AXENDIA™

The Needle is Moving: Digital Transformation in Life-Sciences Manufacturing

An Axendia Market Research Report Presented by AspenTech

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Introduction

Disruption is the new normal and is forcing Life-Science companies to reimagine the way they operate in order to transform and accelerate product development, regulatory review, manufacturing, and distribution cycles aimed at improving patient outcomes.

43% of respondents representing pharmaceutical, biotech and medical device companies, indicated their organizations are currently undergoing digital transformation.

Clear patterns emerged as we analyzed and distilled the survey data including different perspectives regarding the extent to which regulatory frameworks support advanced manufacturing initiatives and the biggest threats to supply chains / manufacturing networks.

Research approach:

Axendia conducted a research study focusing on the state of digital transformation in Life-Sciences manufacturing. The goal was to identify and analyze the drivers for digital transformation in support of advanced manufacturing initiatives.

This report highlights the following research findings:

- The top goals for digital transformation initiatives
- Current and future advanced manufacturing initiatives
- Current and future initiatives to reduce supply chain risk

Accelerating Transformation

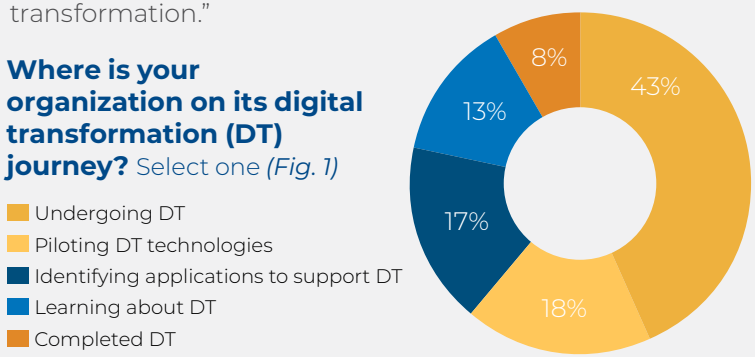
Prior to 2020, "digital transformation" was a buzzword in the Life-Sciences industry. In a 2020 Axendia survey, 69% of Life-Science organizations were still in the process of identifying applications and piloting technologies to support their digital transformation initiatives. In just two years, these numbers have shifted dramatically.

Today, 43% of Life-Science organizations are undergoing digital transformation. Only a combined 35% are identifying applications to support digital transformation and are piloting technologies. 13% are learning about digital transformation. The remaining 8% indicated they have completed digital transformation. *(Fig. 1)*

With reference to 'completed digital transformation,' "It is always very interesting to understand what this means – are they referring to the whole company or a very specific part of the business or a project?" said the technology translation lead at a global biopharma company.

The executive director, digital innovation at a multinational pharmaceutical company, agreed. "Some people tend to be of the same opinion, but we correct it right away. Completing a project in a small operating area is not digital transformation. The projects are typically related to the digital adoption of a process, but completing a project is not the same as completing the journey to achieving digital transformation."

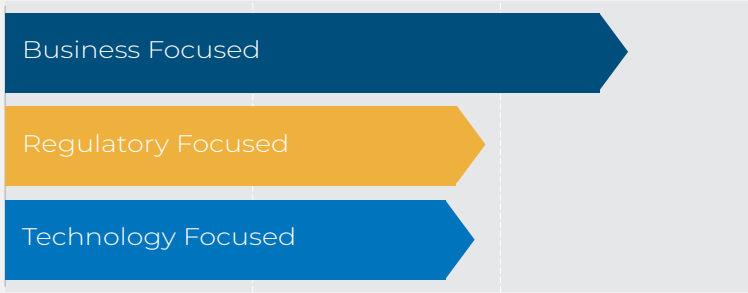
Where is your organization on its digital transformation (DT) journey? Select one *(Fig. 1)*



The Purpose of Digital Transformation

The top reason for digital transformation is to support business focused initiatives. *(Fig.2)*

Please rank the top reasons for digital transformation in your organization. *(Fig. 2)*



"In my experience, nothing happens until you get the business behind an initiative. Once you get the business behind it, you can overcome a lot of hurdles. To me, they're all most important but at different times. Getting a project off the ground requires the business being behind it. Otherwise, it doesn't even start…but once it starts, the other two become equally important," said the director of medical device and combination products QA at a multinational pharmaceutical and biotechnology corporation.

The Director, CMC at a biotechnology company, shared a different perspective. "I think that the drivers are both business and technology. For example, they want us to innovate yet people are slow to innovate."

