MasterControl™

The Ultimate Guide to Digitizing the Shop Floor

Chapter

1

The State of Digital Transformation in Manufacturing

As Industry 4.0 initiatives and digital transformation efforts get off the ground, ongoing advances in Industrial Internet of Things (IIoT), artificial intelligence (AI) and robotic process automation are making their mark on everything from product assembly to quality inspection to equipment maintenance and even good manufacturing practice (GMP) documentation.

It's no wonder that leading manufacturing companies today are focusing heavily on fully digitizing and integrating information technology (IT) and operational technology (OT) capabilities. Worldwide spending on the technologies and services that enable digital transformation is forecast to reach $2.3 trillion in 2023, according to the International Data Corporation (IDC). The market research firm estimates that discrete and process manufacturing will deliver the largest digital transformation spending amounts throughout the forecast, accounting for nearly 30% of the worldwide total. A 2019 report from PricewaterhouseCoopers and the Manufacturing Institute also found that 73% of manufacturers planned to increase their investment in smart factory technology over the next year.

Clearly, manufacturing companies are feeling the pressure to determine how digital fits into their business models and the right ways to leverage its possibilities. Based on data from 300 manufacturing industry CEOs, professional services firm KPMG found that 95% of respondents believe technological disruption is an opportunity and not a threat, and nearly two-thirds of respondents agree that acting with agility is "the new currency of business; if we're too slow, we will be bankrupt."

Of course, strategic initiatives like Industry 4.0 and digital transformation aren't as simple as buying and implementing new software. In KPMG's findings, more than a third of manufacturing CEOs admitted their organizations are struggling to keep pace with the rate of technological innovation in manufacturing, and almost half aid most of their technology investments are tactical.

Even as Industry 4.0 efforts and underlying technologies accelerate in various areas of manufacturing, many manufacturers stop short of digitizing the "last mile" of their factory floor, where operators typically still use paper-based production records. Whether these manual, paper-based records are called batch records, device history records (DHRs), production travelers, routers, etc., companies often pause or falter when it comes to fully digitizing and automating them.

Despite the investments manufacturers have made in core system digitization and industrial automation – from enterprise resource planning (ERP), manufacturing execution systems (MES) and material requirements planning (MRP), to laboratory information management systems (LIMS) and supervisory control and data acquisition (SCADA) – the investments are too often impeded by critical processes that remain manual, disconnected and often paper-based activities. Manual processes still dominate the shop floor, where people on the production line have been left to deal with paper, spreadsheets and other standalone systems to create, maintain, approve and release production records.

At every step, manual processes are slow, cumbersome and subject to human error. Companies that use paper-based production record processes often encounter many of the same problems across production and quality:

1. Inefficient processes.
2. Inaccurate information.
3. Poor data tracking.
4. Disconnected systems.
5. Preventable quality issues.
6. Friction between manufacturing and quality.

Life sciences organizations are well-aware of the high potential costs of relying on outdated, paper-based processes and documentation in a data-driven world – product recalls, warning letters, consent decrees, costly shipping delays and, of course, poor customer satisfaction.

Data integrity is amongst the top items cited on U.S. Food and Drug Administration's (FDA) warning letters, according to GxP inspection analytics firm Govzilla. In fact, the FDA cited data integrity on 79% of the drug warning letters over the last five years, and they have increased the number of warning letters citing data integrity by over four times.

"Failure to document quality unit responsibilities and procedures was once again the top citation in the agency's Form 483 reports," according to an FDAnews analysis of the FDA's good manufacturing practices (GMP) inspection reports for 2019. "It's been the top citation for over a decade – often by a wide margin."

The second most frequent GMP lapse was failure to thoroughly review unexplained discrepancies or batch/component failures to meet specifications, which moved up from third place, according to FDAnews.

While digital technologies create huge opportunities for manufacturers' ability to improve processes and mitigate common errors of manual, paper-based production records that lead to FDA observations, few have taken full advantage of them. According to a recent study by Zebra Technologies, a majority of manufacturing executives surveyed said their organization uses pen and paper to track vital manufacturing steps, while 50% reported using spreadsheets or a computer on wheels.

By digitizing and automating the "last mile" of the production process, life sciences organizations can capture the manufacturing data and insights needed to optimize production, reduce deviations and corrective/preventive actions (CAPAs), improve right-first-time (RFT) metrics and accelerate product release. A digital production records solution can extend digitization to the edge users who need it most, closing the digital gap and delivering significant quality and productivity improvements.

By the Numbers:
Digital Transformation in Manufacturing

95%

of manufacturing industry CEOs believe technological disruption is an opportunity and not a threat.

KPMG

#1

Failure to document quality unit responsibilities and procedures was the top citation in the FDA's Form 483 reports in 2019. It's been the top citation for over a decade – often by a wide margin.

FDAnews

30%

of the $2.3 trillion forecast to be spent worldwide on digital transformation technologies and services in 2023 will likely be driven by discrete (e.g., medical device) and process (e.g., pharmaceutical) manufacturing.

International Data Corporation (IDC)

58%

of biopharma executives, business leaders and analysts say digital is a top management priority.

Deloitte and MIT Sloan Management Review

73%

of manufacturers plan to increase their investment in smart factory technology over the next year.

PricewaterhouseCoopers and the Manufacturing Institute

Discover Manufacturing Excellence

MasterControl Manufacturing Excellence™ is a new breed of manufacturing application: mobile-first, operator-centric and data-driven. Bridging the digital gap between core enterprise systems – resource planning (ERP), manufacturing execution systems (MES), material requirements planning (MRP) and quality management systems (QMS) – and empowering the workforce that drives the last mile of production, MasterControl's Manufacturing Excellence™ solution eliminates human error and maximizes manufacturers' information technology (IT) and operational technology (OT) investments.

MasterControl
Manufacturing Excellence™

Robust Capabilities for Your Workers and Business

1 Digital Production Records	Fully digitize production records – batch records, device history records (DHRs), travelers, routers, etc. – so data is digital from beginning to end, with no paper forms or offline processes to be reconciled manually.
2 Digital Work Instructions	Empower the production workforce with work instructions and standard operating procedures (SOPs) that are always up to date, with real-time tracking of stages, steps and performance.
3 In-Line Quality Assurance	Ensure quality at every step of production, and automatically assess risk and launch quality events, such as nonconformance and deviations, directly from the production line without interruption.
4 In-App Operator Training	Enforce training compliance with fully automated, user-based training checks and in-app training delivery, so your workforce never completes a task without complying with training requirements.
5 Equipment Compliance	Automate and manage equipment calibration and maintenance tasks to improve quality and compliance, minimize downtime and help avoid bottlenecks.

