



Life sciences digital maturity report

The new operating model for life sciences manufacturing: Moving from compliance to continuous readiness



**Rockwell
Automation**

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A shifting landscape for life sciences manufacturing

Life sciences manufacturers are entering a period of significant change.

Across global markets, regulatory agencies are increasing expectations around cybersecurity, data integrity, digital records, AI governance and continuous quality oversight. While the specific requirements vary by region, the direction of travel is clear: regulators are placing greater emphasis on transparency, traceability and the ability to demonstrate control across increasingly digital operations.

For manufacturers, this shift extends beyond compliance.

The same capabilities needed to support evolving regulatory expectations are also becoming critical business enablers. Connected data helps organizations improve quality outcomes. Strong cybersecurity programs protect production and business continuity. AI can accelerate decision-making, optimize processes and unlock greater value from manufacturing operations. The challenge is that these capabilities cannot be built independently. They rely on a shared digital foundation.

Rockwell Automation's latest State of Smart Manufacturing (SoSM) Report suggests life sciences

organizations recognize the importance of that foundation. Digital transformation initiatives continue to accelerate, and manufacturers are increasingly investing in technologies that improve visibility, reduce risk and support more informed decisions. Yet many organizations are also navigating common challenges around data accessibility, system integration, governance and operational complexity.

As a result, readiness is becoming a defining characteristic of industry leaders.

Organizations that can connect data across systems, validate and govern AI applications, strengthen cyber resilience and create greater operational visibility will be better positioned to respond to changing expectations while improving quality, agility and performance. Those that continue to rely on fragmented information, manual processes and disconnected technologies may find it increasingly difficult to keep pace.

This report examines the forces shaping that transition. Combining insights from Rockwell Automation's State of Smart Manufacturing research with the broader trends influencing the life sciences sector, it explores how manufacturers are preparing for a future where digital maturity, cyber resilience and AI readiness are becoming essential components of long-term success.

Where life sciences manufacturers stand today

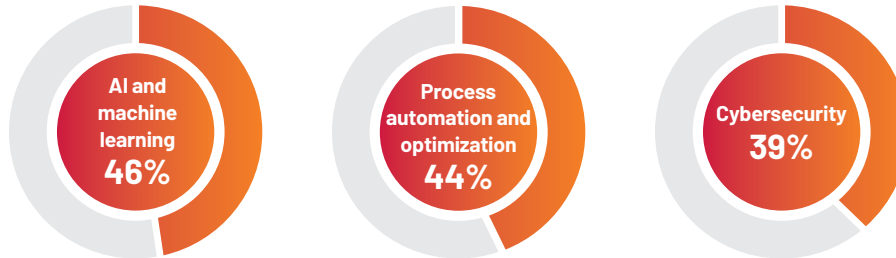
Life sciences manufacturers are investing aggressively in digital transformation to strengthen quality, improve operational performance and navigate an increasingly complex business environment. While evolving regulatory expectations are helping accelerate change, the industry's transformation is also being driven by a broader need for greater agility, resilience and visibility across manufacturing operations.

The State of Smart Manufacturing report finds that **90% of life sciences organizations believe digital transformation is necessary in response to recent changes and challenges in industrial technology.** More than half (58%) have already deployed smart manufacturing technologies either at scale or across portions of their operations, signaling that digital transformation has moved beyond exploration and into execution.

Quality, efficiency and risk reduction drive investment

As manufacturers evaluate where technology can deliver the greatest business impact, priorities are increasingly focused on capabilities that improve operational performance while supporting long-term readiness.

The technologies expected to have the greatest impact include:



These investments are closely tied to business objectives. Life sciences organizations cite improving quality (43%), digitizing operations (36%) and reducing safety, cybersecurity and compliance risks (35%) as leading drivers of transformation efforts.

The findings suggest that manufacturers increasingly view digital transformation as a strategic business initiative rather than a technology project. Success is measured not only by technology deployment, but by the ability to improve consistency, strengthen resilience and create more connected operations.

Progress is real, but readiness gaps remain

While adoption continues to accelerate, many organizations are still working to establish the foundational capabilities required to fully realize the value of their investments.

Manufacturers are expanding their use of AI, automation and connected systems, yet many continue to face challenges around data accessibility, integration and governance. These gaps can limit an organization's ability to scale innovation, operationalize AI and respond efficiently to changing business and regulatory requirements.

As a result, the industry's next phase of transformation will likely be defined less by technology acquisition and more by technology integration.

The organizations best positioned for future success will be those that can connect data across systems, create greater visibility into operations and establish the governance frameworks needed to support quality, cybersecurity and AI-enabled decision-making at scale. These capabilities form the foundation for continuous readiness in an increasingly digital manufacturing environment.



Connected manufacturing moves to the top of the agenda

Digital transformation is no longer viewed as a future initiative in life sciences manufacturing. It is becoming a business imperative driven by the need to improve quality, reduce risk and create more resilient operations. As organizations navigate an increasingly complex operating environment, investments in smart manufacturing are shifting from isolated projects to enterprise-wide strategies.

