Buyer's Guide

Pharma Manufacturing Software Buyer's Guide

What Pharma Companies Need to Know When Evaluating Manufacturing Software Solutions

MasterControl™

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The pharmaceutical industry operates in a highly regulated and competitive environment, demanding precision, efficiency, and unwavering product quality. This buyer's guide is specifically designed to help process manufacturers navigate the complexities of selecting a manufacturing software solution that not only meets current operational needs but also positions them for future growth and compliance across the production lifecycle.

Understanding the full range of available manufacturing software options—from basic electronic batch records to comprehensive manufacturing execution systems—is crucial for making informed decisions. This guide will help you identify the critical gaps in traditional solutions and understand how modern, connected systems can drive operational excellence and reinforce your competitive advantage.

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The Current State of Production Systems in Pharma

Production support in pharmaceutical manufacturing exists across a wide spectrum—from paper-based processes to disconnected digital tools and traditional manufacturing execution systems (MES). Increasingly, these approaches are inadequate for the demands of modern pharmaceutical manufacturing, whether it be data connectivity gaps between critical systems or insufficient agility for producing increasingly personalized treatments.

For those who seek a digital solution, manufacturers can find themselves caught between basic electronic batch record (EBR) systems that lack comprehensive process control capabilities and full-scale MES implementations that are often expensive, inflexible, and resource-intensive. Historically, pharma companies have had limited digital options, resulting in higher error rates, increased costs, and a lack of the requisite configurability and scalability, all of which are essential for today's dynamic operations.

This middle ground—where manufacturers need robust EBR functionality with enhanced process control and connectivity—has remained largely unaddressed by traditional solutions.

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The Evolution of Smart Manufacturing for Pharmaceutical Production

Smart manufacturing can mean many things, and many pharma manufacturers already have islands of intelligence or automation—both in the operational technology (OT) and the information technology (IT) layer. However, the future of process manufacturing lies in systems that bridge the gap between basic documentation and comprehensive execution control. Implementing solutions that provide better production planning, streamlined template management, optimized manufacturing execution, integrated quality control, and comprehensive data management and analytics—without the overhead of more traditional systems—helps **eliminate data silos**.

The key to success is finding solutions that provide the right level of control and connectivity—ones that go beyond simply documenting what happened and begin intelligently guiding and optimizing the manufacturing process. This is where modern, digital manufacturing execution comes into the conversation.

3

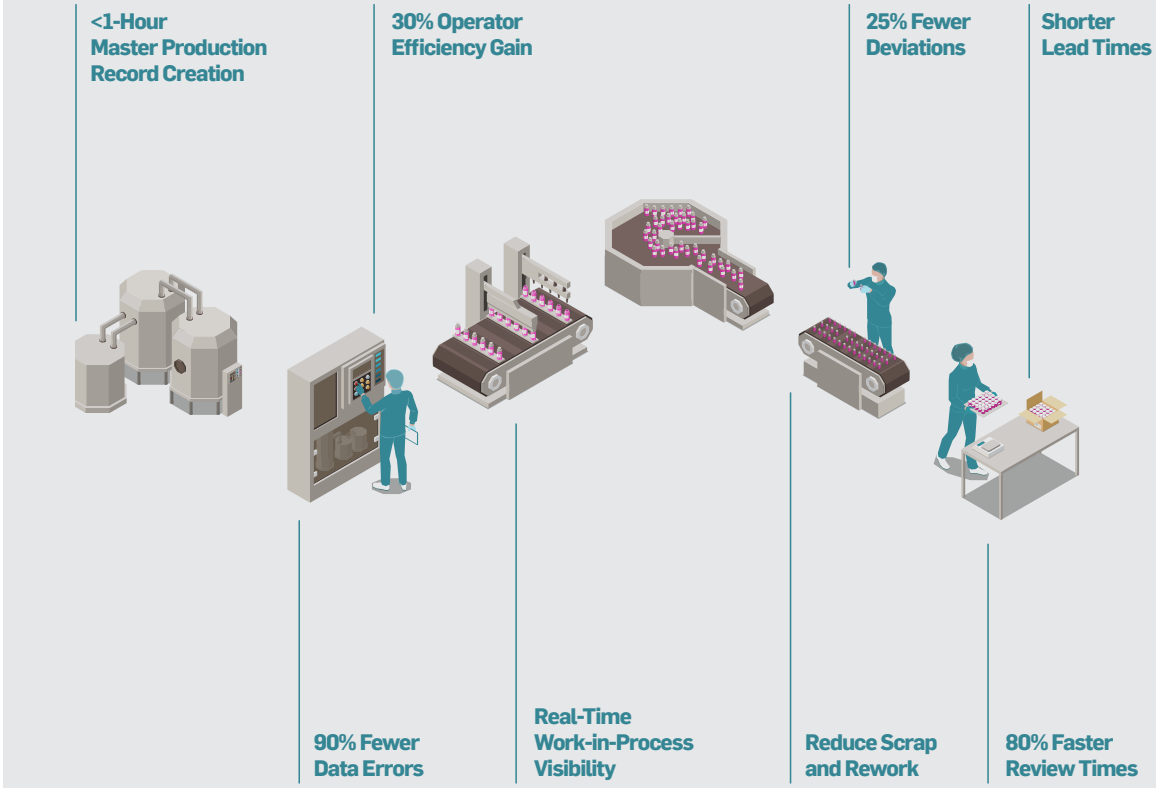
Choosing the Right System for Pharma Manufacturers