2

Digitalizing Quality-at-the-Source

The Problem with Paper-Based Production Records

When manufacturers use a paper-based system to manage production records, line workers and quality teams must rely on inefficient processes and poor data quality. Manual, paper-based systems limit the ability to track manufacturing changes, identify quality events and take corrective action in real time.

Moreover, managing production records manually, with every step of the process undertaken by hand and on paper, often leads to inaccurate or missing information on the production record due to scribal errors. Such human error accounts for downtime, cost overruns and product sitting unshipped. According to a Vanson Bourne and ServiceMax study of the expenses, causes and consequences of unplanned downtime, 20% of all unexpected manufacturing downtime is the result of user error.

Cumulative human errors turn into poor data that then snowballs into deviations and delays. With manual, paper-based production record processes, both time and money are wasted correcting paper records, retrieving information and reviewing records. In a survey of senior executives from medical device, contract manufacturing and pharmaceutical companies, Accenture found that quality testing and batch release accounts for upwards of 70% of manufacturing lead time mainly due to manual processes, disconnected instruments and non-standard paper-based documentation and control procedures.

Manual data entry errors, remediation and review, along with insufficient tracking capabilities, drive production costs up while reducing efficiency, throughput and profits. These preventable errors result in shipping delays, wasted resources and poor cash flow.

20%

Unplanned Downtime

Over 20% of all unplanned downtime in manufacturing is the result of human error.

40%

Preventable Deviations

Up to 40% of all deviations are caused by some form of human failure.

70%

Longer Lead Times

Up to 70% of manufacturing lead time is due to manual processes and paper-based quality and batch review processes.

80%

Poor Data Integrity

The FDA cited poor manufacturing data integrity on almost 80% of FDA warning letters over the last five years.

Achieve Right First Time, Every Time

The shop floor is a critical, but often overlooked, opportunity to make quality proactive rather than reactive. Every operator, every step and every output of the production process is a chance to establish quality and compliance – but only if operators are empowered to deliver quality at the source. MasterControl Manufacturing Excellence™ is the missing link, enabling manufacturers to build quality into the production process, not outside of it.

The fully connected Manufacturing Excellence solution provides a truly paperless, error-reducing system for maintaining and tracking production data that affects quality. Error-proofing features reduce mismarks or missing information on production records, with automated real-time quality review at each step on the production line, to help ensure lots are right the first time. You can track manufacturing changes automatically and identify quality events and take corrective action in real time, to drive immediate improvement and operational efficiency.

1. Eliminate data input errors.
2. Validate production record processes in real time.
3. Reduce deviations and corrective/preventive actions (CAPAs).
4. Enforce quality controls without slowing production.

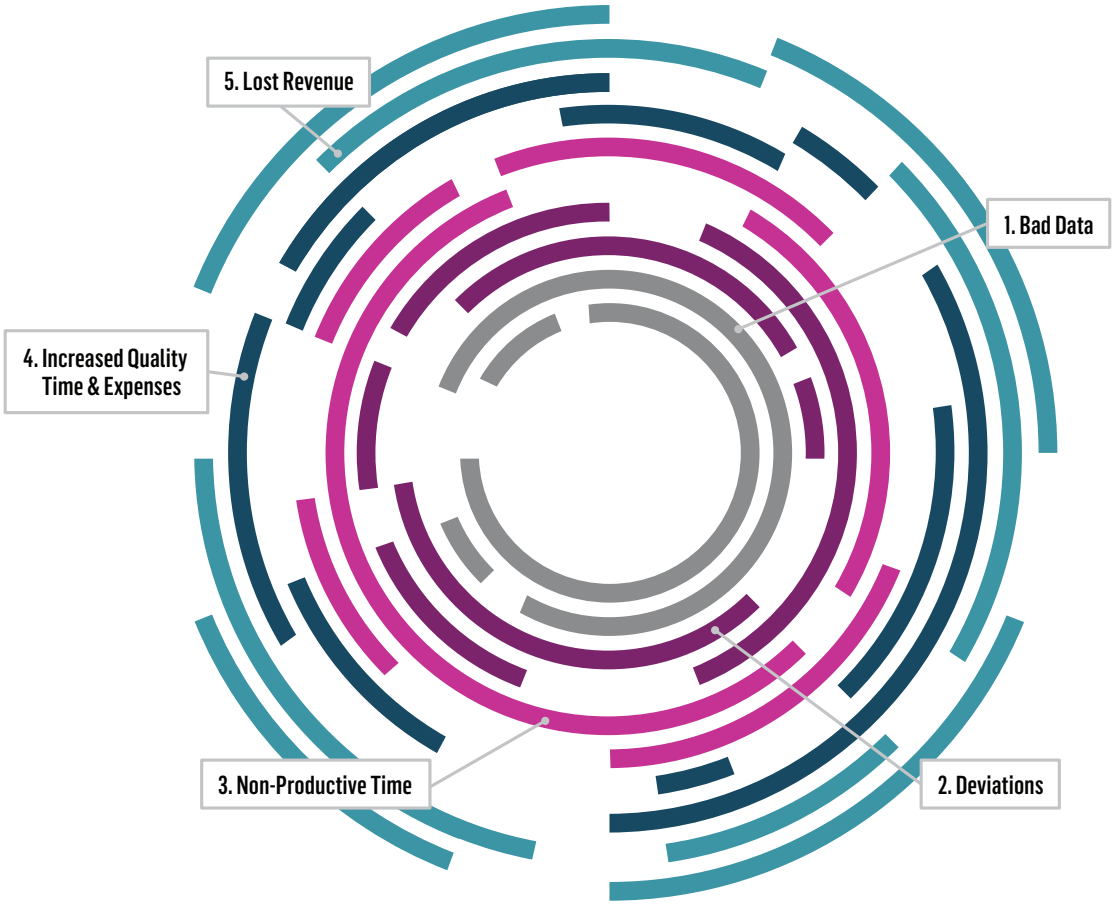
By eliminating the documentation burden and automating the labor-intensive last mile of the production process, MasterControl Manufacturing Excellence™ enables quality managers and plant line supervisors, operators and managers to focus on improving the quality and throughput of their product, not of their production records – achieving right-first-time (RFT) production every time.

Hidden Costs of Quality: A Ripple Effect

The costs of quality are high in modern manufacturing. Even a small amount of paper on the factory floor results in real consequences on a manufacturer's success.

When manufacturers employ paper-based systems, human errors and poor data integrity have a ripple effect as the data advances through the production process, slowing everything down. The ripple effect starts on the shop floor, where data-input errors on the production record lead to paperwork issues, more deviations/nonconformances, holds and downtime. These outcomes result in non-productive time, such as employees having to leave the production line for standard operating procedures (SOPs), work instructions or training. This non-productive time, in turn, requires most organizations to increase their quality control efforts and expenditures to identify and locate the errors they know exist.

