



MasterControl Manufacturing Excellence

A next-generation digital manufacturing execution system (MES) for life sciences, digitizing production records (EBR/eDHR) to accelerate product release and ensure GxP compliance.

<https://www.mastercontrol.com/manufacturing/batch-records/>

Overview

MasterControl Manufacturing Excellence (Mx) is a modern, cloud-based Manufacturing Execution System (MES) designed for life sciences organizations, including pharmaceutical, medical device, and dietary supplement manufacturers, to achieve paperless, errorless, and frictionless production.

It digitizes and automates the "last mile" of the manufacturing process, replacing error-prone paper-based records (travelers, batch records, DHRs) with Electronic Batch Records (EBR) and Electronic Device History Records (eDHR). The platform helps eliminate millions of errors and can accelerate product delivery by up to 70%. Key capabilities include rapidly digitizing manufacturing processes with no-code workflows, automating production processes, and orchestrating resources.

Key Capabilities:

Digital Production Records: Provides 100% paperless data input and documentation for EBR/eDHR.

In-line Quality Control: Embeds operator guidance, training, built-in controls, and alerts to eliminate production errors in regulated environments.

Accelerated Release: Enables smart, real-time review-by-exception for faster product review and release.

Asset Management: Digitalizes equipment and facilities logbooks for audit readiness, ensuring GMP compliance and providing real-time visibility into asset status.

It integrates with systems like ERP, LIMS, and QMS, as well as assets like scales, scanners, equipment, and IoT devices, providing real-time operational visibility through robust analytics and in-process dashboards. Target users span manufacturing operations leadership, line supervisors and operators, quality assurance (QA) and quality control (QC) teams, and IT.

Key Features

- 100% Digital Production Records (EBR/eDHR)
- Review-by-Exception
- Digital SOPs and Work Instructions
- In-line Quality Controls and Alerts
- Electronic Logbooks and Asset Management
- Automated Data Capture and Conditional Pathing
- Real-time Data Management and Analytics
- Seamless QMS/MES Integration

Pricing

Model: subscription

Custom, subscription-based pricing tailored to the organization's needs, including selected modules, number of users, and deployment preferences. Contact sales for a quote.

Target Company Size: startup, small, medium, enterprise

Integrations

SAP ECC, SAP HANA Cloud, ERP, LIMS, QMS, IoT devices

Compliance & Certifications

FDA 21 CFR Part 11, FDA 21 CFR Part 210-211 (cGMP), FDA 21 CFR Part 111, GxP, ISO

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