



MasterControl™

# Manufacturing Software Buyer's Guide

## Manufacturing Execution Simplified: A Buyer's Guide for Modern Manufacturing Software

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# What You Need to Know When Evaluating Manufacturing Execution Systems

New technologies are providing life sciences manufacturers with smarter, faster, and more cost-effective alternatives to traditional manufacturing systems. But choosing the right solution to transform your manufacturing processes can be challenging due to the considerable costs and complexity involved in a large-scale IT effort or the time it takes to implement and validate a new system.

This buyer's guide will help you understand the fundamental components of manufacturing software, how production systems are evolving with changing business dynamics, and how advanced digital tools can help you simplify manufacturing execution now and set you up for sustained manufacturing excellence.

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# The Current State Production Systems

The most common types of production systems used by life sciences manufacturers today are either paper-based, digitized but disconnected, or legacy manufacturing execution systems (MES). Paper-based systems are no longer practical for modern manufacturers. Manufacturing organizations that rely on multiple point solutions to digitize production processes still contend with disconnected systems, standalone spreadsheets, and scanned documents. Meanwhile, the costs and complexities of traditional MES software make it unfeasible in most production environments. As manufacturing becomes more data-driven and flexible, these production systems are increasingly unsustainable.

## Paper-Based Systems / Manual Processes

- **Inefficient:**  
Time-consuming and prone to error.
- **Disconnected:**  
Offline data and siloed information.
- **Low visibility/traceability:**  
No unifying platform and insufficient data tracking.

## Digital but Disconnected

- **Paper on Glass:**  
Scanning and managing an array of documents.
- **Multiple Point Solutions:**  
Limited interoperability, creating unreliable connections.
- **Low visibility/traceability:**  
Disconnected data sources across production.

## Legacy MES

- **Costly implementation:**  
Expensive, time-consuming implementation, slow user adoption, and burdensome validation.
- **Rigid configurability:**  
Hard-coded process configurations and time-consuming re-engineering.
- **Limited scale-up:** Difficult to scale up and cost-justified on limited lines.

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# The Evolution of Smart Manufacturing

In increasingly data-driven manufacturing environments, production systems must empower organizations to unlock the power of their data and remove the inefficiencies of disconnected data. The future of manufacturing execution will be a data-first approach to information, systems, people, and processes – where electronic batch records (EBRs) or electronic device history records (eDHRs), training documents, standard operating procedures (SOPs), and more are quickly and cost-effectively digitized under one platform. Smart manufacturing solutions are providing greater value because the dots can be connected in new ways.

## Charting a Path to Digital and Data Maturity



### Manual

#### Legacy Production

Highly Manual, Paper-Based  
Offline/Siloed Production Data



### Digital

#### Digital Production

MES/EBR On Some Lines  
Digital Process/Data Capture  
Automation Of Basic Processes  
In-Process Data/Insights Available



### Connected

#### Connected Manufacturing

MES/EBR On Every Line  
Broad Integrations (ERP, QMS, LIMS, Etc.)  
IoT Connected Equipment/Assets  
Multi-Site System Standardization  
Unified Product+Production Data  
End-To-End Process  
Data Modeling