Manufacturing leaders can no longer afford to rely on manual, paper-based systems to manage quality and production, largely due to this ripple effect of bad data.



3 Ways to Build Quality Assurance into Production

1. Launch digital quality forms directly from production records.
2. Automatically launch training and enforce training compliance.
3. Link SOPs/work instructions to production record phases.

4 Paper-Based Review Problems

1. Lot release delayed by manual GMP reviews.
2. Lower shipment and delivery-to-commit rates.
3. Resources tied up in paperwork.
4. Human errors slowing cash flow.

6 Benefits of Embedding Quality in the Production Process

1. Integrated quality and manufacturing management.
2. Greater visibility.
3. Robust manufacturing processes.
4. Accelerated production record processes.
5. Improved cycle times and efficiency.
6. Enhanced line performance.

The Digital Difference

MasterControl Manufacturing Excellence™ has the unique ability to deliver very tangible improvements to key manufacturing operations and product quality KPIs in a short timeframe at a relatively low cost. It is also easy for production workers and line operators to learn and use – leading to broad, sustainable end-user adoption.

90%-100%
decrease in common data input errors

75%-80%
acceleration of GMP record review and product release

30%-40%
fewer individuals dedicated to GMP record review

20%-25%
reduction in total manufacturing deviations

Manufacturing and Quality: No More Us vs. Them

Manufacturing operations and quality departments often clash because of their seemingly competing priorities, differing approaches and misalignment.

Whereas quality prioritizes complete paperwork, followed quality control processes and up-to-date training, manufacturing's goals tend to embody minimal downtime, maximum throughput and fast time-to-ship.

"Production and quality, by nature, have never gotten along," says Robin Joyner, MasterControl system administrator at Wellington Foods.

Leveraging digital tools to capture data and glean insights needed by both quality assurance (QA) and manufacturing operations teams benefits both functions and facilitates better communication and collaboration in corrections and verifications. Collecting, connecting and contextualizing metrics, data and insights needed by both quality teams and manufacturing teams helps address shared processes, including:

1. Document revisions.
2. Good manufacturing practices (GMPs).
3. Training.
4. Sampling/testing.
5. Review and release.

For both production and quality teams at Wellington, implementing the MasterControl solution together has been a benefit.

> **"A lot of the input that has come from production, quality sees value in it, and a lot of the stuff that quality has added to it, production sees value in it," according to Robin Joyner, MasterControl system administrator at Wellington Foods. "So, it kind of takes away that 'us against them' mentality."**

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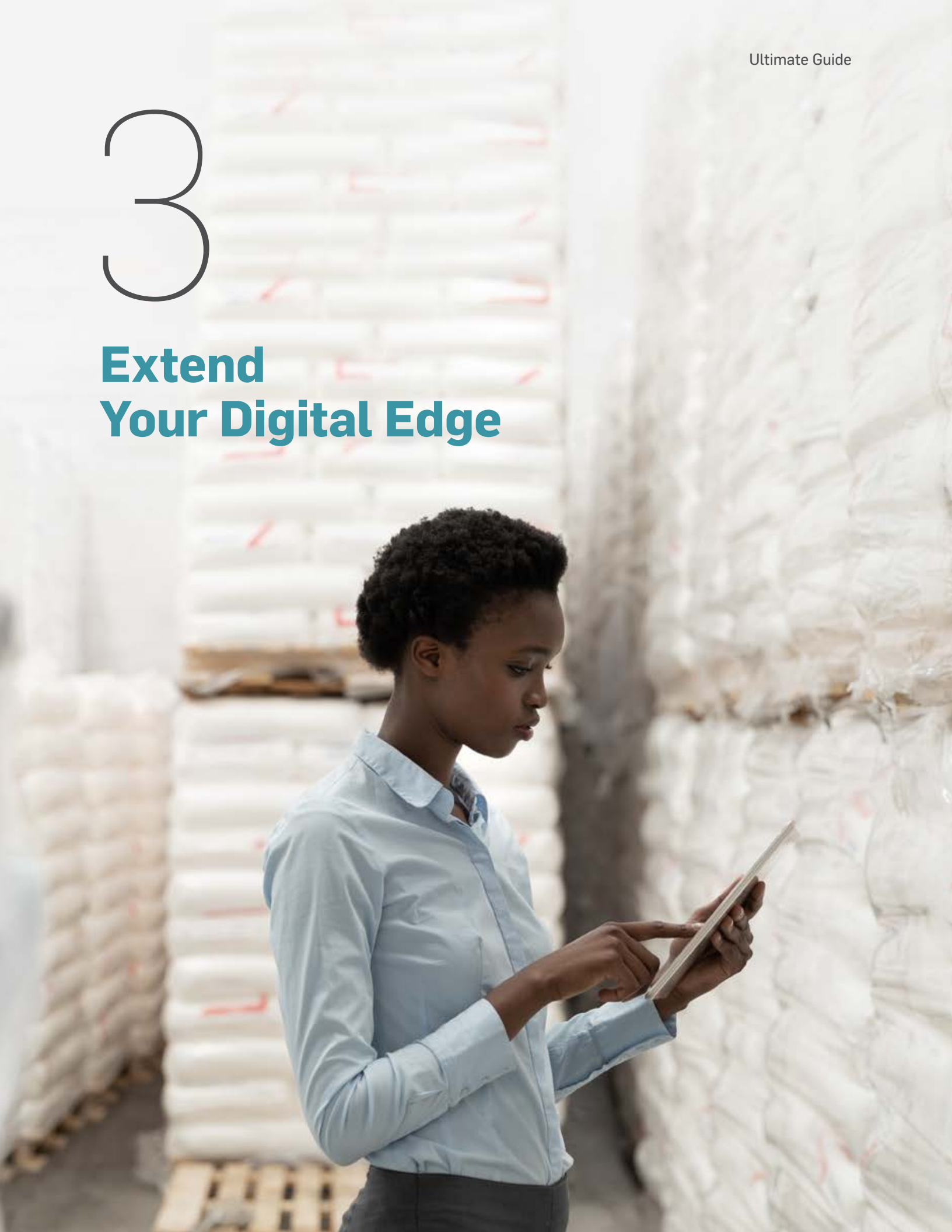
Extend Your Digital Edge



