MasterControl

The State of Digital Maturity in Pharma and Medtech Manufacturing

1.

Executive Summary

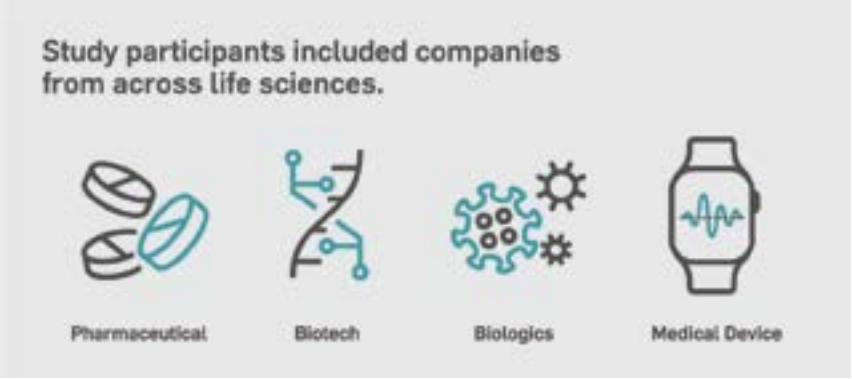
Life sciences product manufacturing is constantly innovating to meet new demands in areas such as personalized medicines and treatments for orphan diseases. These life-saving advancements in manufacturing methods get therapies to market faster and alleviate product shortages.

Advanced manufacturing technologies are necessary to keep up with evolving trends in life sciences. The ability of any company to keep pace with the industry depends on how well it is taking advantage of these modernized technologies and achieving digital maturity. Ultimately, digital maturity is a state where companies adopt the technologies that enable them to establish a seamlessly connected, optimized, and error-free manufacturing operation.

Overall, there is still an abundant amount of paper and siloed, homegrown management systems in life sciences product manufacturing. Regardless of whether companies have some degree of digital manufacturing, paper is still widely used on the shop floor and in most other areas of the organization.

MasterControl has been in the life sciences industry for more than 25 years and has helped thousands of companies that are developing leading-edge innovations. With a unique perspective of what it takes to achieve and sustain success in life sciences manufacturing, MasterControl set out to identify why manufacturers of regulated products are not as digitally mature as those in other industries. A central reason for this study was to find out why companies are still functioning in a manufacturing operation that is largely manual, siloed, and heavily reliant on paper.

To help manufacturers of regulated products get a better idea of where they stand on the spectrum of digital maturity in relation to the current trends and their industry peers, the study comprised 152 life sciences manufacturing professionals based in the following focus areas:



The study participants are located across the globe. They include a representative mix of company sizes ranging from small (less than $10 million in revenue and fewer than 500 employees) to very large enterprises (over $1 billion in revenue and more than 5000 employees). The respondents also included a variety of roles, ranging between 10-14 years of experience across the manufacturing organization.

To better define and measure digital maturity for the study, we designed a manufacturing maturity model with four tiers:

1 Manual	2 Digital	3 Connected	4 Intelligent
Primarily paper-based.	Some processes digitized.	Manufacturing execution system (MES)/electronic batch record (EBR) on every line.	Real-time, integrated operational processes.

In this report, your industry peers reveal:

1. Where they are in the maturity model.
2. Where they thought the industry was.
3. What might be holding them back from implementing modernized technologies.
4. What would compel them to pursue digital maturity.

2.

The Life Sciences Digitization Picture

The life sciences industry is often considered a digital laggard as regulatory burdens have historically slowed the adoption of new technologies. That said, we were a little surprised when at first glance, the majority of respondents (57%) reported that they already have an MES/digital manufacturing solution in place.

Upon closer inspection of what that actually means in terms of digitization at the facility and line level, a much different story unfolds.

Of the 57% that indicated they had a MES/digital manufacturing solution in place, only 9% actually have it implemented at all facilities and sites; 62% have the technology fully implemented, but only at some facilities; 25% have it only partially implemented, and 3% are in the process of initial implementation.