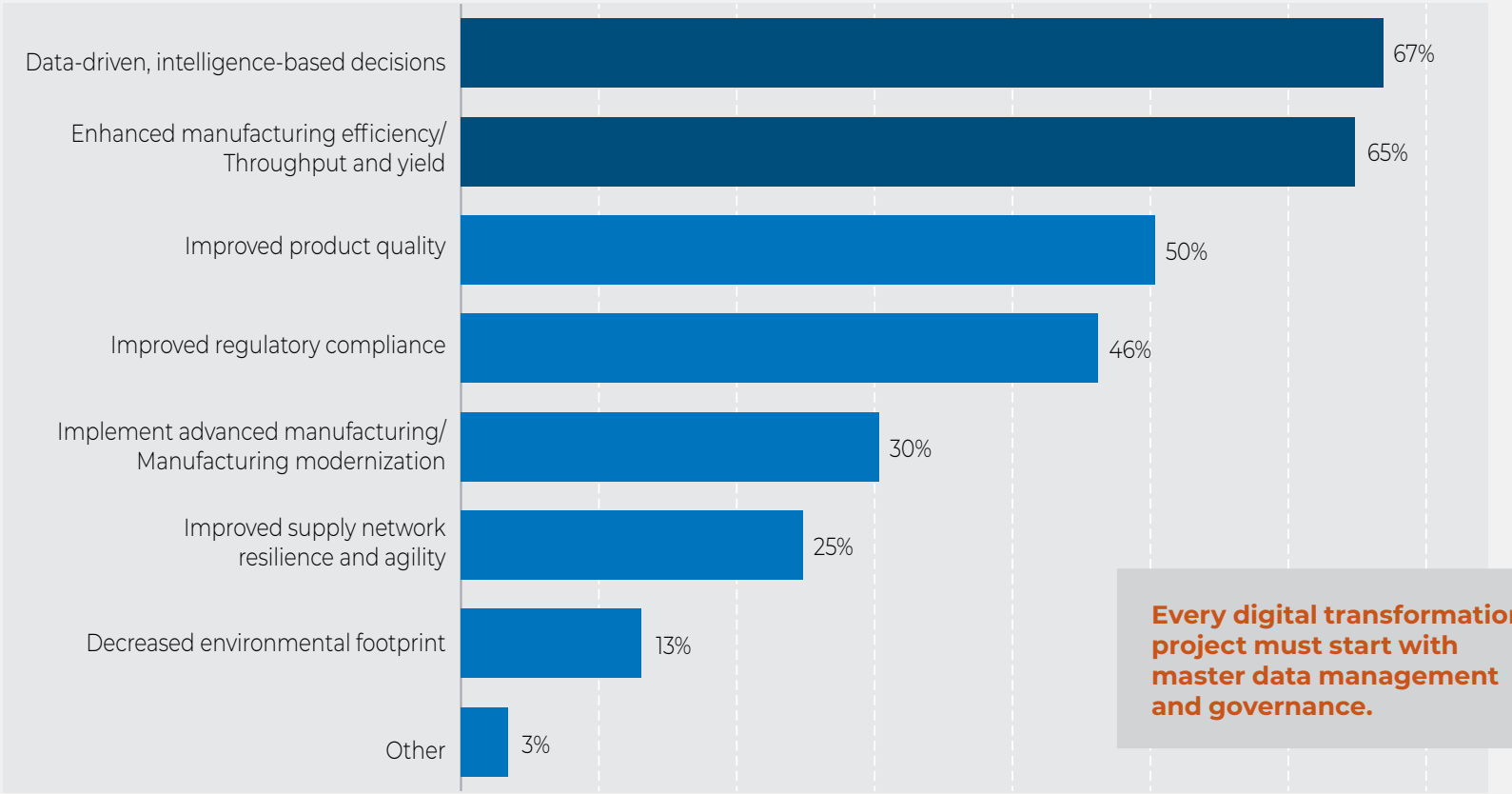
"I think the regulatory aspect of it is kind of a given," he continued. "It's something regulatory agents and the FDA highly support and want us to continue to pursue. For a small company transitioning into a larger company, the technology is a factor as we move into the next phase of what the regulators require from us."

[1] Axendia Industry Webinar: Building the Life-Science Factory of the Future Today

Advanced manufacturing initiatives are supporting digital transformation

Data-driven, intelligence-based decisions and enhanced manufacturing efficiency/throughput and yield are the top goals for digital transformation in manufacturing. *(Fig. 3)* However, companies cannot implement modern technology and undergo digital transformation on a foundation of bad master data. Every digital transformation project must start with master data management and governance.

What are the Top 3 goals for your digital transformation initiatives in manufacturing?
Select 3 *(Fig. 3)*



Every digital transformation project must start with master data management and governance.

When it comes to continuous manufacturing as an advanced manufacturing initiative, 50% of the companies surveyed have already implemented, are piloting or plan to implement in less than two years.

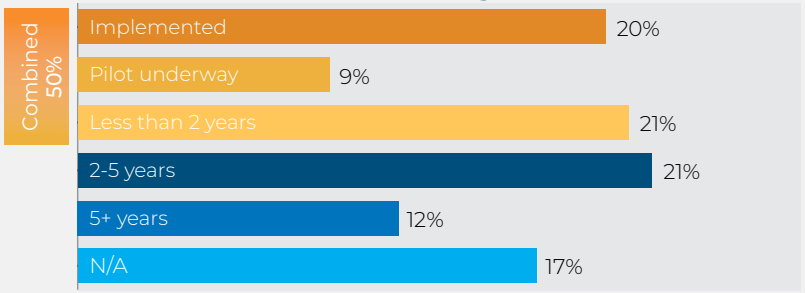
(Fig. 4) Continuous manufacturing is being implemented in a number of industries, but its adoption in pharma has historically been slow. These data show promise that a greater proportion of companies now see the benefits outweighing the barriers.