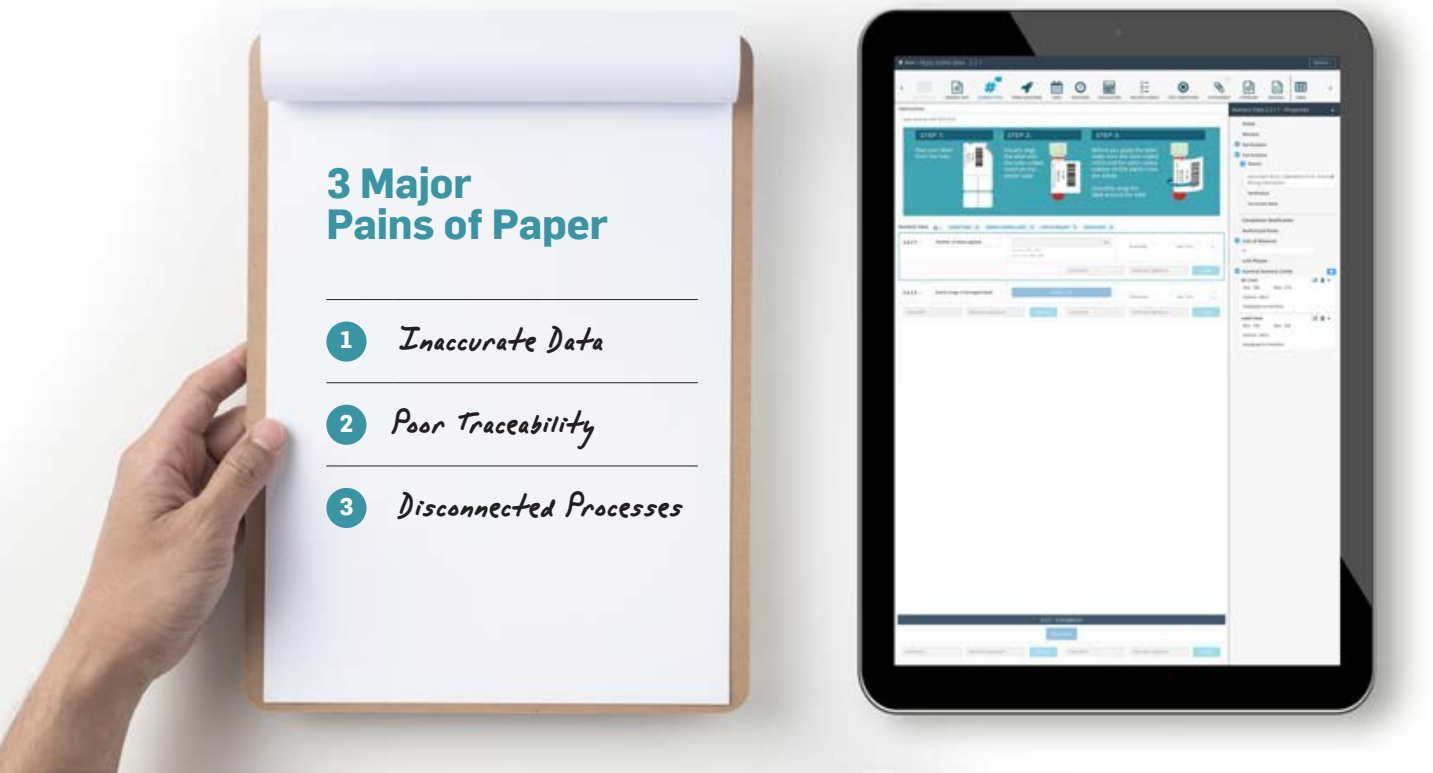
Disconnected Systems, Data Sources and Processes

Despite manufacturers investing heavily in enterprise automation, particularly enterprise resource planning (ERP), material requirements planning (MRP), and manufacturing execution systems (MES), people responsible for production records have been left to deal with paper, spreadsheets and other standalone systems to monitor, collect and aggregate data surrounding production and quality processes.

Many manufacturers still rely on a variety of only partially digitized processes – therefore partially paper-based – or disconnected information systems that offer little communication or interoperability between one another. Paper-based production records don't automatically integrate with electronic systems or other quality processes, making complete information transfer all but impossible. Like paper-based systems, electronic systems, if siloed, insufficiently track data and documents from different areas throughout the production life cycle, resulting in information gaps, blind spots and preventable errors.

In terms of systems where connecting via digitization reduces information gaps, consider as an example reconciling the ERP bill of materials (BOM) with the production BOM in real time. Here, challenges are common due to manually recorded materials, scrap, etc., leading to variances. Other areas where disconnected information systems cause problems are in inventory management, time-logging systems and personnel training, among many others.

Poor communication between disconnected information systems like ERP, MES, learning management systems (LMS) and quality management systems (QMS) severely limits the throughput between manufacturing, quality and other critical business areas, which impedes physical operations and generally undermines stakeholder collaboration. These disconnects, bad data and the resulting lack of visibility and collaboration across the enterprise lead to a host of business inefficiencies. According to IBM, poor data quality in the U.S. alone costs $3.1 trillion a year.



Digitize Beyond Your Core Systems

When it comes to digital transformation in both quality and manufacturing, LNS Research recommends an integrated network of systems and processes.

To collect, connect and contextualize the data and insights needed to optimize manufacturing and ensure quality throughout the production life cycle, companies must integrate their production record processes with their ERP, MES, QMS and other core information systems for a more complete view of the data within their business. For example, operators on the shop floor should be able to input production data directly into tablets and pull product or materials info from the organization's ERP.

With a digital system like MasterControl Manufacturing Excellence™, you can create productive connections between enterprise systems, data sources, processes and people throughout your entire organization, for a holistic view of data. Rather than replace your organization's existing ERP, MES and MRP systems, the MasterControl solution extends them to the shop floor, automating the labor-intensive "last mile" good manufacturing practice (GMP) review and release to drive immediate operational productivity and quality improvements.

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

According to Aberdeen, approximately 47% of manufacturing organizations believe they must become more data-driven to remain competitive. By integrating the disparate enterprise applications in your manufacturing IT ecosystem with a fully digital production record system, you can close the digital gap and glean truly actionable, data-driven performance insights to deliver significant quality and productivity improvements. This way, personnel can focus on the product rather than paperwork.