When evaluating manufacturing software, pharma manufacturers should understand that there's a broad range of options available, from basic EBR systems to comprehensive MES solutions. The ideal solution for many manufacturers lies somewhere in between—a "connected EBR" that provides robust batch record management with enhanced process control capabilities.

MasterControl's **Manufacturing Excellence** (Mx) solution offers this balanced approach—more robust than a traditional EBR that simply documents production activities, but more flexible and accessible than a full MES. Keeping in mind how critical flexibility and accessibility are in modern process manufacturing, consider these key factors when evaluating manufacturing solutions:

- **Production Visibility With Actionable Guidance:** Real-time visibility into work-in-progress and operator execution, paired with guided actions to keep production moving smoothly.
- **End-to-End Process Data Capture and Contextualization:** Capture every step of the manufacturing process—at the time of execution and with full context—to support repeatability, traceability, and right-first-time production.
- **Real-Time Process Exception Management:** Identify process exceptions (such as deviations) instantly from the shop floor to minimize disruptions, scrap, and production delays.
- **Connected Analytics Across People, Processes, and Systems:** Integrated insights that combine data from execution, training, quality, and enterprise systems support continuous improvement.
- **Integrated Operator Training and Readiness:** Built-in training verification and enforcement ensures operators are trained and qualified at the moment of execution, reducing errors and rework.
- **Collaboration Across Production, Engineering, and Quality:** Shared visibility and connected workflows help teams speed issue resolution and supports tech transfer.
- **Configurability Without Heavy Customization:** Tools that allow process updates and record changes quickly—without coding, complex configuration, or long validation cycles.
- **Built-In Data Integrity and Compliance Guardrails:** Secure, traceable, and enforced execution practices help maintain data integrity and compliance without slowing production.