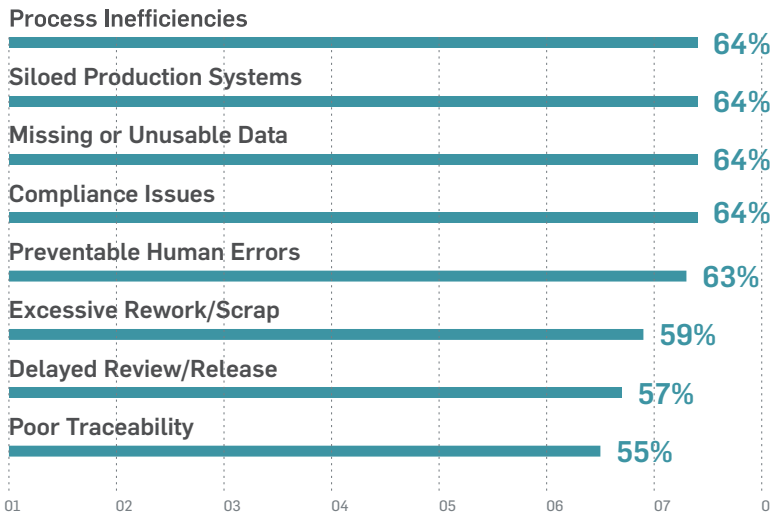
Taken in aggregate, the vast majority of facilities and lines do not have a MES/digital manufacturing solution in place today, meaning many life sciences manufacturers are in fact still lagging behind in digital transformation.

The Burdens of Manual/Paper-Based Systems

The fact that life sciences companies are slow to adopt digital technologies means they are not reaching their full potential as a contributor to the life sciences value chain. For those that try to refute this assertion with the "if-it-isn't-broke-don't-fix-it" argument, here is what respondents said about their experience with their current operations:

Common Challenges With Manual Systems

Companies that adopt a modern MES overcome these issues.



"Digitalization aids in the collection of additional data and information for the purposes of improving the manufacturing process and gaining a better understanding of customer demands in the future," said a life sciences product manufacturer.

3.

State of MES Adoption: Why This Research Matters

Life sciences product manufacturing is one of the most innovative sectors, making significant contributions to public health on a global scale. Companies in this industry continue to push more breakthrough products and advanced therapeutics into mainstream health care. Still, companies are pursuing these developments using outdated methodologies, such as legacy MES solutions and paper documentation and reporting processes.

Many manufacturers have implemented traditional MES solutions on only the largest, most automated lines and sites. This means these companies have struggled to adopt digital solutions across all product lines — even though according to the research, most consider it a high priority.

Many of the most innovative pharma and medtech products come from small companies that understandably function in largely paper-based operations. What's surprising is the number of large-scale companies that continue to use paper and manual processes in all or some parts of their manufacturing operations. Many leading companies, such as multinational pharmaceutical, medical device, and biotechnology organizations, might have a traditional MES for their high volume, blockbuster lines. However, they still keep many product lines manual. Consequently, this decision impacts the bottom line as they struggle to meet key performance indicators (KPIs) and goals.

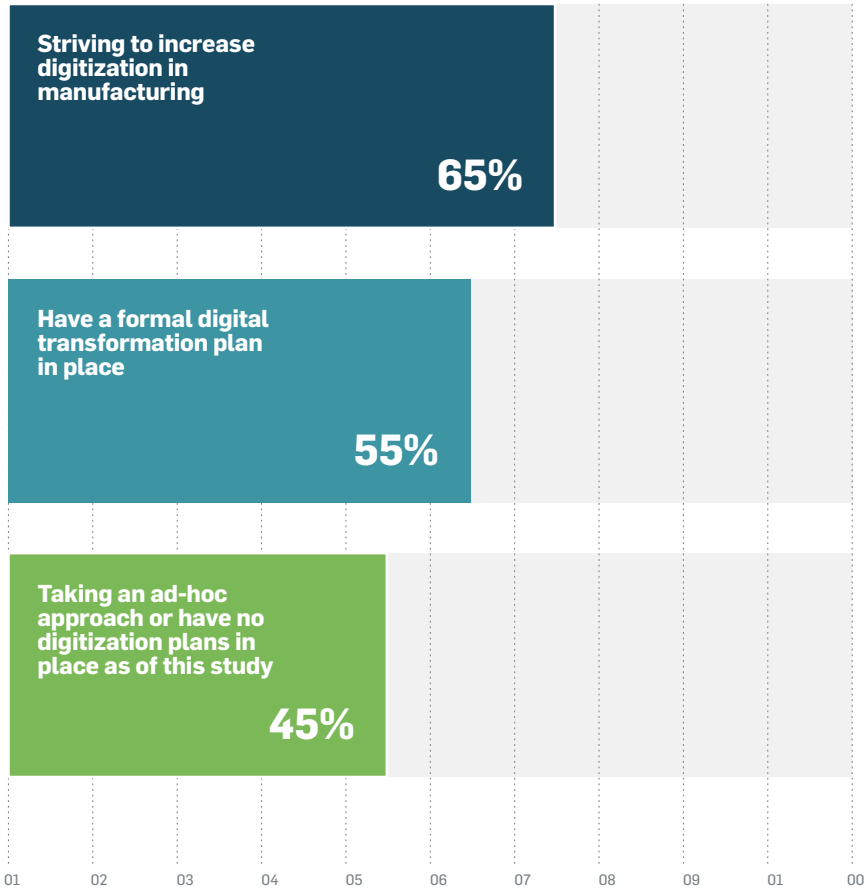
Only 9% of the 57% that have an MES said they have the system fully implemented across all sites and lines. The problem is product lines that are still paper-based are inefficient as they require more employees and time to complete all the manual processes.