The Digital Difference

30% increase

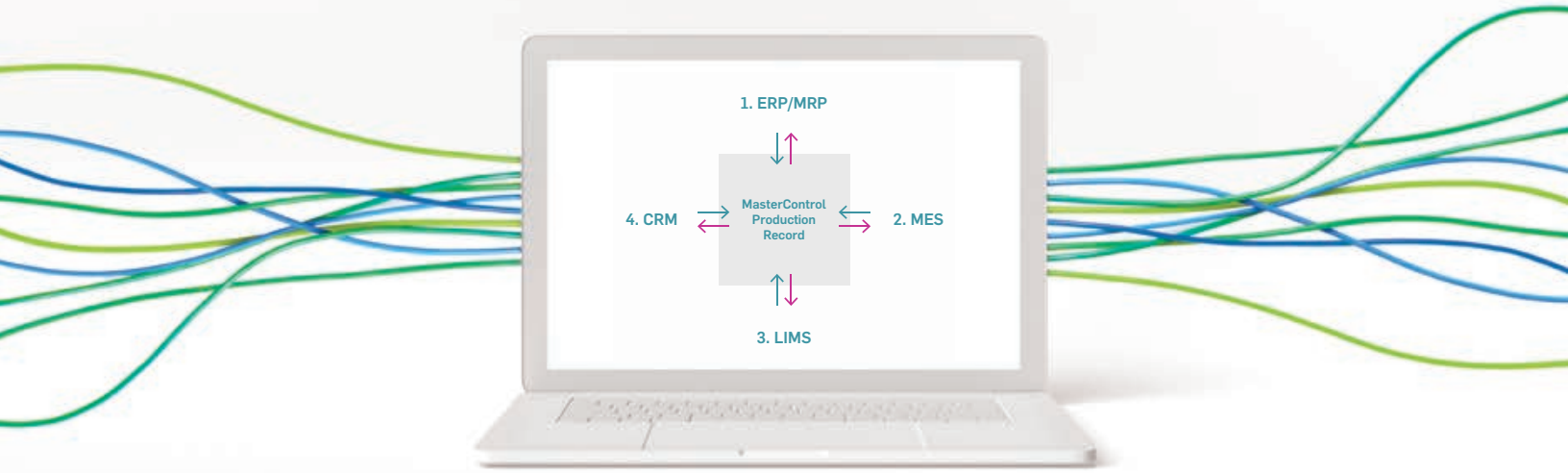
in employee efficiency, reducing overall production costs.

Legacy Pharmaceutical Packaging, LLC

50% reduction

in individuals required to manage production record paperwork.

Wellington Foods

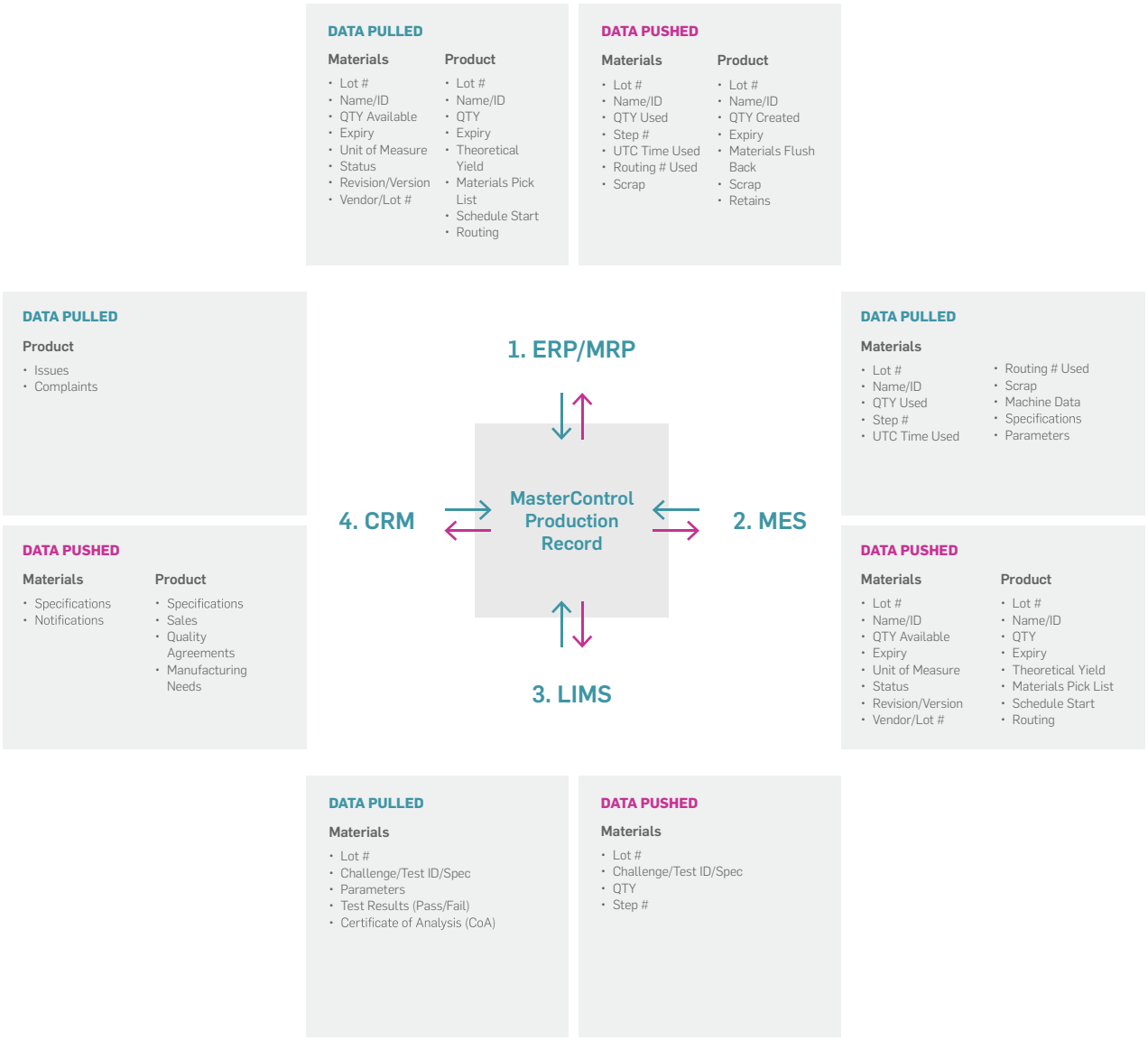


Collect, Connect and Contextualize Your Production Data

MasterControl Manufacturing Excellence™ connects production and quality data with control, execution and enterprise systems by leveraging integration platform as a service (iPaaS) technology. The solution is also compatible with proprietary application program interface (API) connections.

Integrate Manufacturing Excellence with your:

- Enterprise resource planning (ERP).
- Material requirements planning (MRP).
- Manufacturing execution system (MES).
- Laboratory information management system (LIMS).
- Customer relationship management (CRM).
- Quality management system (QMS).



By the Numbers:
Mind the Information Gap

18.4%

of executives from all life sciences industries emphasized disparate quality systems and data sources when asked their top quality management challenges.

LNS Research

20%

of executives in manufacturing operations management cite disparate systems and data sources among key challenges in addressing top manufacturing objectives for life sciences companies.

LNS Research

27%

of manufacturers are collecting data from production, supply chain and workers, yet the data is remaining in silos, rendering useless much of the intelligence it can provide.

Zebra Technologies

46%

of manufacturers say increased visibility across their operations will support growth and that they expect technology and automation to continue transforming the plant floor and delivering quality improvements across all stages of production.

Zebra Technologies

4

Empower Smart Operators

When Digitization Leaves People Out of the Process

Smart manufacturing efforts have too often focused on systems and machines rather than on people, sometimes "optimizing" workers out of the process altogether.