See Immediate Impact



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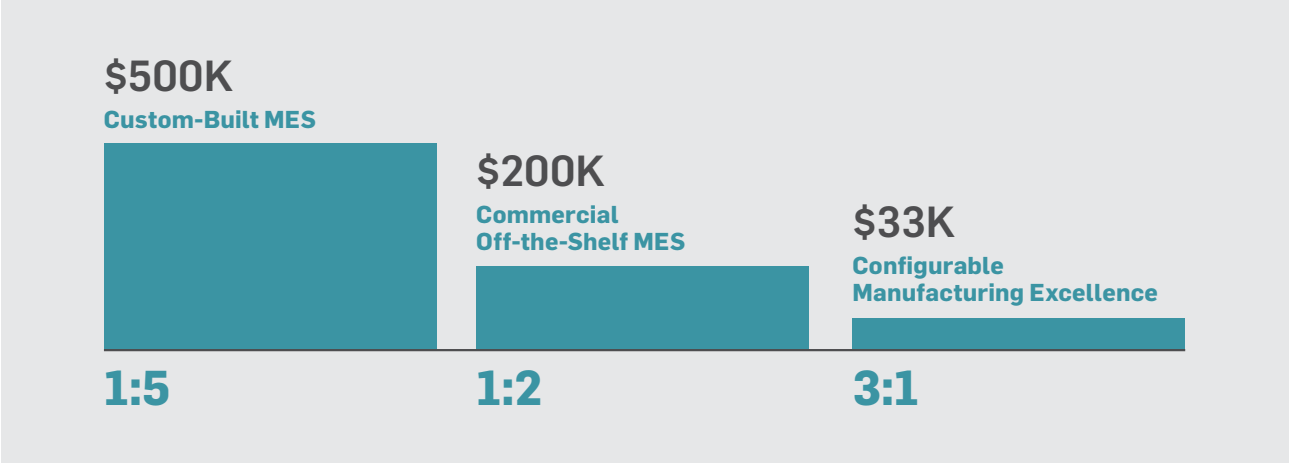
Why Traditional MES May Not Be the Right Choice for Pharma

Traditional MES solutions represent one end of the manufacturing software spectrum. They excel in high-volume, low variability production environments, where deep equipment orchestration and control are essential for consistent output. But for most pharmaceutical manufacturers—where production varies by product, batch, site, or modality—a traditional MES provides more system than is needed, requiring significant investment, long deployment and validation timelines, custom configurations, and ongoing maintenance.

The reality is that many pharmaceutical manufacturers don't rely on extensive automation-layer control. Instead, they need a solution that strengthens process execution, ensures product quality, connects critical data, and can adapt quickly as products, lines, and teams evolve.

MasterControl Manufacturing Excellence brings a right-sized approach. It provides robust digital execution, integrated quality guardrails, and connected data without the cost, rigidity, or heavy automation footprint of traditional MES. For pharma manufacturers who need more than a basic EBR but are not seeking full equipment orchestration, Manufacturing Excellence offers a scalable, configurable, and cost-effective solution that elevates manufacturing execution without unnecessary complexity.

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



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Benefits of MasterControl Manufacturing Excellence for Pharma

MasterControl Manufacturing Excellence combines the speed and simplicity of an EBR with the connected, controlled execution traditionally found in MES. As a cloud-based SaaS solution designed for pharma, it provides robust process management and end-to-end visibility without heavy infrastructure, long deployments, or specialized IT resources.

Key advantages include:

- **Dramatic Reduction in Production Errors Through Connected Processes:** Digitizing, automating, and connecting production steps significantly reduces operator errors and deviations, improves right-first-time (RFT) performance, and accelerates product release. Many pharma manufacturers report notable reductions in execution errors and faster batch throughput after adopting Manufacturing Excellence.
- **Real-Time Production Intelligence Across the Shop Floor:** Capturing data at the point of execution brings offline activity online, ensuring data integrity and giving teams real-time visibility into work-in-progress. Manufacturers using a digital-first approach gain comprehensive process visibility, enabling manufacturing teams to foresee and prevent issues proactively.
- **Less Paper, More Process Control:** Eliminating paper increases accuracy, reduces manual entry risk, and strengthens process control across operations. It facilitates 100% paperless data entry and documentation on the shop floor, which is crucial for batch record creation and process control. One pharmaceutical manufacturer reported a 20%-25% reduction in out-of-specifications and deviations and a 90%-100% reduction in data integrity errors.
- **Connected Equipment Status in the Flow of Production:** Real-time visibility into equipment status ensures operators only use assets that are in-spec and ready for production. This prevents unplanned downtime, avoids batch disruptions caused by out-of-calibration equipment, and keeps lines running smoothly.
- **Review by Exception for Faster Batch Release:** By focusing only on true exceptions—rather than reviewing every record line-by-line—manufacturers see an average reduction of 75%-80% in batch cycle times. Real-time identification and correction of data issues further shortens review and supports real-time-release.