More than 90% cited that they don't have any digitized processes, or they have significant gaps in the processes that are digitized.

4.

Key Findings on Manufacturers' Progress Toward Digitization

Going digital involves strategic planning. Here are the stats on the respondents' current digitization status:



5.

Popular Reasons Manufacturers Digitize Operations

Digitization is a high priority for many companies in life sciences. Here are some of the top reasons for deploying advanced technology:

- Increase data visibility to make more informed decisions.
- Keep up with or stay ahead of their competition.
- Improve inventory management and tracking.
- Establish more efficient labor management.
- Improve cross-department collaboration.
- Accelerate root cause analysis/diagnosis.
- Boost productivity.
- Reduce waste.

63%

credit competitive advantage as the biggest driver to increase digital maturity.

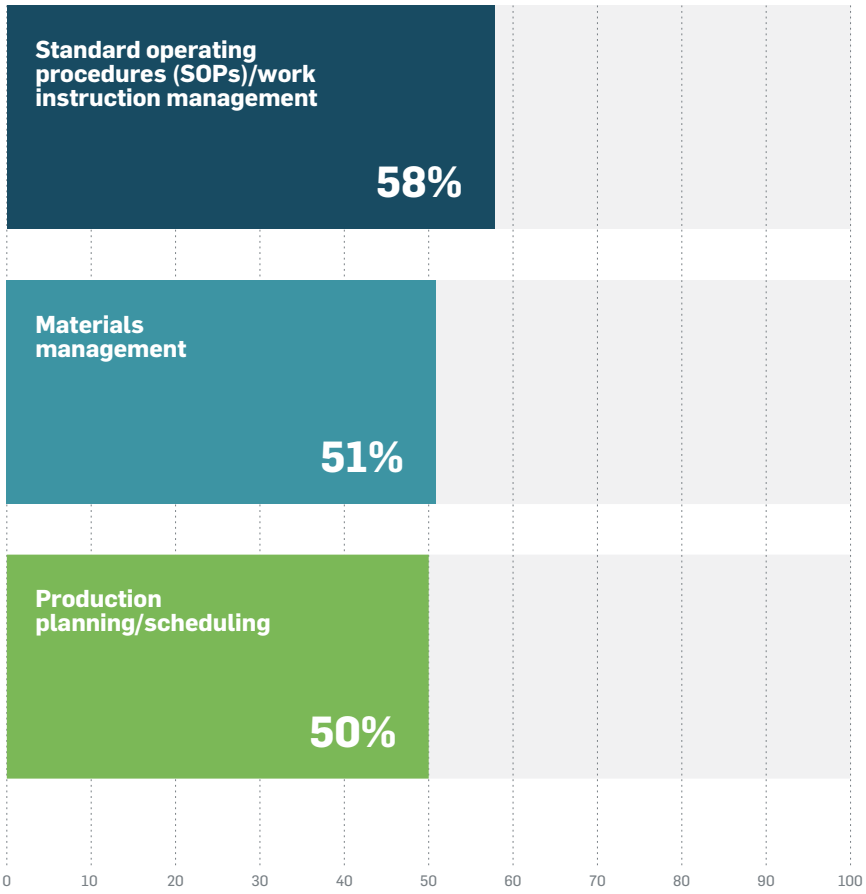
"What we found is that with every competitor, we were obligated to change our processes to meet the solution. With MasterControl and its customization capabilities, we were able to customize the solution to meet our processes. And what this led to was an easier implementation overall. Our operational units really didn't feel the change was that hard," said a quality systems manager at a biotherapeutics company.