Now, organizations are shifting to a more holistic view of connected operations that digitally integrates people and systems across operations. Like the industrial revolutions before it, Industry 4.0 is bringing about changes that are based on the degree of connectivity between frontline workers and their work environment.

"Use cases in the initial wave of industrial transformation (IX) investment focused on using asset-related data and advanced analytics to drive improvement in areas such as asset reliability, energy management, and product quality," LNS Research says. "Now, there is a strong trend towards an integrated approach that incorporates workforce considerations into IX initiatives and using people-related data to drive improvement in the overall operational management system."

With a human-centric approach to technology, life sciences manufacturers can extend process improvement activities to the edges of operations – where paper persists and enterprise systems are disconnected from the factory floor – empowering digitally connected workers to thrive within a data-driven manufacturing environment. In this environment, personnel can leverage such technologies as augmented reality and smart wearables for use cases across production, maintenance, field service and more. In LNS Research's findings, asset- and equipment-focused IX use cases are among the most impactful, including asset performance monitoring, predictive maintenance and prescriptive service.

The rise of digitally connected workers reflects "the conventional wisdom that improvement, whether incremental or step-change, calls for holistic alignment of the right people, process and technology capabilities," the research and advisory firm says.

The real benefits of digital transformation can only be achieved when it supports workers. Process automation is about optimizing people and processes to increase efficiencies and decrease the chance of human error. This releases humans from needing to perform specific, repetitive tasks, which in turn leads the way to enhancing worker performance.

"With a human-centric approach to technology, life sciences manufacturers can extend process improvement activities to the edges of operations – where paper persists and enterprise systems are disconnected from the factory floor – empowering digitally connected workers to thrive within a data-driven manufacturing environment. "

Smart Applications to Drive Transformation

Digital technology should support and enhance people, not replace them.

On the factory floor, where the next generation of employees entering the workforce and advancing through the ranks are digital natives, digital technology should extend the critical role people play in frontline operations from limited interaction with elements of the overall operations management system to a high degree of interconnectivity.

"I'm a digital person. I'm not into the paperwork and having to do all of the documentation," says Jimmy Sareñana, manufacturing operations manager for MasterControl customer Wellington Foods, a contract manufacturer of dietary supplements and nutritional products. "And the other personnel, these kids, coming into the operations ... a lot of them are used to tablets and phones, so that kind of stuff is just going to make it a whole different game."

MasterControl Manufacturing Excellence™ takes a human-centric approach to digitization, focusing on such areas as data input, information access, in-context information and prescriptive actions. The solution error-proofs data input, automates review/traceability of changes on records, facilitates the multi-directional flow of data and actionable insights and applies advanced analytics to equipment calibration and maintenance. Line workers can easily capture all entries on a production record in real time, with automatic data-integrity checks ensuring the data is entered completely and correctly. The solution provides contextualized intelligence, prompts and risk-based recommendations to operators in real time.

1. Integrated, data-driven prompts guide operators through work instructions, enforce out-of-specification and nonconformance limits and thresholds, ensure operator training is always current, and notify operators of all open deviations and corrective/preventive actions (CAPAs).

2. In-process dashboards provide real-time visibility into the status of production lines, batches or lots, and operator performance between different lines and shifts.

3. Lot runtime dashboards display current runtime data alongside historic runtime data, including throughput metrics, CGMP error rates, out-of-specification and nonconformance events.

Time spent in the past on paper systems and manual data formatting and math calculations can now be done electronically and automatically, freeing up people to focus on value-adding activities, leverage their intuition, experience and insight, and drive transformation.

> **"The leadership now has visibility from anywhere in the company to look at a batch record. They can watch this in real time," according to Robin Joyner, MasterControl system administrator at Wellington Foods. "It makes my job a whole lot easier because I'm not trying to justify and prove to them the benefits of it. They're seeing the true benefits, not just from a dollar standpoint but from freeing up employees."**

Better Data for Better Decision Making

With improved access to shop floor data, process engineers can make better, quicker decisions about nonconformances, deviations and corrective/preventive actions (CAPAs). Data from the digital production records can be used to glean real-time insights, identify bottlenecks and evaluate the results of quality and compliance checks.

Data-driven manufacturing with digital production record tools empowers manufacturers to:

- Gain greater visibility throughout the production life cycle.
- Improve efficiency and optimize operations.
- Address production issues before problems arise.
- Improve overall product quality.

> **“Our management’s philosophy from day one with using MasterControl’s electronic batch records was to get people to focus on the right things. What makes a quality product better is being able to focus on the work, not the paper.”**
>
> Robin Joyner,
> *MasterControl System Administrator at Wellington Foods*

> **“As MasterControl’s EBR makes processes more efficient, we are able to find more hours in people’s days that can be applied in much more efficient and beneficial ways.”**
>
> Tony Harnack,
> *President of Wellington Foods*

5

Achieve Perfect Production

A Shortage of Actionable Insights

There can be no "smart manufacturing" without operational intelligence. Manufacturers' goal is always to deliver more product faster, at lower costs and with fewer quality issues.

Yet inadequate or siloed data is rendering much of the intelligence that data can provide useless in efforts to accelerate product delivery, reduce costs and minimize quality issues.

To capture and leverage the data and insights needed to optimize production, reduce deviations and corrective/preventive actions (CAPAs), improve right-first-time (RFT) metrics and accelerate product release, manufacturers must use digitization to create productive connections and product data flows across value streams through systems, machines, processes, departments and people, to and from a company's physical assets – all for a more holistic view of data.

"Companies that are able to leverage ubiquitous data in meaningful ways – across product development, sales and operations; across devices; and with customers – are developing new models of collaboration," according to PricewaterhouseCoopers (PwC). "The winners will be those companies that use digitization to successfully introduce greater flexibility, customization and speed into their operations while also staying cost-competitive."

Manufacturers are not oblivious to this opportunity. According to 2018-2019 research from Gartner, 64% of manufacturing decision makers expect more than 50% of their production data and information flows to be automated in two years.

> **"Companies that are able to leverage ubiquitous data in meaningful ways – across product development, sales and operations; across devices; and with customers – are developing new models of collaboration."**
>
> PricewaterhouseCoopers (PwC)

By the Numbers:
Impossible Performance Insights with Inaccessible Data

25%

of executives in manufacturing operations management cite timely visibility into manufacturing performance metrics among key challenges in addressing top manufacturing objectives for life sciences companies, followed by disparate systems and data sources (20%) and lack of collaboration across different departments (20%).

LNS Research

26.3%

of executives from all life sciences industries placed considerable focus on effectively measuring quality metrics when asked about their top quality management challenges.

LNS Research

79%

of the FDA's drug warning letters over the last five years cited data integrity.