MasterControl Manufacturing Excellence Solutions

MasterControl EBR

MasterControl's **connected EBR solution**, a part of the Manufacturing Excellence suite, is designed to improve right-first-time capabilities through data integrity checks, automated calculations, **review by exception**, real-time collaboration, deviation tracking, real-time transparency, and scalability. It's rapidly deployable, highly configurable, scalable, user-friendly, and incorporates a risk-based validation process.

MasterControl Logbooks

Another component of the Mx suite, **MasterControl Logbooks**, offers a critical solution for managing essential manufacturing and quality documentation in pharmaceutical settings. It streamlines logbook management, enhances quality control through enforced data integrity, and provides customization options for evolving processes.

In addition to electronic batch records and digital logbooks, **MasterControl's Mx suite** provides robust capabilities including digital work instructions, in-line quality control, and in-app operator training. Collectively these fully integrated capabilities contribute to a more agile and resilient manufacturing process, helping pharmaceutical manufacturers adapt to constant changes in the life sciences industry and ensuring operations run faster, leaner, and smarter.

Manufacturing Excellence goes beyond merely digitizing records, delivering a much-needed modern solution that exists in the space between traditional EBR and MES systems. It connects frontline operations, enterprise systems, and quality processes to deliver a digital manufacturing layer that gives a unified view of production—not just a digital binder. Manufacturing Excellence extends EBR with real-time connectivity and enterprise integration yet is still less complex than a traditional/full MES.

Pharma, biologics, and biotech companies that implement MasterControl Manufacturing Excellence get:

- Digital work instructions that deliver task-level guidance and basic data capture.
- Electronic batch records that add data integrity, structure, review-by-exception, and connectivity.
- Robust connectivity/integrations, in-process production visibility, real-time review, lightweight orchestration (e.g., equipment status, materials or inventory information), and embedded quality and compliance guardrails.

What Customers Are Saying About MasterControl Manufacturing Excellence

"[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

"We knew we needed to get rid of the paper in the clean room; 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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Conclusion

The pharmaceutical manufacturing software landscape offers a continuum of options, from basic EBR systems to comprehensive MES solutions. However, many manufacturers find themselves caught in the gap between these extremes—needing more process control than a basic EBR provides but not requiring the complexity of a full MES.

By embracing modern solutions like MasterControl Manufacturing Excellence, pharmaceutical manufacturers can achieve significant improvements in efficiency, compliance, and time-to-market while implementing a system that provides the right level of process control and connectivity for today's manufacturing challenges.

MasterControl offers a connected platform designed to empower pharmaceutical companies in their journey toward Pharma 4.0

Mx Manufacturing Excellence

Configurable, intelligent digital manufacturing platform that connects operators, equipment, and quality processes to improve consistency, visibility, and speed of execution across the organization.

Qx Quality Excellence

Integrated quality management environment that centralizes documentation, change control, and deviation handling and ensures data integrity, compliance, and traceability through the product lifecycle.

Ax Asset Excellence

Unified maintenance, calibration, and utilization data delivers visibility into equipment performance and rediness, improves reliability, ensures compliance, and extends asset life.

About MasterControl

Manufacturing, Quality, and Asset Management — Simplified With Life Sciences-Specialized AI.
MasterControl Solutions Inc. is a leading provider of cloud-based quality, manufacturing, and asset management software for life sciences and other regulated industries. For three decades, our mission has been the same as that of our customers – to bring life-changing products to more people sooner. MasterControl helps organizations digitize, automate, and connect quality, manufacturing, and asset management processes and has a proven track record of improving product quality, reducing costs, and accelerating time to market. Over 1,100 companies worldwide use MasterControl to streamline operations, maintain compliance, manage critical assets and equipment, easily analyze and interpret large amounts of data, and visualize business insights in real time.

For more information, visit **www.mastercontrol.com**.