MasterControl is leading the industry with new, flexible manufacturing software to help companies digitize their manufacturing processes. Our Manufacturing Excellence solution is a modern MES that is fast to deploy, simple to use, and cost-effective, making it feasible to roll out across all your lines and sites without disrupting operations. Quickly digitize your processes and easily build, manage, and execute production records. Allow your staff to focus on the work rather than completing multiple document reviews to ensure all errors are identified and corrected.

6.

Key Findings on the Order of Tasks Companies Digitize

Organizations tend to implement updates incrementally. The most common processes life sciences product manufacturers digitize first include:



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Key Findings on the Level of Improvement Achieved Through Digitization

41% of respondents reported that improving connectedness in their organization was a driver for increasing digital maturity. These five systems are ranked in order of priority for integration.

1	**Enterprise Resource Planning (ERP)** Automates and manages core business processes like supply chain management, operations, financials, and human resources (HR).	63%
2	**Supervisory Control and Data Acquisition (SCADA)** Connects the sensors that monitor and control equipment on the shop floor to an on-site or remote server.	49%
3	**Lab Information Management System (LIMS)** Manages samples and associated data such as workflows, test results, derived sample data, and study metrics.	49%
4	**Quality Management System (QMS)** Automates quality throughout the entire product life cycle to help companies navigate ever-changing regulations and standards, streamline processes, and demonstrate compliance.	48%
5	**Product Lifecycle Management (PLM)** Manages the complete journey of a product from ideation, development, service, and disposal — focused on product development and processes.	40%

Life sciences manufacturing encompasses a vast network of systems and technology. To optimize production and reach the level of Intelligent in the digital maturity paradigm, integration across the organization is essential. MasterControl's MES creates a seamless connection between plant operations, line performance, and quality teams for truly paperless and error-free manufacturing.

8.

Modernization: Your Path to Intelligent Manufacturing

Expanding on the concept of the maturity model, our research provides insights about where life sciences product manufacturers currently are on the path to maturity. The graphic below pro vides a more detailed definition of each stage of the digital maturity model.

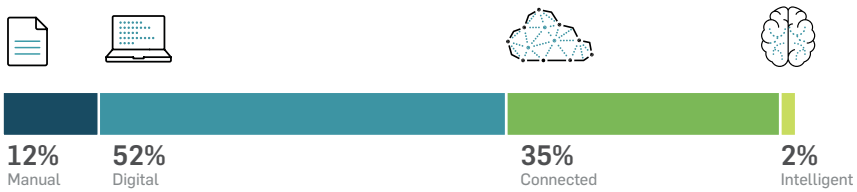
Manual Legacy Production	Digital Digital Production	Connected Connected Manufacturing	Intelligent AI-Driven Manufacturing
• Highly manual, paper-based. • Offline/siloed production data.	• MES/EBR on some lines. • Digital process/data capture. • Automation of basic processes. • In-process, data insights.	• MES/EBR on every line. • Broad integrations (ERP, QMS, LIMS, Etc.). • IoT connected equipment/assets. • Multi-site system standardization. • Unified product plus production data. • End-to-end process data modeling.	• Real-time operational intelligence. • Continuous process optimization. • Dynamic planning/ scheduling. • Self-optimizing equipment. • Autonomous production. • Augmented decisioning. • Real-time release.

Based on the research, most companies categorize themselves in the Digital or Connected stage, but also report that their MES/EBR systems are not fully implemented and integrated.