Similarly, a combined 60% have already implemented, are piloting or plan to implement advanced planning and scheduling in less than two years. *(Fig. 5)*

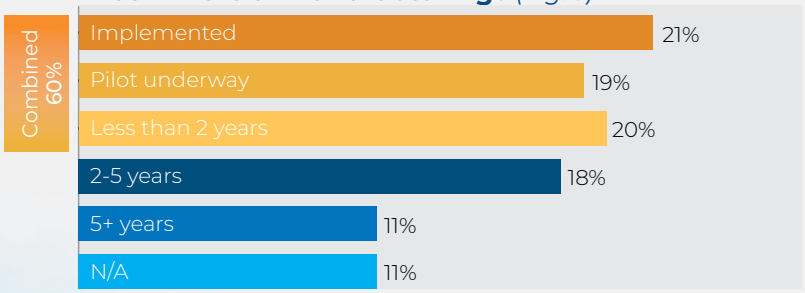
Continuous process verification is also being more widely adopted in commercial manufacturing. A combined 62% of companies have implemented, are piloting or will implement continuous process verification within the next two years. *(Fig. 6)*

When do you expect to...
Select one for each response

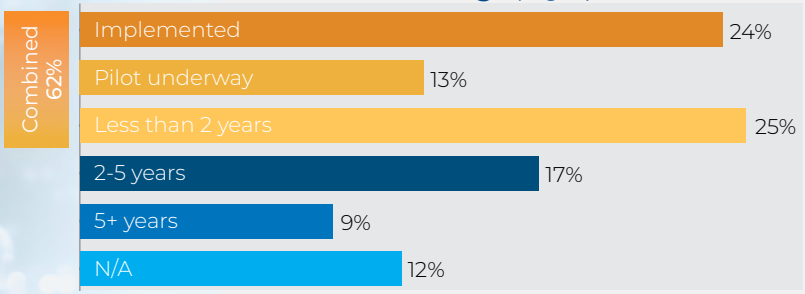
Implement Continuous Manufacturing in commercial manufacturing? *(Fig. 4)*



Implement Advanced Planning and Scheduling in commercial manufacturing? *(Fig. 5)*



Implement Continuous Process Verification in commercial manufacturing? *(Fig. 6)*



Predictive and prescriptive maintenance are no longer a nice-to-have but are a must-have. A combined 63% of companies have implemented, are piloting or plan to implement predictive and prescriptive maintenance initiatives within the next two years. *(Fig. 7)*

The Life-Science industry historically lags in the implementation of new and advanced technologies. This is often due to the misinterpretation of regulations, lack of process understanding and an unwillingness to overcome cultural inertia. As a result, many companies are manufacturing next generation products using last generation technologies.

Should companies continue rolling out 10-year-old technology and client-server applications running on virtual machines or is this the right time to leapfrog to achieve digital sustainability? In a Digitally Sustainable state, companies are proactively seeking tomorrow's technology – today.[2]

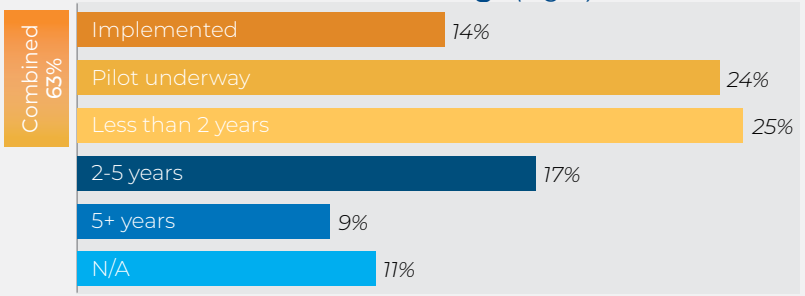
When it comes to IT/OT convergence, inclusive of cloud, a combined 60% of companies have already implemented, are piloting or seek to adopt net new capabilities and offerings that leverage the cloud within the next two years. *(Fig. 8)*

As the industry embarks on digital transformation, it must realize that this is a journey towards "digital sustainability."[3]

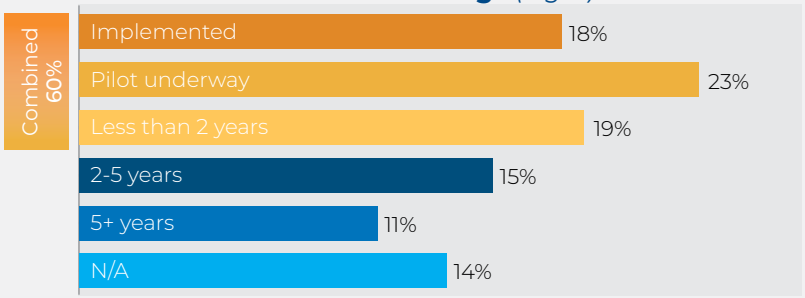
Lastly, while a combined 33% have implemented or are piloting technology to digitally streamline batch execution and release, 32% of companies are currently planning to implement technology to support this initiative in the next two years. *(Fig. 9)* These data fall in line with the amount of time it typically takes to implement manufacturing execution systems (MES), particularly in larger organizations with revenues over $1B.