The latest State of Smart Manufacturing report shows that 58% of life sciences organizations have already implemented smart manufacturing technologies either at scale or across portions of their operations. At the same time, **90% believe digital transformation is necessary to respond to changes and challenges in industrial technology.** These findings suggest that manufacturers are moving beyond asking whether to transform and are increasingly focused on how to scale and deliver value from their investments.

Digital maturity depends on connected operations

As organizations deploy new technologies, many are discovering that value is not created by individual systems alone. Greater impact comes from connecting data, workflows and decision-making across functions.

For life sciences manufacturers, this means breaking down silos between production, quality, engineering and business systems. It means creating greater visibility across operations and establishing a trusted foundation for advanced capabilities such as AI, predictive analytics and continuous improvement programs.

The next phase of digital maturity will be defined not by the number of technologies organizations deploy, but by how effectively they integrate those technologies to create a connected, data-driven operating model. Organizations that can successfully align technology investments with business processes, people and governance will be better positioned to improve performance and adapt to evolving industry demands.

Technology investments are focused on business outcomes

The technologies expected to deliver the greatest impact reflect the industry's evolving priorities:

AI and machine learning (46%)

46%

Process automation and optimization

44%

Cybersecurity (39%)

39%

While these investments often receive attention for their technological capabilities, manufacturers are pursuing them to achieve measurable business outcomes.

When asked about the primary drivers behind smart manufacturing initiatives, respondents identified:

Improving quality

43%

Digitizing the operating environment

36%

Reducing risk across safety, cybersecurity and compliance

35%

These priorities highlight an important shift. Manufacturers increasingly recognize that operational excellence, compliance and business performance are interconnected. The ability to collect, contextualize and act on manufacturing data is becoming essential for improving decision-making across quality, production and supply chain operations.

Interest in AI is growing rapidly

As regulatory expectations increasingly emphasize data integrity, traceability and AI governance, life sciences manufacturers are accelerating investment in AI. Among organizations already using AI and machine learning, 64% plan to expand usage over the next 12 months, while 49% expect to increase investment over the next five years.

Manufacturers see AI as a key tool for improving performance across operations. Planned applications over the next year are concentrated in:

Quality control (50%)



Cybersecurity (45%)



Process optimization (44%)



These priorities reflect a broader push to improve quality, reduce risk and operate more efficiently in an increasingly complex environment.

Data foundations need to catch up

While AI adoption is accelerating, only 32% of organizations report effectively using more than half of the data they collect. Without connected, trusted and contextualized data, it becomes harder to scale AI initiatives and consistently generate value from them.



Barriers to continuous readiness

Digital transformation is accelerating across the life sciences industry, but technology adoption alone does not guarantee readiness. The findings point to several foundational challenges that continue to limit progress and make it more difficult to scale digital initiatives, AI programs and cybersecurity efforts.

Connectivity brings new exposure and complexity

Cybersecurity is the leading external obstacle to growth for life sciences organizations, and 54% experienced at least one cyberattack during the past year. The most significant vulnerabilities are linked to IT systems and enterprise networks (41%), remote access and connected equipment (33%) and IT/OT integration points (29%). As digital transformation continues, cybersecurity must be embedded into operational strategies, technology decisions and risk management programs.

Data is growing faster than organizations can use it

Manufacturing systems generate vast amounts of information, yet only 32% of organizations report effectively using more than half of the data they collect. Without a connected data foundation, efforts to support AI, improve decision-making and increase operational visibility become more difficult to sustain.

Technology alone is not enough

Many organizations have already invested in smart manufacturing, AI and cybersecurity solutions. The next phase of maturity will depend on how effectively those technologies are integrated across systems, processes and teams. Successful transformation requires a foundation built on trusted data, clear governance and operational alignment.

7 actions to strengthen digital readiness

The findings in this report suggest that life sciences manufacturers are making meaningful progress in digital transformation, AI adoption and cybersecurity. However, many organizations still face challenges related to data, governance, visibility and operational resilience. As regulatory expectations continue to evolve, manufacturers will need capabilities that not only support compliance but also enable greater agility, quality and business performance.

The following priorities can help organizations build the digital foundation required for continuous readiness.

1. Digital evidence management for Remote Regulatory Assessments (RRAs) and electronic records requests

Implement an inspection-ready “evidence layer” including a secure portal, curated exports, standardized record packages and audit trails that can rapidly assemble and deliver batch records, deviations, Corrective and Preventive Action (CAPA), change control, validation evidence and product quality reviews with full context.

2. Cyber resilience for connected products and digital operations

Build resilience into connected products from design through deployment and maintenance. By improving visibility, strengthening vulnerability management, enhancing governance and managing supply chain risk, organizations can reduce cyber exposure, maintain trusted operations and adapt to evolving regulatory expectations and emerging threats.

