



MasterControl Manufacturing Excellence

Digital Production Records for Modern Manufacturing



It is crucial for today's manufacturers to drive measurable, scalable impact to product quality, overall operations and site performance. Achieving this next level of manufacturing excellence requires fully digitized production records and processes to create a seamless connection between plant operations, line performance and quality teams.

The MasterControl Manufacturing Excellence solution helps you bridge the paper gap between quality management systems (QMS) and manufacturing execution systems (MES) by automating the labor-intensive last mile of the manufacturing production process to drive immediate improvement and operational efficiency. MasterControl is making it easier than ever for manufacturers to finally address critical digital transformation imperatives:

- **Paperless** – Remove the remaining paper from the shop floor, and ensure that product review and release is fully digital, connected and accelerated.
- **Errorless** – Eliminate the preventable errors, long review cycles and costly waste created by manual data entry to achieve right-first-time (RFT) production.
- **Frictionless** – Reduce the friction between manufacturing operations and quality assurance priorities and metrics to improve line performance and accelerate production.

Manufacturing Excellence for the Digital Era

Paperless manufacturing has been a top initiative for years, yet for many manufacturers, challenges persist in the last mile of production where operators still typically use paper-based production records – often referred to as travelers, batch records or device history records (DHRs) – that create errors and delays.

MasterControl's Manufacturing Excellence provides 100% paperless data input and documentation, as well as unique automation capabilities that enable in-line quality event management, built-in limits, integrated training, review by exception and a unique data set that enables personnel and supplier optimization.

- ✓ **Eliminate Paper, Drive Higher Production Efficiency**
MasterControl enables 100% paperless data entry and documentation on the shop floor to reduce overall manufacturing costs by digitizing the last mile of the production process.

30% increase in employee efficiency while scaling manufacturing.

– Biotechnology Producer

- ✓ **Cut Production Errors, Improve Right First Time**
MasterControl helps you reduce data input errors that create data integrity issues across your organization. Better data drives shorter documentation review cycles and fewer deviations. This helps you scale products and production to grow the company more efficiently.

90% to 100% decrease in data entry/input errors.

– Contract Manufacturer

- ✓ **Reduce Deviations and CAPAs, Optimize Production**
MasterControl helps you reduce deviations, deviation impact, and the number of those that turn into corrective and preventive actions (CAPAs) by optimizing your manufacturing production processes.

25% to 30% reduction in total deviations related to data integrity.

– Pharmaceutical Packaging

- ✓ **Accelerate Release of Products, Improve Cash Flow**
MasterControl enables review by exception, which dramatically decreases your lead time from batch/lot completion to product release – ensuring products are predictably shipping out and cash is coming in.

Batch review cycles reduced from 2-3 days to 15 minutes.

– Pharmaceutical Packaging

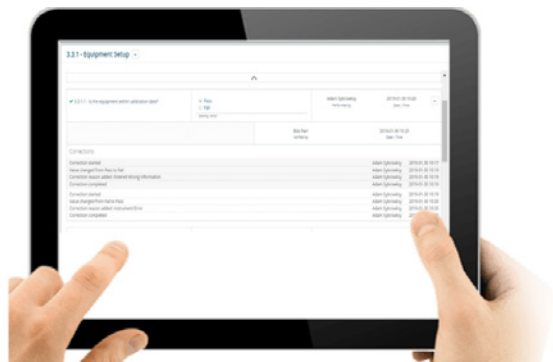
Unifying Manufacturing Operations and Quality Priorities

Build it faster and cheaper or build it better – you know the old adage. It implies there has to be a trade-off between quality and efficiency. With MasterControl's Manufacturing Excellence solution, that adage is now obsolete – bring quality directly in-line with line operation to remove friction, improve quality, improve cycle times and accelerate product release. From manufacturing operations leadership to line supervisors and operators, QA and QC teams and IT – MasterControl has created a system that delivers unique value across the production environment.