When do you expect to...
Select one for each response

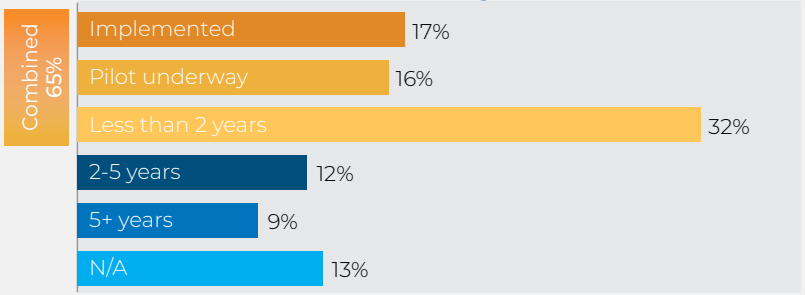
Implement Predictive and Prescriptive Maintenance in commercial manufacturing? *(Fig. 7)*



Have IT/OT Convergence (inclusive of Cloud) in commercial manufacturing? *(Fig. 8)*



Digitally streamline Batch Execution & Release in commercial manufacturing? *(Fig. 9)*

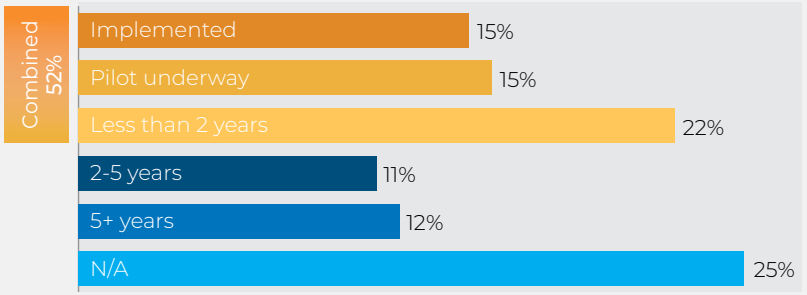


 [2,3] An Axendia Straight from the Source Webinar: The Journey to Digital Sustainability in the Life-Sciences Industry, 2022

Closed-loop control in commercial manufacturing has also gained the attention of Life-Science companies. A combined 30% of companies have implemented or are piloting technologies to support this advanced manufacturing initiative, with 22% planning to implement closed-loop control in the next two years. *(Fig. 10)*

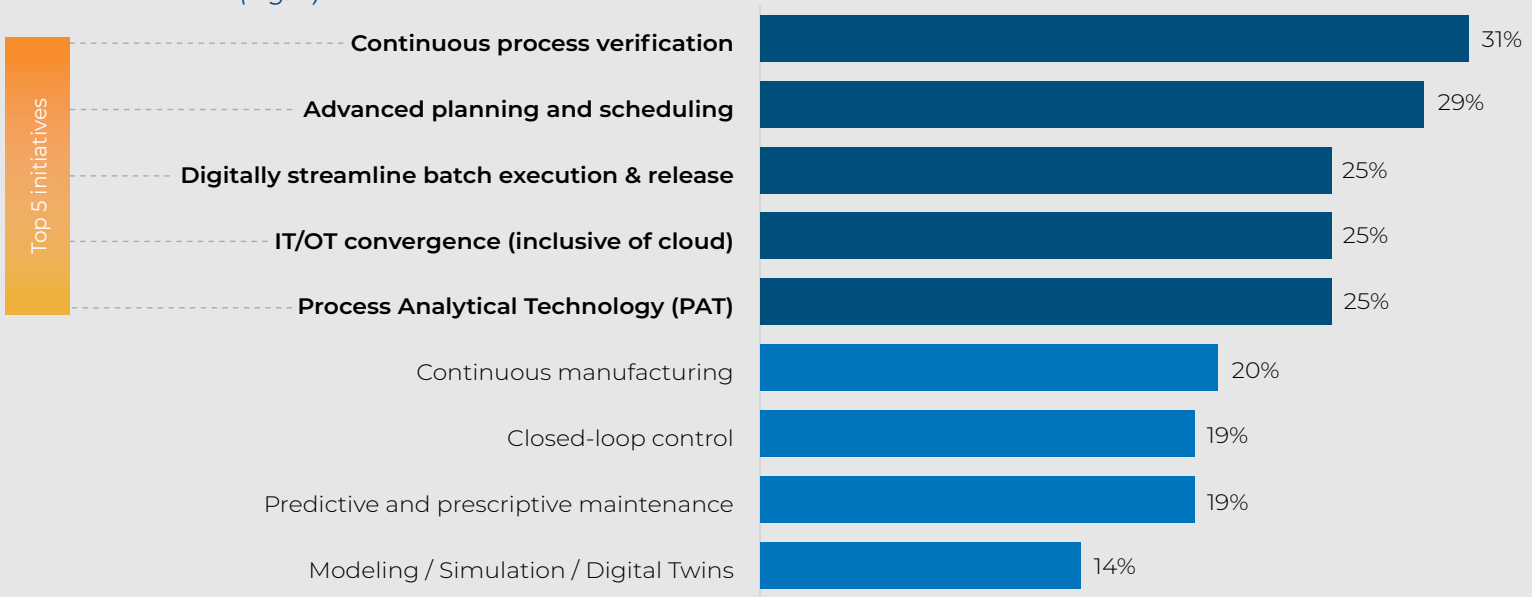
When do you expect to...
Select one for each response

Implement Closed-loop Control in commercial manufacturing? *(Fig. 10)*



Companies who have completed and are undergoing Digital Transformation, have Implemented the following:

Of the 51% of companies who have completed or are undergoing digital transformation, the top five advanced manufacturing initiatives cited were: *(Fig: 11)*