3. Industrial data operations and standardized data models

Establish industrial data operations to connect, contextualize and govern operational data across equipment, processes and manufacturing systems. Standardize metadata, data models, lineage and access so information from historically fragmented OT and enterprise systems can be trusted, reused and traced. This foundation improves interoperability and operational visibility while preparing manufacturers for advanced analytics and validated AI use cases.

4. Scaled AI from practical, validation-ready use cases

Start with well-defined, lower-risk AI applications that augment engineering workflows while maintaining human oversight. This includes helping generate and interpret control code and identify gaps between specifications and logic. As data readiness improves, manufacturers can expand AI into process modeling, tech transfer, validation documentation, equipment performance and quality monitoring, with clear intended use, traceability and validation controls.

5. Building Quality by Design into the manufacturing backbone

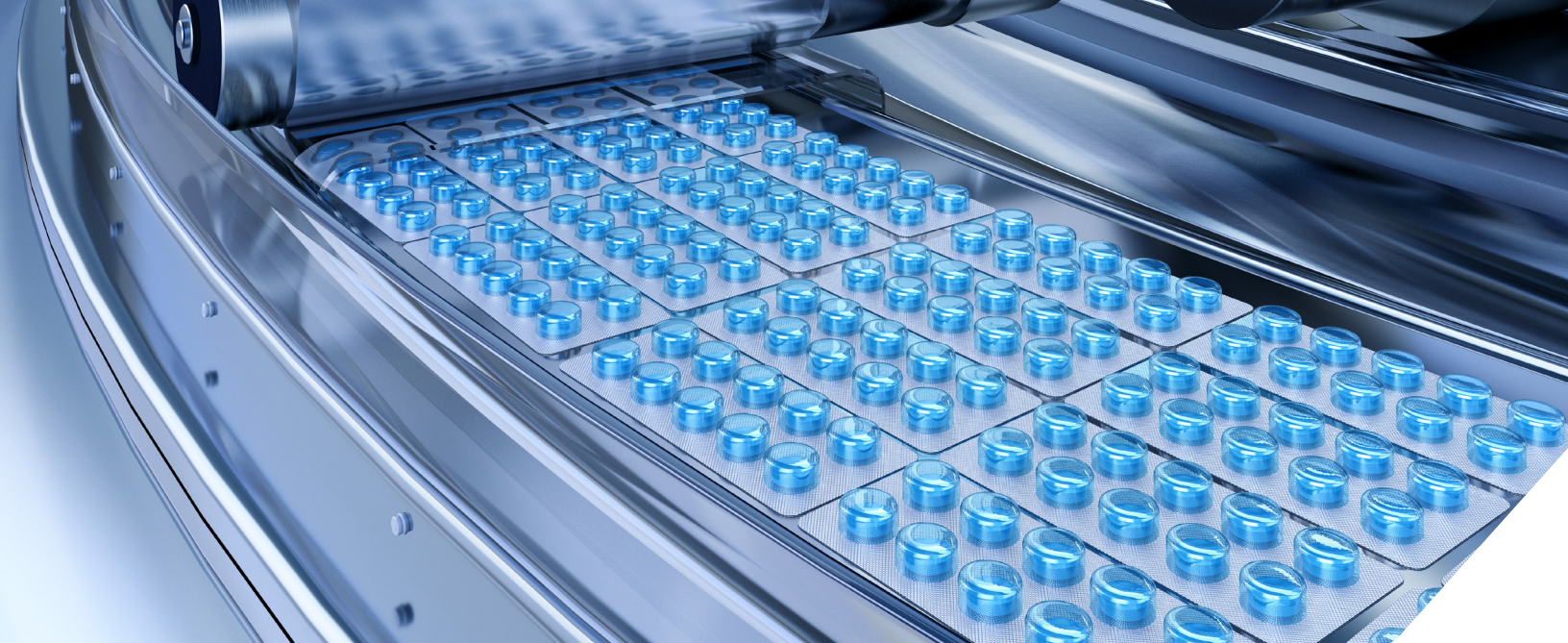
Support Quality by Design (QbD) principles by connecting process development data to manufacturing execution, so processes validated at smaller scale transfer directly to clinical and commercial-scale production.

6. Continuous software assurance for validated systems

Adopt validation approaches supported by automated testing, Continuous Integration/Continuous Deployment (CI/CD) controls, where appropriate, and continuous monitoring, so objective evidence is generated efficiently and control is maintained through frequent software changes.

7. Knowledge management across the lifecycle

Deploy product lifecycle management (PLM) capabilities that connect development, tech transfer, manufacturing and post-approval change management, enabling faster, more consistent execution and stronger lifecycle knowledge management.



Methodology

The data cited in this report is based on the responses of 104 managers and executives from life sciences manufacturers, original equipment manufacturers (OEMs), system integrators and engineering procurement companies (EPCs) in 16 countries. It is part of Rockwell Automation's [11th annual State of Smart Manufacturing report](#), which surveyed 1,560 decision makers across various industries and was conducted in association with Sapio Research and Rockwell Automation.



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Publication LIFE-BR023A-EN-P - September 2026

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