| Imperative | Plant Operations | Quality Leadership | Line Workers | IT Leadership |
|----------------------|--|--|---|---|
| Errorless Production | Eliminate rework and scrap, and reduce review and release. | GMP and regulatory data integrity, and review by exception. | Built-in limits, integrated training and current SOPs/ work instructions. | Real-time push and pull linkage between ERP, MRP, MES and QMS. |
| Efficient Resourcing | New insights into how production is impacted by personnel, suppliers and equipment directly from production record. | Free up time spent tracking/reconciling records, and prioritize analyzing data to focus on process improvement. | Simple user interface for mobile/terminals, plus built-in limits and controls, auto witness/approval routing and in-process training. | PDF redundancy for business continuity, and quarterly upgrades with risk-based validation. |
| Proactive Quality | Streamline inventory management through QMS/ERP/ MES integration, and make real-time line adjustments to minimize misallocations, rework and waste/ scrap. | Traceability across the production process; real-time batch/lot/line data to analyze/trend events to shift from corrective to preventive posture, and streamline audits. | Streamline inventory management through real-time QMS/ERP/ MES integration. | System prevents data corruption. Global data structure standardized across sites improves access, analysis and audit. |
| Real-Time Review | Dramatically reduce variations in product release and delivery, and eliminate operational blind spots and lag in issue resolution. | In-line inspection and review for faster GMP and market disposition, and ability to correlate and trend data for instant management review. | In-process training and access to current SOPs and work instructions removes need to re-engage operators to implement changes. | Fully integrated database and document management removes need to integrate with separate document management system. |

Industry and Manufacturing Process-Specific Solutions

The MasterControl Manufacturing Excellence solution helps you accelerate production record processes, improve cycle times and efficiency, enhance line performance, provide greater visibility throughout your manufacturing life cycle – all while integrating quality management and ensuring regulatory compliance.



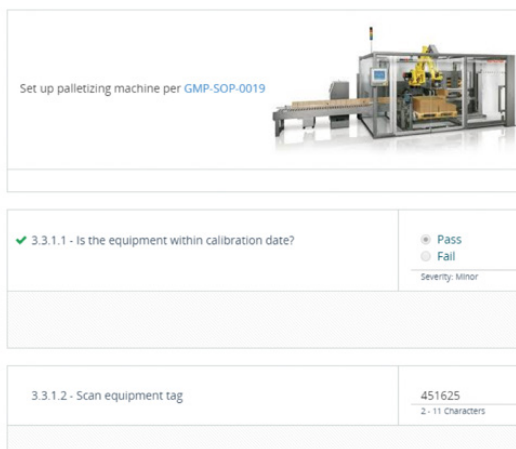
Digital production record management

MasterControl EBR contains essential tools that pharmaceutical, nutraceutical and other batch process manufacturers need to streamline and maintain master templates and batch production records.

The product connects standard operating procedures (SOPs), training, inputs, specifications, change control, quality events, traceability and more.

MasterControl eDHR provides all the capabilities needed by medical device and discrete manufacturers to gain total control of DHRs and device master records (DMRs).

Enhanced functionality includes complete data capture, data integrity checks, real-time deviation tracking, enforced employee training and robust collaboration tools.



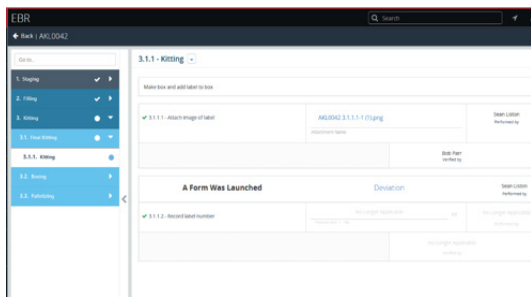
Integrated calibration and equipment maintenance

MasterControl Equipment Calibration automates equipment calibration for more efficient manufacturing performance.

The product manages the calibration process, including task completion and review, automatically triggering calibration events before they're due. Complete records are maintained, and advanced reporting provides insight into calibration activities.

MasterControl Equipment Maintenance manages the equipment maintenance schedule and automatically generates preventive maintenance tasks before they're due.

The product routes tasks containing instructions to appropriate personnel for completion and review. Detailed reporting capabilities provide insight into maintenance activities and help avoid bottlenecks.