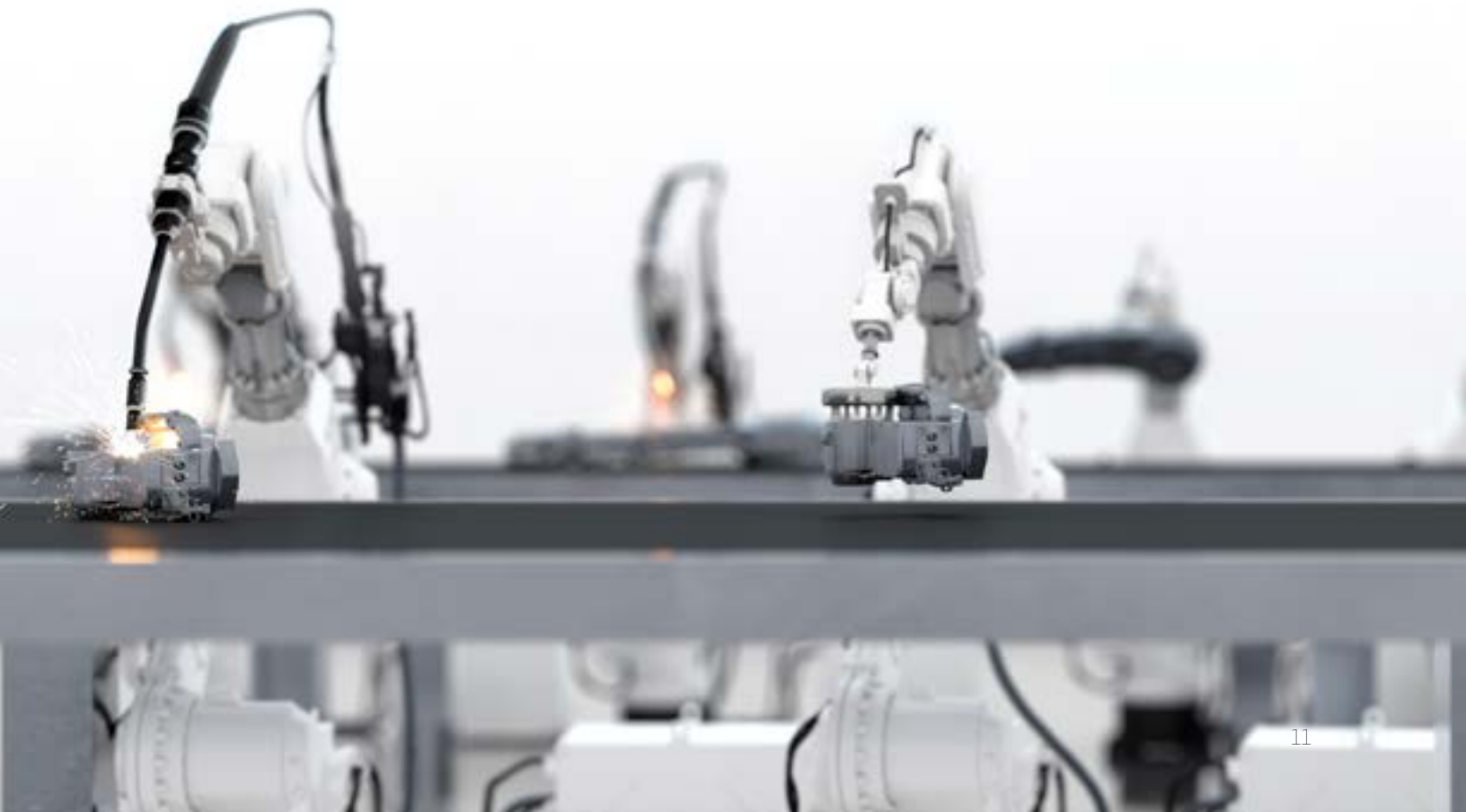
9.

Key findings on where companies see themselves in the maturity model

Life sciences companies reveal their current level of digital maturity.



Companies in the biologics industry rated themselves as mostly Connected (63%), suggesting that newer therapeutics (like cell and gene therapies) are becoming more common and advanced technologies are essential for developing these therapies.



