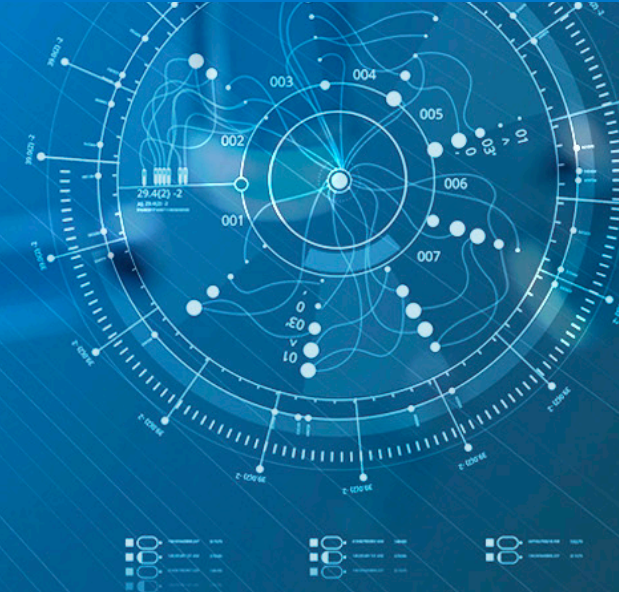
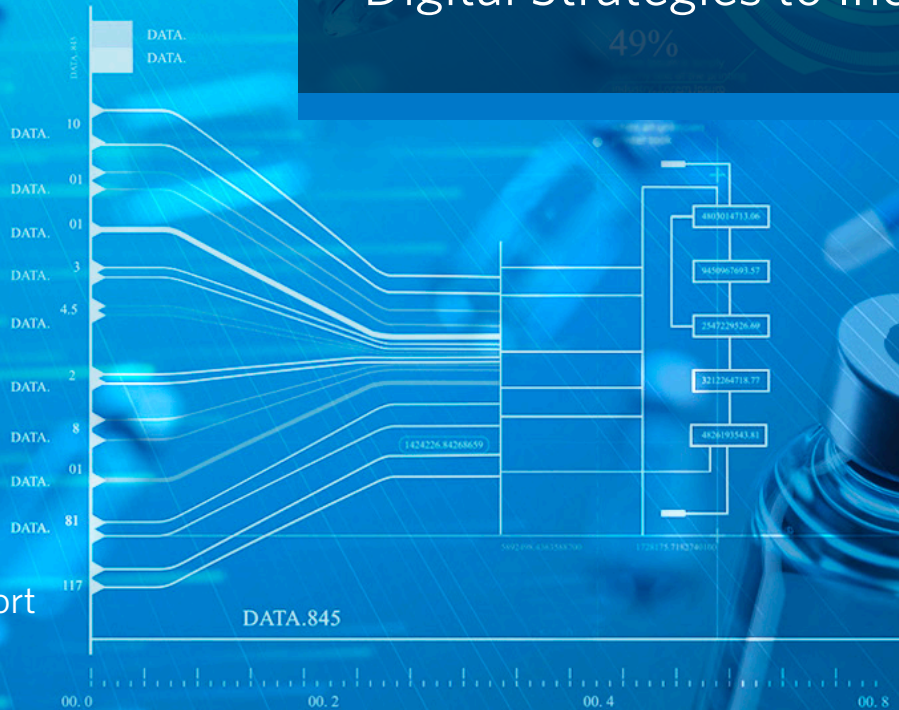


Seizing New Opportunities: Pharma's Roadmap for Smarter Manufacturing Digital Strategies to Increase Operational Agility





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This report was authored by FT Longitude, the specialist research and content marketing division of the Financial Times Group, in collaboration with Aspen Technology, Inc. The concepts, views and directions outlined in this paper should be viewed as a guidance/position paper and should not be viewed as the strategies or commitments by any individual member company.

Foreword

As the pharmaceutical industry forges ahead in its mission to improve quality of life for the patients it serves, manufacturers face a complex landscape. Geopolitical tensions and the COVID-19 pandemic have disrupted supply chains and yet expectations for increased speed to market are higher than ever.

Currently, half the world lacks access to essential health services¹, and with the population expected to grow from 7.8 billion in 2020 to 9.7 billion in 2050², the demand for consistent access to vital drugs and vaccines will continue to increase.