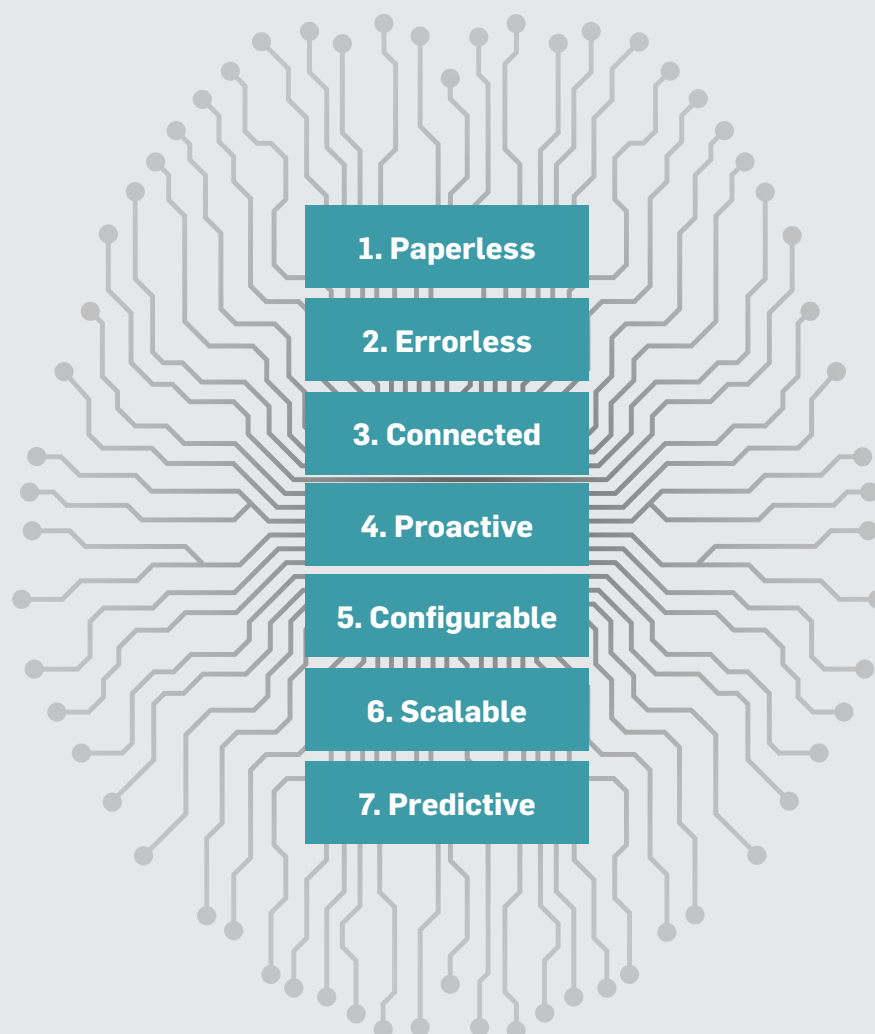


### Intelligent

#### AI Driven Smart Manufacturing

Real-Time Operational Intelligence  
Continuous Process Optimization  
Dynamic Planning/Scheduling  
Self-Optimizing Equipment  
Predictive Product Quality  
Autonomous Production  
Augmented Decisioning  
Real-Time Release

# Modern Smart Manufacturing Is:



## Desired State: Manufacturing Execution Simplified

- 100% paperless
- Connects people, processes, and data
- Eliminates human error and enhances data integrity
- Builds quality into the production system
- Capitalizes on cloud-native platform dynamics
- Enables holistic visibility and end-to-end traceability
- Provides a new, previously missing dataset for business intelligence
- Facilitates data-driven product- and process-related decision-making
- Incorporates advanced tools such as artificial intelligence (AI), machine learning (ML), and natural language processing (NLP)
- Easily scales to meet the demand of changing environments
- Provides a considerable competitive advantage

## 3

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# The Future Shop Floor Technology

Digital tools are enabling manufacturers to close the persistent offline data gap that slows production, quality review, and product release and finally achieve complete, end-to-end smart manufacturing. By extending your digital edge to those on the shop floor who need it most, you can deliver immediate, data-driven performance gains from beginning to end.

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**Production Planning and Template Management**

Plan and organize manufacturing projects with the right tools to improve production accuracy and productivity. Quickly author, launch, and manage configurable production records, and automate change control. Leverage global elements, templates, and a single tool for managing product recipes and variations. Link SOPs and work instructions to ensure the correct versions are always used. Automatically track and store all relevant records electronically with a compliant audit trail.

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**Manufacturing Execution**

Accelerate product release by optimizing manufacturing production processes and reducing delays and downtime. Ensure up-to-date work instructions, with real-time tracking of stages, steps, and performance. Achieve right-first-time (RFT) production every time, with automatic data integrity checks. Enforce limits, controls, and thresholds using integrated, data-driven prompts. Gain real-time work-in-progress (WIP) visibility and traceability with in-process dashboards.

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**Quality Control and Assurance**

Ensure quality at every step of production. Automatically assess risk and launch quality events directly from the production line without slowing production. Enforce in-line quality assurance and operator training compliance. Automate and easily manage QC sampling/testing, as well as equipment calibration and maintenance processes, including scheduling. Accelerate production record review and approval with review-by-exception capabilities.