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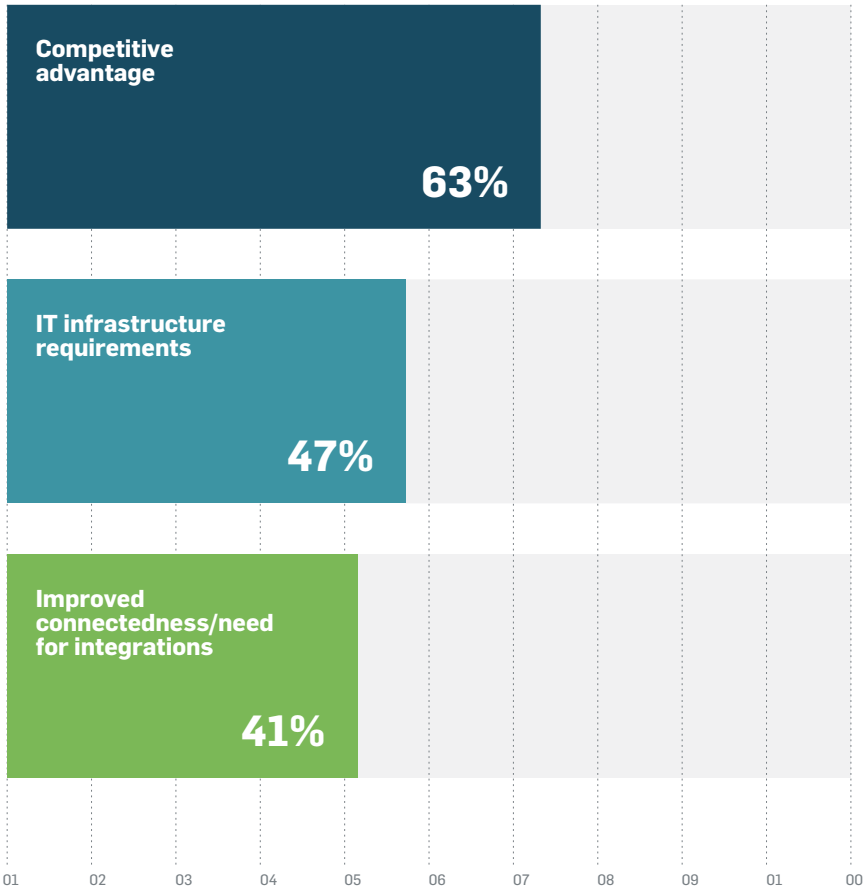
Key findings on reasons for increasing digital maturity

Common reasons companies are compelled to digitize their manufacturing operation.

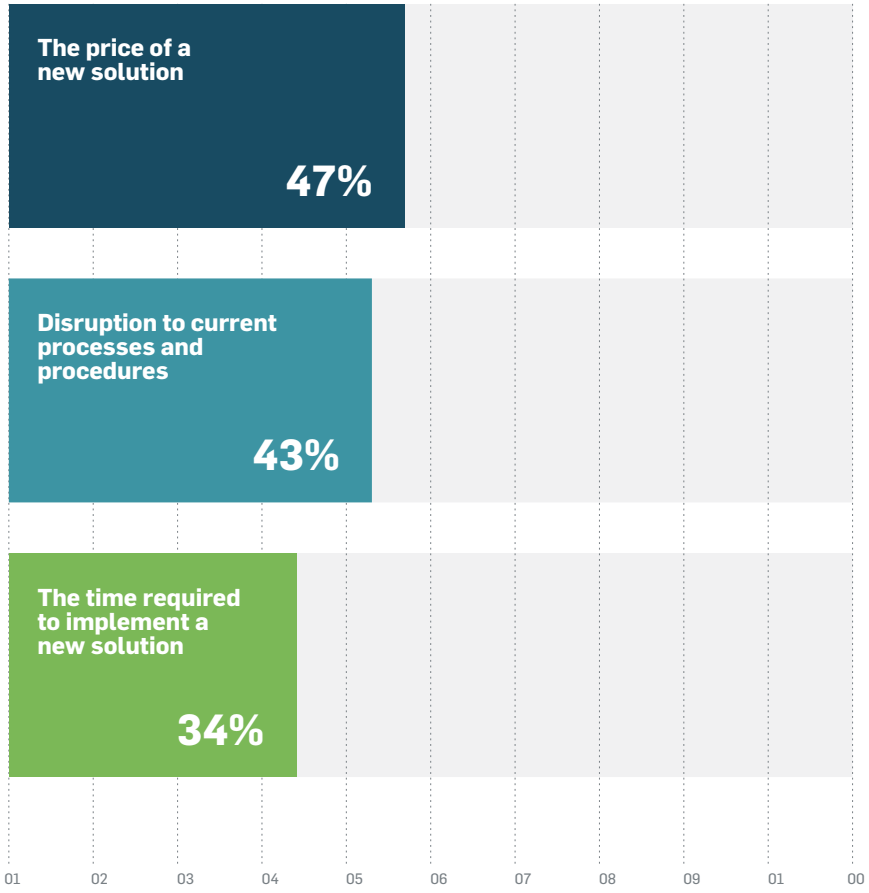


"Organizations are moving quickly. Maybe not all will reach that top tier, but there are definitely more [companies moving toward] Digital and Connected tiers," said a life sciences industry professional.