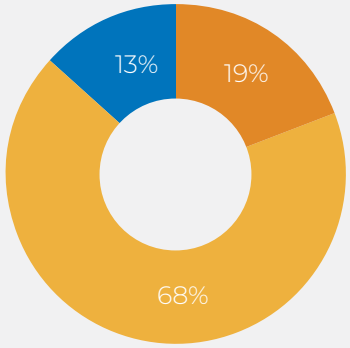
The Role of Regulatory Frameworks

While most respondents were indifferent as to the degree to which regulatory frameworks support advanced manufacturing initiatives, the Director, CMC at a biotechnology company shared his insights on the 13% who did not agree. *(Fig. 12)*

"There could be many factors, when deciding if regulatory frameworks do or don't support advanced manufacturing. One being the size of the company. There are often institutional myths in larger companies such as, 'Hey, we can't do that because that's just not going to be supported by the agency. When there's direct contradiction to what the agency espouses, they write it in their guidance documents for our industry -- that they want to encourage technology and advancement. However, many companies are just too conservative because it costs too much to get shot down by a regulator. For example, if you try to take an incremental step in advancing your technology and the agency says, 'We don't agree with that'... or you need more data to support your thoughts on this or on going this direction, it can cause delays of up to two or three years, which at any given burn rate could cost a company tens of millions of dollars."

In your opinion, to what degree do current regulatory frameworks support your company's Advanced Manufacturing initiatives?
Select one *(Fig 12)*:

- Fully supports
- Somewhat supports
- Does not support

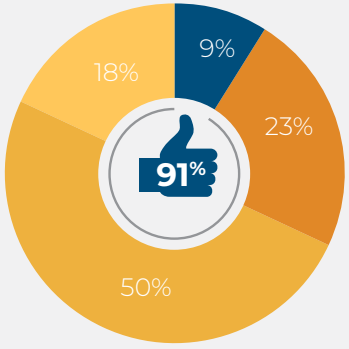


We saw a tremendous difference between companies who are of the opinion that regulatory frameworks support advanced manufacturing versus those that don't.

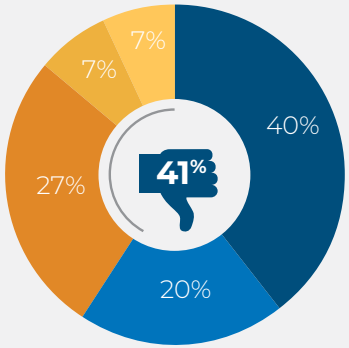
A combined 68% of companies who believe regulatory frameworks fully support advanced manufacturing initiatives are undergoing or have completed digital transformation. On the other hand, only a combined 14% of companies who believe regulatory frameworks do not support advanced manufacturing initiatives are undergoing or have completed digital transformation. *(Fig. 13)*

Where is your organization on its digital transformation journey? *(Fig 13)*:

- **Learning** about digital transformation
- **Identifying applications** to support digital transformation
- **Piloting** digital transformation technologies
- **Undergoing** digital transformation
- **Completed** digital transformation



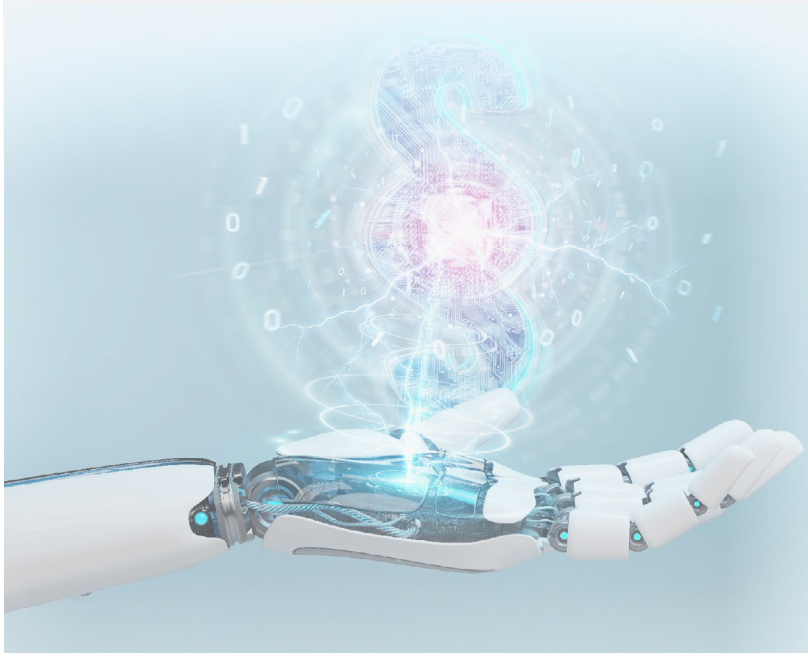
Fully supports



Does not support

Another major difference is the rate at which continuous process verification has been adopted. Combined, 45% of companies who believe regulatory frameworks fully support advanced manufacturing initiatives also have already implemented continuous process verification or are in the pilot phase versus only a combined 20% of the group who believe that regulatory frameworks do not support advanced manufacturing. *(Fig. 14)*