Govzilla

Real-Time Production Intelligence

The full effect of digitization on manufacturing operations is only realized when manufacturers are able to correlate production, supplier and quality data to glean real-time, actionable insights. MasterControl Manufacturing Excellence™ achieves this by creating connections. The digital solution enables the free flow of data and communication between different enterprise systems, equipment and people.

With Manufacturing Excellence, machine operators can input data directly into tablets or computers on the shop floor, connect and pull information directly from an enterprise resource planning (ERP) system and log customized production record documents in real time. Operators can link standard operating procedures (SOPs) and work instructions to production record phases, launch deviations, CAPAs and other quality processes directly from the production record, automatically launch and enforce training on the production line, and even ensure equipment compliance in real time.

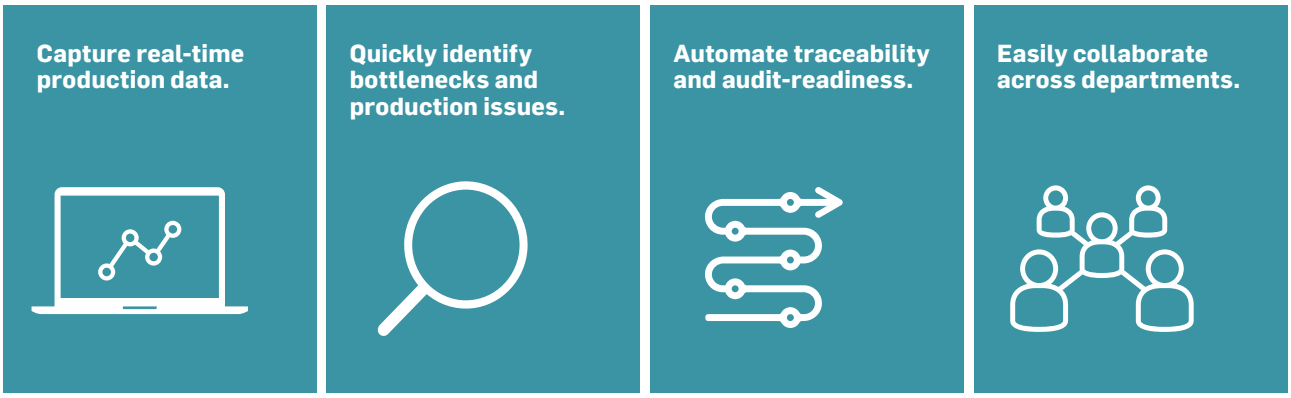
For instance, the MasterControl solution automates and manages routine calibration activities and record-keeping for more efficient manufacturing performance, and it manages the equipment maintenance schedule and automatically generates preventive maintenance tasks before they're due. Digital production record forms can easily be revised to reflect a company's quality and compliance efforts, allowing equipment maintenance procedures to be updated in-process, resulting in quicker maintenance activity completion and more reliable uptime for crucial components in the manufacturing process.

Digitizing the collection and flow of data means manufacturers can better understand how their shop floor is working and make data-driven product- and process-related decisions. Greater access to data from the factory floor enables quicker, more informed decisions when it comes to nonconformances, deviations and CAPAs. Providing stakeholders with immediate access to this data will increase efficiency, reduce unplanned downtime and enable end-to-end traceability throughout production and beyond.

The culmination of this data-centric, platform-connected and easily integrated ecosystem will be a model in more dynamic intelligence and manufacturing operations being brought closer to perfect production. On average, life sciences manufacturers that have gone fully paperless on the shop floor with MasterControl's digital manufacturing solution have seen a 90% decrease in data input errors, a 21% reduction in total deviations and a 75% reduction in post-production review.

Paperless Initiatives on the Shop Floor

Advantages of going paperless with a digital system:



The Digital Difference

1. No more missing or illegible data fields.
2. No more incomplete documents.
3. No more outdated worker training.
4. No more disconnected quality events.

> **“Manufacturers should harmonize processes, automate these processes with software, connect automated processes to other systems and operations, and leverage collective analytics and learnings to continuously improve system autonomy. This approach shifts the focus of high-value staff away from the mechanics of execution and toward innovation and improvement.”**
>
> LNS Research

Technology-Driven Process Improvements

Gaining immediate access to digital production record data will:

1. Streamline production processes.
2. Reduce unplanned downtime.
3. Ensure process compliance.
4. Enable end-to-end traceability throughout production.

3 Fundamental Ways to Leverage Data Using Manufacturing Excellence

By integrating critical software applications with MasterControl's Manufacturing Excellence™ solution, manufacturers can leverage their data in three valuable ways:

1

Collect data

Easily configure the type, timing and frequency of data to be collected, eliminate human errors that are common when manually inputting and transferring data, and ensure data integrity as data moves between systems.

2

Connect data sources

Integrate the production record process with other business systems, including ERP, MRP, MES and LMS, and share data between those systems and functional areas completely, seamlessly and in real time.

3

Contextualize data

Guide operators and enforce limits, thresholds and training with integrated, data-driven prompts, gain real-time visibility into lines, batches or lots, and access current runtime data alongside historic runtime data.

SPOTLIGHT

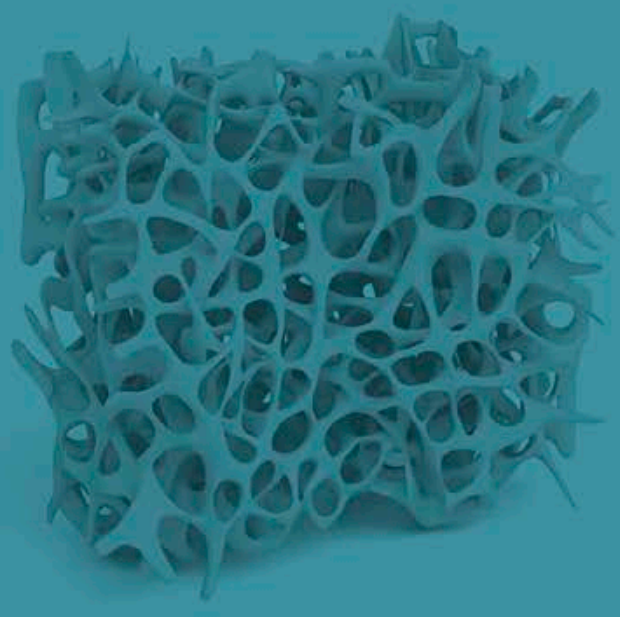
Digitizing production records with MasterControl Manufacturing Excellence™ has empowered EpiBone, an innovative regenerative medicine company, to build quality into production, eliminate paper-based inefficiencies and ensure continuous validation.