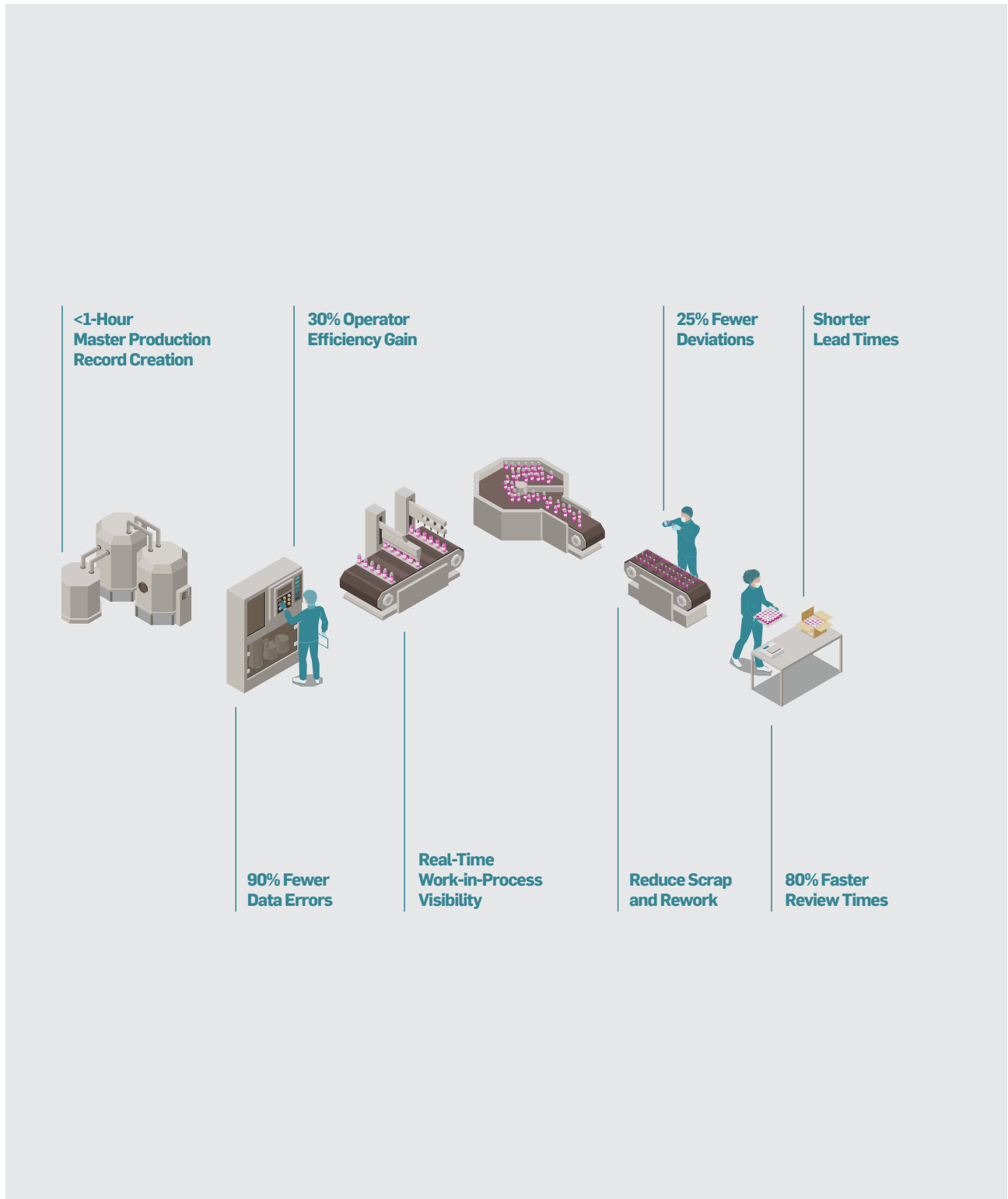
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**Data Management and Analytics**

Close information gaps caused by paper and disconnected systems to unlock real-time insights and unleash powerful intelligence. Proactively track production data and resolve data integrity issues before they spread. Access data on shop floor performance using operational or role-based dashboards. Connect systems, processes, and people for a complete view of data and actionable insights. Apply advanced analytics using AI/ML to make data-driven improvements.

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## See Immediate Impact



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# Choosing the Right System for Your Environment

Evaluating the manufacturing software available on the market today requires examining your most pressing production needs and inefficiencies alongside the wide range of functionalities that proven software solutions have to offer. By determining the capabilities that fundamentally complement your quality manufacturing goals and current practices, you'll be better prepared to select the digital tools you need to succeed today while positioning your organization for future growth.