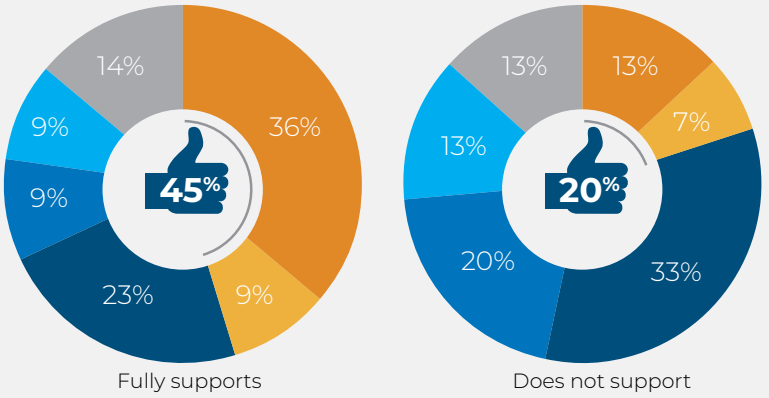
Predictive and prescriptive maintenance initiatives also have a higher rate of adoption by companies who agree that regulatory frameworks support advanced manufacturing initiatives. A combined 32% of companies have implemented, are piloting or will implement solutions within the next two years. This is a stark contrast to the combined 14% of companies who do not agree. *(Fig. 15)*



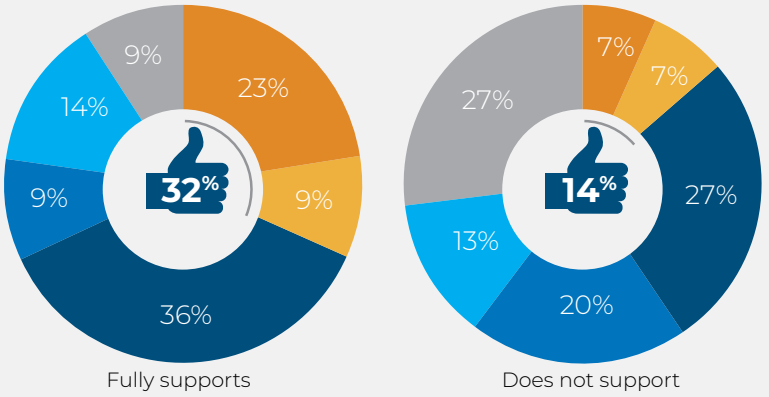
When do you expect to implement...

- Implemented
- Pilot underway
- Less than 2 yrs
- 2-5 yrs
- 5+ yrs
- N/A

Continuous Process Verification in commercial manufacturing? *(Fig 14):*



Predictive & Prescriptive Maintenance in commercial manufacturing? *(Fig 15):*



Supply Chain Woes

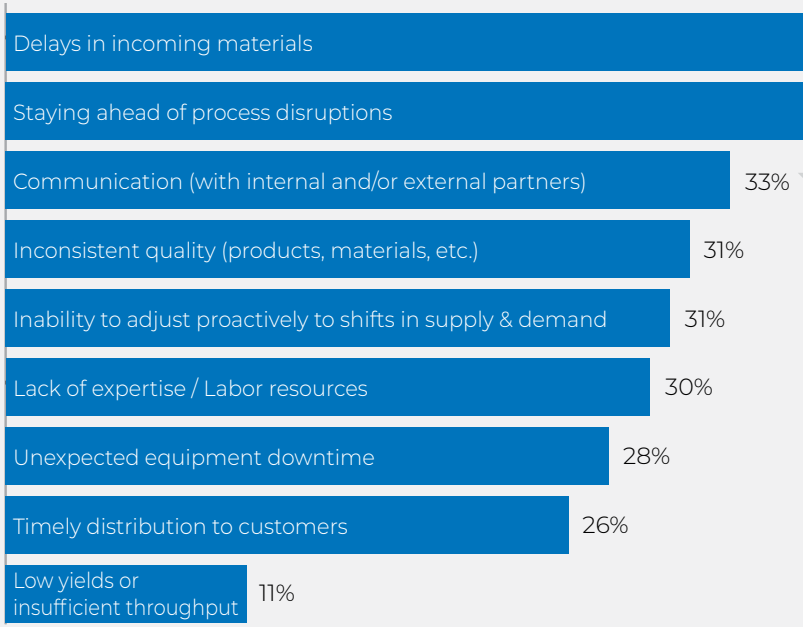
Delays in incoming materials and staying ahead of process disruptions are the top two cited threats to supply chains and manufacturing networks. *(Fig. 16)*

To gain resilience in the supply chain, we propose the transition to smart sourcing, with a focus on value networks. Standardized and optimized practices executed across value networks drive improvements in operational efficiencies and on-time deliveries, while reducing inventory, operational costs, and the cost of quality. These practices are supported by a technology foundation that provides adaptability, flexibility, and creativity to solve the problems of the future.

Having a network of suppliers that are qualified to provide raw materials, sub-assemblies, intermediates or APIs that can be leveraged throughout the manufacturing process, is the desired state of the value network.

It's also imperative that when a supplier ships the product, they also share the data associated with the product. This includes not just a certificate of quality saying it met a company's standards, but actual valuable actionable insight and data that can be used to fine-tune the manufacturing process receiving the material. The processes affected cover the full range of primary, secondary, packaging, and in-house versus outsourced or contracted production.