Advances in the fields of generative medicine, computational biology and medical imaging are paving the way for personalized medicine, which promises to be a key driver of the combination product market. Regenerative medicine company EpiBone is among the innovative upstarts looking to harness personalized medicine to improve people's lives.

Based in Brooklyn, New York, EpiBone is developing living grafts for skeletal reconstruction. With just over a dozen employees, the company produces a combination product that is a biologic with the attributes of a medical device, which must meet FDA 21 CFR 820 requirements. Due to the personalized nature of most of its products, EpiBone is often producing a unique product that is a batch of one. As a regenerative medicine company with a personalized approach and a five-week production cycle, efficiency is critical – production records must be reviewed and released quickly, completely and transparently.

With MasterControl's cloud-based digital quality and manufacturing platform, EpiBone has built quality into production and dramatically improved the manufacture of the company's clinical grade products.

EPIBONE



Time savings since implementing MasterControl:

FEATURE:	FEATURE:	FEATURE:
Master Record Template Builder	**Review By Exception**	**Validation Excellence Tool™ (VxT)** (U.S. Pat. 10,324,830)
BENEFIT: Reduce time spent building master record templates from months to days, and fully automate version change management.	**BENEFIT:** Close out a production record in less than a day, compared with the two weeks it took to sign off on paper-based records.	**BENEFIT:** Reduce time spent validating software from weeks to hours, taking an FDA-recommended risk-based approach to validation.

> **“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

6

What a Truly Connected, Paperless Environment Looks Like

The Digital Difference

Paperless

Remove the last vestiges of paper from the shop floor, and ensure that product review and release is fully digital, connected and accelerated.

Errorless

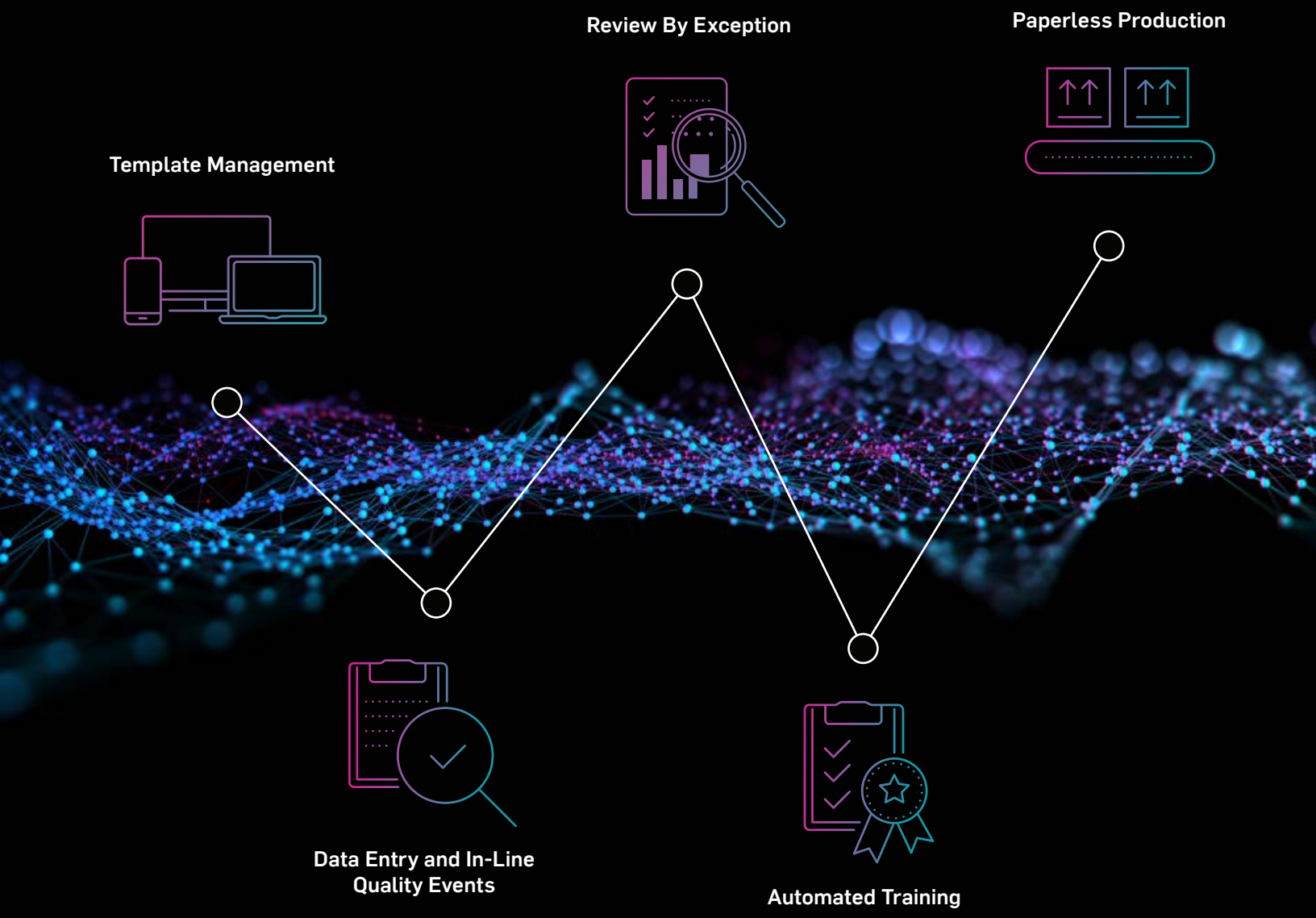
Eliminate preventable errors, long review cycles and costly waste created by manual data entry to achieve right-first-time (RFT) production.

Connected

Integrate production records with your core information systems for a complete view of your business data and actionable performance insights.

Frictionless

Reduce the friction between manufacturing operations and quality assurance priorities and metrics to improve line performance and accelerate production.



Achieve Manufacturing Excellence with MasterControl

Delivered through the powerful MasterControl platform, the fully connected Manufacturing Excellence solution reduces production errors, improves cycle times and efficiency, enhances line performance, accelerates product release, and integrates manufacturing and quality management – ultimately unifying manufacturing operations and quality priorities.

MasterControl
Manufacturing Excellence™

Powerful Tools for Your Quality Manufacturing Needs

1 MasterControl eDHR™	provides the capabilities needed by medical device manufacturers to gain total control of device history records (DHRs) and device master records (DMRs).
2 MasterControl EBR™	contains essential tools that pharmaceutical manufacturers need to streamline and maintain orderly master batch records and batch production records.
3 MasterControl Equipment Calibration™	automates equipment calibration for more efficient manufacturing performance.
4 MasterControl Equipment Maintenance™	manages the equipment maintenance schedule and automatically generates preventive maintenance tasks before they're due.
5 MasterControl Validation Excellence™	reduces the time required to conduct risk-based software validation from months down to hours.
6 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.
7 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.

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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