## Core Quality Areas

## Essential Functionality

## Capability

### Batch Records (Pharmaceutical)

- Complete EBR data capture
- Enhanced data integrity
- Real-time deviation tracking
- Up-to-date operator training
- Robust collaboration
- Production progress visibility and traceability
- Analytics and reporting



### Device History Records (Medical Device)

- Complete eDHR data capture
- Enhanced data integrity
- Real-time deviation tracking
- Up-to-date operator training
- Robust collaboration
- Production progress visibility and traceability
- Analytics and reporting





<b>Equipment Calibration</b>	<ul style="list-style-type: none"><li>• Calibration data automatically routed and tracked</li><li>• Easily managed calibration schedule</li><li>• Calibration tasks generated before the due date</li><li>• Complete records maintained securely</li><li>• Advanced reporting capabilities</li></ul>	 Included with MasterControl
<b>Equipment Maintenance</b>	<ul style="list-style-type: none"><li>• Maintenance data automatically routed and tracked</li><li>• Easily managed maintenance schedule</li><li>• Preventive maintenance tasks generated before they're due</li><li>• Complete records maintained securely</li><li>• Advanced reporting capabilities</li></ul>	 Included with MasterControl
<b>Product Recipes (Pharmaceutical)</b>	<ul style="list-style-type: none"><li>• Simplified product recipe creation</li><li>• Easily managed substitutions and change control</li><li>• Consolidated recipe data</li><li>• Ensured consistency across all products</li><li>• Quick to scale up and out</li></ul>	 Included with MasterControl
<b>Product Variants (Medical Device)</b>	<ul style="list-style-type: none"><li>• Simplified product variation creation</li><li>• Easily managed substitutions and change control</li><li>• Consolidated product variant data</li><li>• Ensured consistency across all products</li><li>• Quick to scale up and out</li></ul>	 Included with MasterControl
<b>Analytics and Reporting</b>	<ul style="list-style-type: none"><li>• Effective and instant data access and analysis</li><li>• Cross-platform, user-determined data insights</li><li>• Prebuilt interactive dashboard library</li><li>• User-friendly data exploration and visualization</li><li>• Robust data sharing and scheduled reporting</li></ul>	 Included with MasterControl
<b>Validation</b>	<ul style="list-style-type: none"><li>• Risk-based validation approach that focuses on critical business processes</li><li>• Advanced technology that accelerates overall validation time</li><li>• Proven process that leverages software provider's internal validation testing to reduce overall effort, cost, and time</li><li>• Simpler upgrades and sustainable validation in the cloud</li><li>• Methodology based on FDA guidelines and proven best practices</li></ul>	 Included with MasterControl

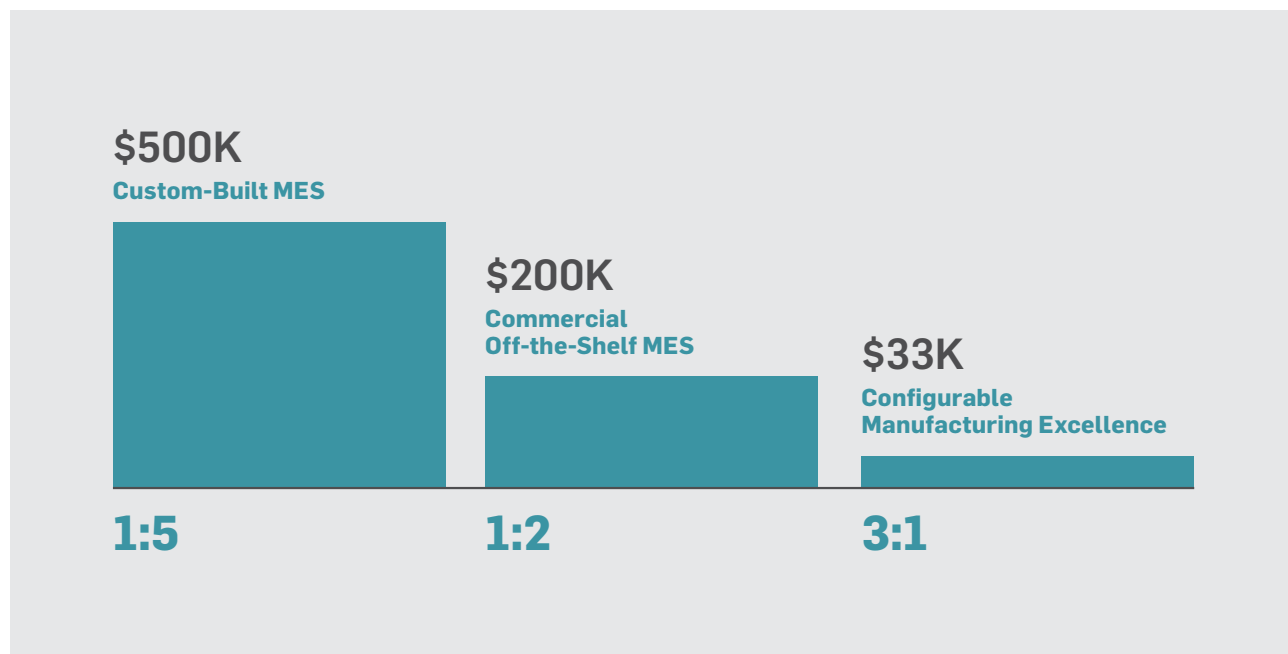
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# Why Traditional MES May Not Be the Right Choice for You