Versatile recipe and variant management

MasterControl Recipe helps batch process manufacturers manage recipe changes and substitutions – from ingredients to equipment and formulations – in a single master recipe template, significantly reducing product documentation and improving data visibility, tracking and analysis.

MasterControl Variant allows discrete manufacturing companies to easily manage product variant changes and substitutions in one master template to efficiently scale operations and create new products for existing or new markets.

MasterControl Manufacturing Packages

MasterControl Manufacturing packages include our proven configurable products, process applications, validation services and platform functionality to provide unmatched flexibility, performance and value.

- **MasterControl Manufacturing – Base** provides essential manufacturing production record management along with equipment calibration and equipment maintenance. The industry’s most expansive validation services are offered, so you can quickly implement, operationalize and accelerate your production processes.
- **MasterControl Manufacturing – Standard** provides enhanced variant and recipe production record management and all the proven production record management capabilities that come with MasterControl Manufacturing – Base.

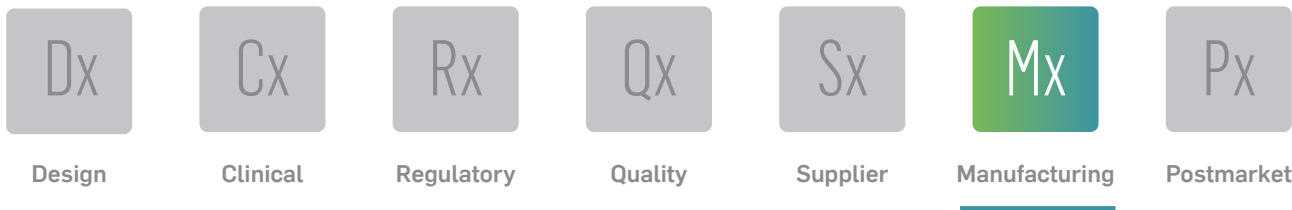
Base

Standard

| | |
|--|--|
| ✓ MasterControl Electronic Batch Records (EBR) | ✓ MasterControl Electronic Batch Records (EBR) |
| ✓ MasterControl Electronic Device History Records (eDHR) | ✓ MasterControl Electronic Device History Records (eDHR) |
| ✓ MasterControl Equipment Calibration | ✓ MasterControl Equipment Calibration |
| ✓ MasterControl Equipment Maintenance | ✓ MasterControl Equipment Maintenance |
| ✓ Corrective Maintenance | ✓ Corrective Maintenance |
| ✓ Preventive Maintenance | ✓ Preventive Maintenance |
| MasterControl Variant | ✓ MasterControl Variant |
| MasterControl Recipe | ✓ MasterControl Recipe |
| ✓ MasterControl Platform | ✓ MasterControl Platform |

End-to-End Product Life Cycle Excellence

MasterControl is committed to driving digital process excellence at every stage of your regulated product development life cycle – from concept to commercialization. We understand the importance of integrating manufacturing excellence with quality excellence, which is why we continue to work with our customers to replace manual, paper-based processes with connected solutions and data that help them bring life-changing products and treatments to market sooner while ensuring quality and compliance.



MasterControl Insights

Turn static, siloed information into actionable intelligence. Transform product development with dynamic data management and exploration through powerful, personalized reporting and dashboards.



Unlock the Power of Your Data

Every cloud instance of MasterControl includes MasterControl Insights. Insights is an interactive business intelligence and data management tool that gives you complete access to your data. Pre-configured, role-based dashboard visualizations give you a comprehensive view of quality and manufacturing processes.

Additional Insights Features:

- Customized dashboards to meet your business needs.
- Robust reporting.
- Advanced analytics and artificial intelligence (AI) capabilities.
- Export application programming interface (API).
- Key performance indicator (KPI) management.

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality, compliance and production management software for life sciences and other regulated industries. Our mission is the same as that of our customers – to bring life-changing products to more people sooner. The MasterControl Platform helps organizations digitize, automate and connect critical processes across the regulated product development life cycle.

Learn more at mastercontrol.com