11.

Key Findings on Why Companies Don't Digitize

Despite the urgency to digitize, many companies are opting out of modernization. The following are the top three reasons companies gave for not moving forward with digital transformation:



These statistics speak to the common pain points of a traditional MES, which could account for the lag in digital maturity in life sciences.

"With MasterControl, 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," said a product development engineer at large medical device manufacturing company.

12.

Assessing Your Digital Manufacturing Maturity

This is where you take an honest look at where your company is in its digital transformation. The notion of digitizing your operations can seem daunting, but it doesn't need to be. Taking a methodical approach, you can assess your current state of digitization and take incremental steps to achieve your goals.

Take an online assessment.
Find out how you stack up against your competitors.

Take Assessment

By responding to these questions in concert with the research data you can gain valuable insight for comparing your current state of digitization to that of the industry.

1

Where does digitization rank in your business-strategy priorities?

Based on our research, most companies consider digital maturity a high priority, but not the top priority. That's a good starting point. We found that the importance of digitization was fairly consistent across all industries. It's important to note that the biggest driver of digitization is competitive advantage. Leading in the market is critical for long-term relevance. Having accurate metrics and relevant data at your disposal is extremely valuable for elevating your position in the industry, which can only be achieved through digitization.

2

How advanced is your current manufacturing operation?

To determine your level of modernization, start by looking at how much paper is being shuffled around on your shop floor and other areas of the organization. Are employees making hand-written notes on reports and manually moving them through approval cycles and manufacturing phases? Does the staff need to treat paper documents and reports before they go into sterile areas? Do lengthy paper documents need to be scanned to create electronic versions for inspectors? Or is your operation interconnected, allowing you to easily exchange information digitally between all your enterprise systems as well as external auditors?

3

How many digital processes do you have across your organization?

Breaking this question down, how many of your systems are digitized? How many of these systems are integrated? How many of your different sites are digitized and integrated? Ideally, your digital systems will be fully implemented at all sites. However, we found that this is only the case with 25% of the companies in the survey. Still, as mentioned earlier, pursuing digital maturity is how you sustain a competitive advantage.

One MasterControl customer immediately recognized the advantages of digitization during the COVID-19 lockdown.

"With COVID-19, the benefits of MasterControl's Manufacturing Excellence are even more clear. Instead of having face-to-face conversations, we needed to automate processes as well as share information, collaborate, and get approvals remotely. Having a system that allows us to do that is critical," said a quality manager for a large pharmaceutical company.

4

What are your goals for modernizing your manufacturing processes?

Where does digitization appear on your organization's road map? It's common for companies to want to digitize, but less common for them to have a plan in place for how to do it. Less than half (42%) of the respondents have a formal digital transformation plan. This was another metric tied directly to the size of an organization, with formal plans being more common in larger companies.

Creating a tactical plan to achieve your organizational goals for digitization is critical for success and future relevance. Your plan needs to include a way to measure progress; otherwise, you'll never know if you're making progress or what you've gained from your digitization.

<42%

Less than half of the respondents have a formal digital transformation plan.

13.

How Respondents Rated the Industry

Based on the outcome of their self-assessments, there is a notable difference between the respondents' perception of where their companies are and where the industry is in general in terms of digital maturity. For example, many of the respondents (52%) believed that most large, international companies are in the Intelligent level, while fewer than 5% are actually at this level.

14.