For most production environments, the barriers of adopting a traditional MES have kept many organizations from digitizing their manufacturing environment. At most, 30% of the manufacturing capacity in life sciences can be addressed by a legacy MES due to the high cost and complexity of conventional solutions. Contrary to the longstanding view among manufacturers, a traditional MES is not the only path to digitizing and automating the shop floor when there are next-gen solutions like MasterControl Manufacturing Excellence.

Common Barriers	Traditional MES	MasterControl Manufacturing Excellence
<b>Implementation Time and Cost</b>	<ul style="list-style-type: none"> <li>• Expensive</li> <li>• Time-consuming</li> </ul>	<ul style="list-style-type: none"> <li>• Cost-effective</li> <li>• Fast to deploy</li> </ul>
<b>Configuration</b>	<ul style="list-style-type: none"> <li>• Rigid, hard-coded process configurations</li> <li>• Costly, time-consuming process re-engineering</li> </ul>	<ul style="list-style-type: none"> <li>• Configurable, purpose-built, no-code application</li> <li>• Easily supports existing processes/workflows</li> </ul>
<b>Adoption</b>	<ul style="list-style-type: none"> <li>• Machine-centric design creates poor UI/UX</li> <li>• Requires dedicated support (internal/vendor/3rd party)</li> </ul>	<ul style="list-style-type: none"> <li>• Pick-up-and-use simplicity for engineers and operators</li> <li>• Rapid adoption with no ongoing support resources</li> </ul>
<b>Scalability</b>	<ul style="list-style-type: none"> <li>• Cost justified on only high-volume/margin lines</li> <li>• Rarely deployed across all sites and lines due to fit and/or cost</li> </ul>	<ul style="list-style-type: none"> <li>• Cost-effective and quickly scales up</li> <li>• Ideal for lines MES has difficulty serving – high-mix, high-variability, low-volume, or batch of one</li> </ul>
<b>Validation Complexity</b>	<ul style="list-style-type: none"> <li>• Difficult to validate</li> <li>• Requires extensive people hours for change control</li> </ul>	<ul style="list-style-type: none"> <li>• Employs a risk-based validation process</li> <li>• Simplifies change control</li> </ul>

## License-to-Services Ratios — \$100K in Product



“We knew we needed to get rid of the paper in the cleanroom; it leads to far too many particulates, cellulose, etc., and we can’t have that. We tried to implement a traditional MES in 2011, but it was too static and not built for our business; software from 30 years ago couldn’t do what we need it to do. And while most software requires the client to adapt our processes to their software, MasterControl doesn’t – that’s one of the reasons we chose Manufacturing Excellence.”

– **Biotech producer of personalized immunotherapy treatments to fight cancer**

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# About MasterControl

What can MasterControl do for your organization? Here are a few ways MasterControl's modern, game-changing manufacturing solution is revolutionizing quality manufacturing for our customers.

## Enhanced Data Integrity

"[Manufacturing Excellence] has allowed us to finally move forward and adopt a SaaS approach to digitalizing manufacturing. Our initial pilot has shown very positive results reducing GMP errors and driving greater productivity/efficiency."

- Jennifer Rodriguez,  
Corporate Quality  
Systems Manager,  
QuVa Pharma

## Faster Quality Reviews

"One of the features that has improved our process is review by exception, which dramatically decreases lead time from batch/lot completion to product release."