What are the biggest threats to your supply chain / manufacturing network?
Select the top 3 *(Fig 16):*



Of the 33% who selected communication with internal and/or external partners, the technology translation lead at a global biopharma company shared his thoughts:

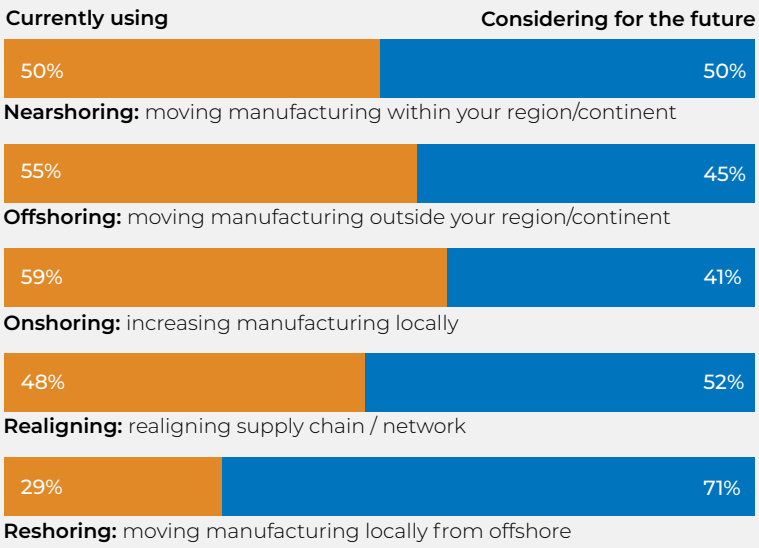
"Perhaps part of the reason, when looking at contract manufacturing organizations (CMO) versus internal manufacturing, is that the data is as important as the final product. Especially when you want to have that agility … if you're still waiting three months to effectively release material, because you're waiting for the documentation to come back and forth, it's not necessarily fixing your supply chain in that space. You're just pushing the pain onto someone else within your organization. It's not manufacturing, it's the quality organization."

59% of the companies participating in our research study are currently onshoring their supply chains and manufacturing networks. 71% of companies are considering reshoring in the future. *(Fig. 17)*

The technology translation lead at a global biopharma company shared his thoughts again:

"I imagine that some of the new therapeutic areas are going to take a closer look at localized manufacturing. Companies need to be closer to their patient in terms of the supply chain piece. But it all comes back to whether companies see themselves manufacturing within big facilities or not. What does the future of their network look like if they decide to take a more decentralized approach?"

Which of these strategies are you using or considering to de-risk your supply chain/manufacturing network? *(Fig 17)*



Conclusion

Recognizing continuous disruption as the new normal, Life-Science companies are being forced to reimagine the way they operate. Almost half of the pharmaceutical, biotech and medical device companies surveyed indicated their organizations are currently undergoing digital transformation, which is a significant increase from even two years ago.

Other notable observations include a greater adoption or planned adoption of continuous manufacturing, continuous process verification, IT/OT convergence, predictive and prescriptive maintenance, digitally streamlining batch execution and release, and to a lesser extent, closed-loop control.

Companies who are of the opinion that regulatory frameworks fully support advanced manufacturing initiatives are much further along in their digital transformation journey as compared to those who do not. The data suggest that these companies are years ahead in implementing continuous process verification and predictive and prescriptive maintenance technologies, for example.

Globalization and outsourcing have increased the volume of geographically dispersed partners, facilities, and suppliers in the Life-Science global supply chain. These factors have increased complexity and variability, which when coupled with the inevitability of Black Swan[2] events, results in an overall instability of the healthcare ecosystem and increased risk to the supply chain.

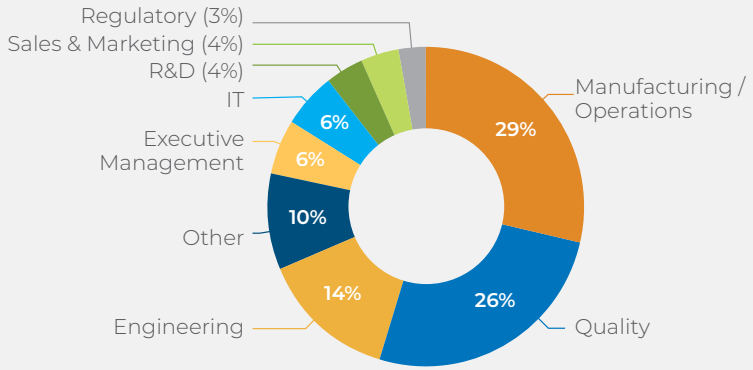
To improve supplier management and mitigate risks associated with complex supply chains, many organizations are working diligently to optimize their supplier base. 7 out of 10 companies surveyed indicated they are considering reshoring in the future. The topic of supply chain resilience is back on the agendas of industry executives as they seek to maintain product availability and integrity across the globe.

[2] In his book "The Black Swan: The impact of the highly improbable," Nassim Taleb defines a 'Black Swan' as an event characterized by rarity, extreme impact, and retrospective (though not prospective) predictability.

