Design processes.
- Utilizing conditional logic, version control, and template management.
- Techniques for converting legacy paper MBRs into effective electronic recipes.
- Case Study: Designing a Single MBR template that supports 10+ similar products with configurable process steps.
- Master Batch Record (MBR), QbD, Recipe Management, Version Control, Configuration.

Module 4: Review-by-Exception (RBE) Implementation Strategy

- Defining and configuring Critical Process Parameters and tolerances for automated exception flagging.
- Designing the QA Review Workflow to focus only on flagged deviations and non-conformances.
- Metrics and KPIs for measuring RBE efficiency and QA time savings.
- Case Study: Implementing RBE on a high-volume sterile product line, cutting QA review time by 60%.
- Review-by-Exception, CPP, Deviation Management, Quality Metrics, Workflow Automation.

Module 5: End-to-End System Validation Lifecycle

- Developing the Validation Master Plan (VMP) and leveraging a risk-based approach.
- Advanced techniques for writing and executing IQ, OQ, and Performance Qualification protocols.
- Automating test script execution and managing system changes under a qualified state.
- Case Study: Performing a successful re-validation following a major MES/EBR software upgrade and integration.
- System Validation, GAMP 5, IQ/OQ/PQ, Validation Master Plan (VMP), Risk-Based Approach.

Module 6: MES/EBR System Integration Architecture

- Architectural considerations for integrating EBR with ERP, LIMS, and QMS.
- Data transfer protocols and middleware for real-time, validated data exchange.
- Integrating shop-floor equipment and instruments for automated data capture.
- Case Study: Troubleshooting and solving a critical data synchronization failure between EBR and LIMS during a batch run.
- MES Integration, ERP, LIMS, SCADA, Middleware, System Architecture.

Module 7: Change Management and User Adoption

- Strategies for overcoming organizational resistance to a Paperless Manufacturing environment.
- Developing role-specific training programs for operators, QA, and maintenance staff.
- Establishing a Super-User and change champion network for post-go-live support.
- Case Study: Implementing a communication and training plan that achieves >95% system adoption within the first three months.
- Change Management, User Adoption, Super-Users, Training Strategy, Organizational Readiness.

Module 8: Advanced Operational Data Capture

- Configuring EBR for Automated Data Capture from weigh scales, sensors, and equipment.
- Implementing electronic logbooks, maintenance records, and cleaning verification within the EBR.
- Designing user interfaces and user experiences for error-proof operator guidance.
- Case Study: Automating a complex formulation process, reducing manual data entry steps from 50 to 5.
- Automated Data Capture, User Interface, Electronic Logbooks, Operator Guidance, Error-Proofing.

Module 9: EBR for Atypical and Advanced Therapies

- Adapting EBR for the unique challenges of Cell and Gene Therapy manufacturing
- Managing complex supply chain and chain of custody/identity records within the EBR.
- Implementing risk mitigation strategies for high-value, low-volume advanced therapy batches.
- Case Study: Designing a fit-for-purpose EBR for a personalized medicine product requiring complex donor-to-patient traceability.
- Cell & Gene Therapy, Personalized Medicine, Chain of Identity (COI), Traceability, Atypical Manufacturing.

Module 10: Cybersecurity and Cloud-Based EBR

- Evaluating the security implications and Compliance of Cloud-Based EBR vs. On-Premise solutions.
- Implementing robust Role-Based Access Control and user authentication policies.
- Disaster recovery, data backup, and business continuity planning for electronic records.
- Case Study: Conducting a Cybersecurity Risk Assessment for a new cloud-deployed EBR system.
- Cybersecurity, Cloud EBR, Access Control, Disaster Recovery, Business Continuity.

Module 11: Audits, Inspections, and Electronic Archival

- Best practices for preparing for a "paperless" Regulatory Inspection.
- Configuring the EBR for easy, secure auditor access and electronic record retrieval.
- Defining policies for long-term Electronic Record Archival and data retention.
- Case Study: Simulating an FDA audit and successfully presenting the EBR's automated audit trail and RBE reports.
- Regulatory Audit, Audit Readiness, Electronic Archival, Data Retention, Inspection Strategy.

Module 12: Performance Monitoring & Continuous Improvement

- Leveraging EBR data to generate Real-Time KPIs and Overall Equipment Effectiveness metrics.
- Using Process Analytical Technology principles with EBR data for in-process control.
- Implementing Predictive Analytics and machine learning to forecast process deviations.
- Case Study: Utilizing EBR data to identify the top three time-consuming steps in a process and optimizing them for a 15% efficiency gain.
- Real-Time Quality, KPIs, OEE, Predictive Analytics, Continuous Improvement.

Module 13: Multi-Site Rollout and Harmonization

- Developing a global strategy for harmonizing MBRs and EBR processes across disparate sites and geographies.
- Managing data localization, multilingual support, and regional regulatory variances.
- Phased rollout strategies and cutover planning to minimize production disruption.
- Case Study: Managing the simultaneous deployment of a new EBR system across four global manufacturing sites.
- Multi-Site Rollout, Process Harmonization, Global Implementation, Cutover Planning, Regional Compliance.

Module 14: System Governance and Maintenance

- Establishing a cross-functional System Governance committee for long-term ownership and decision-making.
- Defining procedures for routine System Maintenance, patching, and minor configuration changes.
- Developing a formal system for managing and documenting all system changes
- Case Study: Creating a 5-year system roadmap and governance structure for a newly implemented EBR.
- System Governance, Change Control, Maintenance Strategy, IT Service Management

Module 15: Future Trends and Emerging Technologies

- Exploring the impact of Augmented Reality and AI/Machine Learning on EBR workflows.
- Integrating Blockchain technology for enhanced supply chain transparency and traceability.
- Discussing the shift from MES/EBR to modular, integrated Manufacturing Operations Management platforms.
- Case Study: Evaluating a pilot project using AR glasses for guided assembly and direct data capture into the EBR.
- AI in Pharma, Augmented Reality, Blockchain, MOM Systems, Future of Manufacturing.

Training Methodology

This course employs an **Advanced Blended Learning** approach, focusing on practical application and strategic decision-making:

1. Interactive Lectures & Discussions.
2. Hands-On Simulation.
3. Real-World Case Studies.
4. Group Project & Presentation.
5. Role-Play Exercises.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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