- Tony Harnack,  
CEO, Wellington  
Foods

## Improved Resource Utilization

"[The staff] love not having to worry about out-of-calibrated equipment. They don't have to worry about expired materials, and they don't have to worry about not being trained on a procedure. They also love not having to do GDP [good documentation practices], having to cross everything out, footnote it, and sign and date it."

- Tian McCann, New  
Product Development  
Engineer, Northeast  
Scientific

## Streamlined Record Management

"By improving the efficiency of master record revisions, we have produced cost savings equivalent to cutting man-hours from one month down to one week."

- Pete Raghubans,  
Quality Assurance  
Manager, EpiBone

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# Why Choose MasterControl?

At MasterControl, we believe digitizing the shop floor should be fast, affordable, effective, and scalable – even in highly regulated environments that require a fully validated system. See why MasterControl Manufacturing Excellence offers the fastest, most cost-effective path to 100% paperless manufacturing.

## 1 Highly Configurable and Usable

Manufacturing Excellence's cloud-based, no-code configuration lets you configure quickly to adapt processes and parameters for product and process changes. It supports existing processes and workflows, so there isn't costly process re-engineering. The solution's simplicity is focused on the operator and their ability to quickly adopt the software without the need for ongoing support resources.

- Rapidly design, modify, approve, templatize, and execute your master batch records or DHRs.
- Easily manage product recipes and variations, substitutions, and change control.
- Accelerate user adoption with pick-up-and-use simplicity on mobile shop floor devices.

## 2 Cost-Effective on Any Line

MasterControl's modern MES is cost-effective enough to eliminate paper-based processes for all production lines, rather than only on high-volume or high-margin product lines like a legacy MES. The Manufacturing Excellence solution's configurability lets you quickly scale up or down as needed. The product family tool reduces costs associated with managing large numbers of master records.

- Quickly scale up and out across production lines, plants, and facilities.
- Ideal for high-mix, high-variability, low-volume, or batch-of-one lines.
- Easily build master templates and adjust for different product recipes or variants.

## 3 Cloud-Based Platform Connectivity

Manufacturing Excellence is natively connected to MasterControl's reliable, proven platform for enterprise document management and control, closed-loop quality management, learning management, supplier quality management, and complaints management. The solution also lets you digitally integrate your batch records or DHRs with a wide range of enterprise applications in your manufacturing IT ecosystem for a more complete view of the data.

- Capture and share real-time production data across systems and departments seamlessly.
- Connect all users across the shop floor, letting operators input data directly into tablets.
- Eliminate data integrity issues before they spread through the production life cycle.

## 4 Rapid Time-to-Value

Manufacturing Excellence can be implemented in under six months for a single-site electronic batch record or electronic device history record solution – including parallel pilot and system validation. Once implemented, the solution can deliver results fast, so you'll see ROI in under 12 months and achieve dramatic, sustainable process and operational improvements.

- Initial payback is 4-8 months depending on the size of your facility.
- First-year savings can be \$250,000-\$300,000 depending on facility size.
- Achieve immediate operational improvements that drive long-term value.

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# How to Measure the Success of Your Manufacturing Solution

MasterControl Manufacturing Excellence offers unmatched time-to-value.

## Paperless in As Fast As 1 Month

**From paper-based to full eDHR in 4 weeks.**

-Innovative Biotechnology Manufacturer

**Implemented QMS and EBR in 8 weeks.**

-EEG/ECG Technology Manufacturer

**U.S. and China sites fully paperless in 6 months.**

-Global Medical Imaging Manufacturer

## Initial Payback in Less Than 1 Year

Manufacturing facilities with under 100 operators.

Initial Payback	4 months
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First-Year Savings	\$300K
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Five-Year Savings	\$2.5M
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Manufacturing facilities with over 100 operators.

Initial Payback	8 months
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First-Year Savings	\$250K
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Five-Year Savings	\$2M
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# Immediate Operational Improvements that Drive Long-Term Value

- **30% Greater Efficiency**
- **30% Faster Product Release**
- **80% Acceleration of GMP Record Review**
- **Shorten product record signoff process from 6 weeks to 20 minutes.**

- **25% Fewer OOS/ Deviations**
- **80% Faster GMP Review**
- **90% Fewer Data Errors**
- **Create master templates in less than 1 hour.**

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