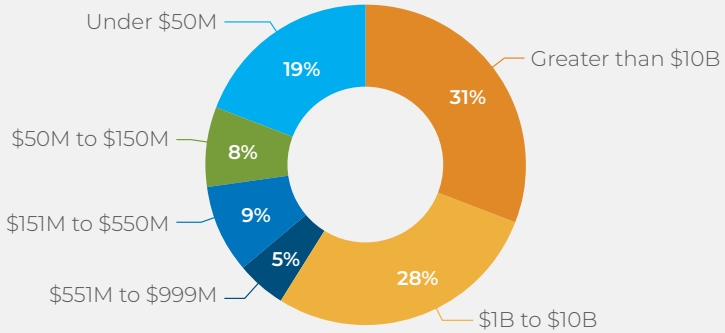
Demographics

In support of this research, we surveyed 199 Life-Science professionals representing a wide range of manufacturers who market and sell medical products worldwide. 57% of respondents hold roles of responsibility at the level of manager/supervisor or above. 59% of the companies surveyed have annual revenues of $1B or more.

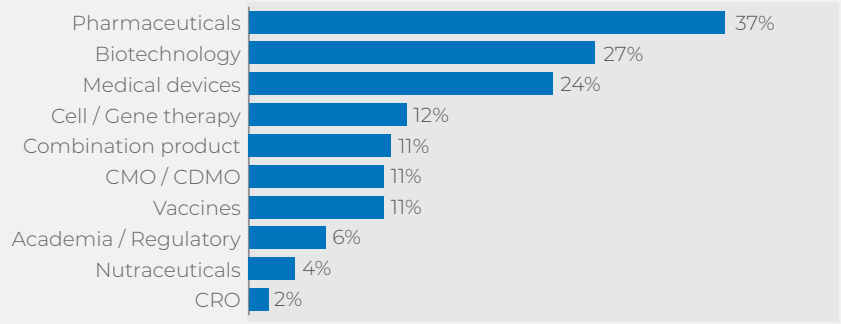
By current functional role*



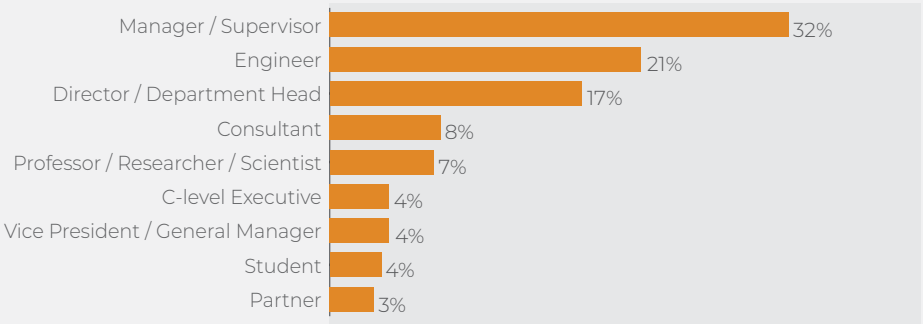
By company annual revenue* (USD)



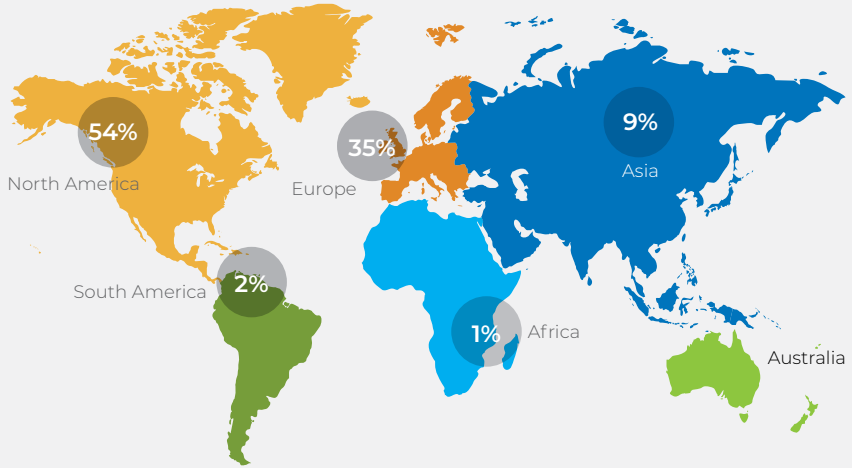
By company's products and services* (respondents selected all that apply)



By level of responsibility*



By company headquarters location*



*Rounded to the nearest whole number.

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About Axendia

Axendia is a leading analyst and strategic advisory firm focused exclusively on the Life-Sciences markets. The company provides strategic advice that enables its clients to prepare for, adapt to and overcome disruption. Axendia conducts primary quantitative and qualitative research that clients leverage to support their strategies and enables them to make informed decisions based on their unique needs. Industry stakeholders and regulators have relied on Axendia for trusted advice on Business, Regulatory and Technology issues and trends based on trusted sources. Axendia serves the entire Life-Science ecosystem ranging from start-ups to Fortune 100 companies including: Life-Science Organizations, Technology & Service Providers, and Regulatory Agencies.

Axendia is recognized as a Top 10 Analytics Consulting company by Pharma Tech Outlook and as a one of the 20 Most Promising Life Sciences Technology and Services providers by CIOReview.

For more information, visit www.axendia.com or contact us at info@axendia.com

The following team members contributed to the research study and report:

Sandra K. Rodriguez,
Sr. Industry Analyst

Mónica V. Matlis,
MSIE, CPE
Chief Operations Officer