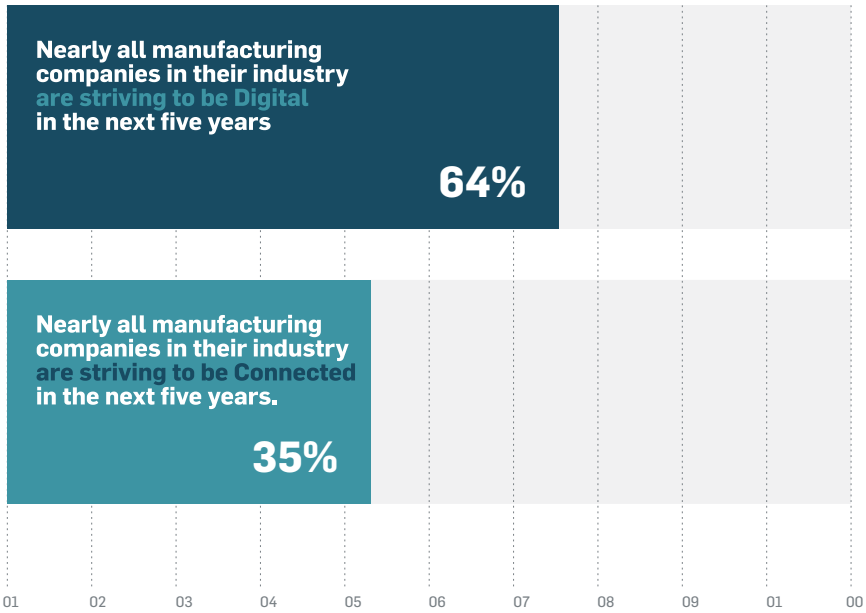
Looking Ahead

Companies in the life sciences industries are becoming more aware of the importance of advancing their manufacturing system technology in order to keep up with evolving trends and remain competitive in their respective markets.

15.

Key findings for companies reaching the Intelligent level

Respondents indicated that they felt their industry was moving toward the following levels of digital maturity.



> “Before, we did one 510(k) a year. Right now, we’re doing four or five 510(k)s simultaneously. Now we’re competing at a level we should be.”
>
> – CEO, Medical Device Manufacturer

The data presented in this report shows that digitization is here and that it will continue to expand and gain traction in manufacturing. Companies need to have modern platforms that are resilient, so when disruptions happen, it’s easier to overcome them. They need to have processes and data across the entire enterprise, and they need to focus on outcomes.

Reaching the Intelligent level is achievable and has significant advantages. Gain the full potential of your manufacturing data.

- **More visibility into manufacturing operations** – At a glance, obtain all the information necessary to make accurate, data-driven decisions.
- **Advanced analytics** – You can discover deeper insights, reduce the time necessary to investigate production issues, and generate recommendations for actions. A big part of advanced analytics is natural language processing (NLP), which enables gathering insight from text provided by end users.
- **Contextual Analytics** – Achieve the next level of business intelligence.

16.

How to Progress Toward Digital Maturity

MasterControl has been an industry leader in the life sciences for more than 25 years. Our lightweight, modern MES ensures that companies of all sizes can digitize from end-to-end. We provide AI-enabled functionality to help you avoid tedious tasks and spend more time on meaningful ones. The flexible technology provides the technical elements you need for integrating all enterprise systems and advance to the next level of digital maturity.

- **Digital production records** – Digitize data from beginning to end with no paper forms or offline processes to manually reconcile.
- **Digital work instructions** – Empower your production crews with work instructions and SOPs that are always up to date. Employ real-time tracking of stages, steps, and performance.
- **In-line quality assurance** – Ensure quality at every step of production. Automatically assess risk and launch quality events, such as nonconformance and deviations, directly from the production line without interruption.
- **In-app operator training** – Enforce training compliance with fully automated, user-based training checks and in-app training delivery. Your workforce will never complete a task without complying with training requirements.
- **Insights/analytics** – View and report on data in real time, such as monitoring training tasks, viewing production record status, and tracking critical KPIs. Reduce downtime and work more efficiently.
- **Review by Exception** – Eliminates line-by-line reviews at the end of production. Simply review exceptions to processes and documentation. Fix data-entry errors in real time and easily identify issues creating exceptions.
- **Validation** – Our patented Validation Excellence Tool (VxT) accelerator provides a fast, efficient, and seamless validation experience. On average, customers using the tool have reduced 104 hours of labor-intensive validation activities to 20 hours and have cut at least 336 hours in overall project preparation time.

Contact us for more information on how to move your company further along on the maturity model and how MasterControl can help.

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality and manufacturing 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 and manufacturing processes. Innovative MasterControl tools have a proven track record of improving product quality, reducing cost, and accelerating time to market. Over 1,100 companies worldwide use MasterControl solutions to streamline operations, maintain compliance, easily analyze and interpret large amounts of data, and visualize business insights in real time.

For more information, visit www.mastercontrol.com.