Yet there is a silver lining. The pandemic uncovered the urgent need to accelerate digital transformation, propelling the industry to more advanced manufacturing processes, and as a means to address current and future patient needs. Our research suggests that digital transformation continues to be a priority for pharma, with many companies moving forward, although a large number still have not implemented a fully integrated digitalization strategy.

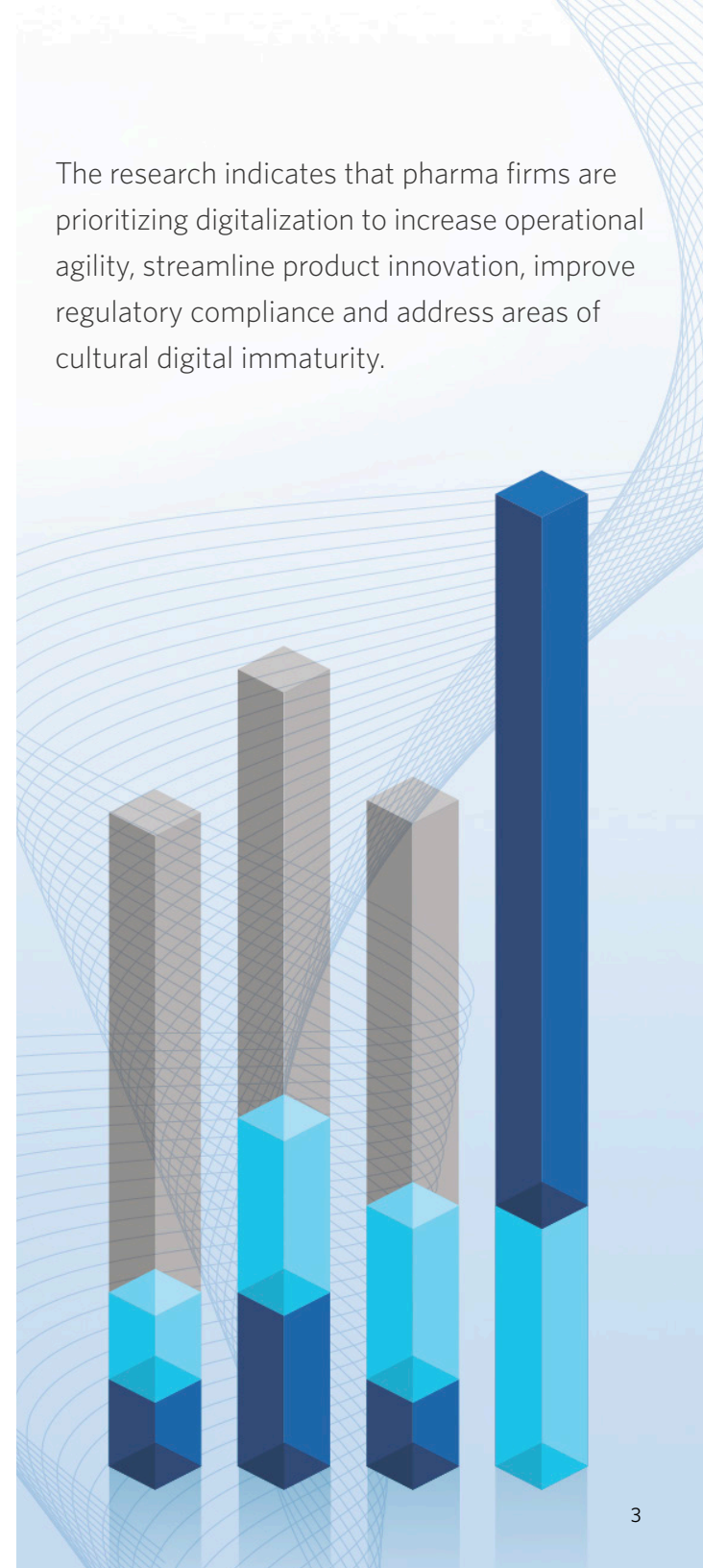
The pharma manufacturing DNA of the future is expected to be highly digitalized, converging Informational Technology (IT) and Operational Technology (OT) systems. Data collected

during the manufacturing process will be harnessed to inform and enhance the agility of production lines across factories and supply chains. Continued advances in manufacturing technology and smart sensors will further enhance data integrity, product quality and safety.

“Digitalization is already improving the efficiency and visibility of drug and vaccine manufacturing,” says Raman Bhatnagar, Vice President & General Manager, Pharmaceutical Business Unit, AspenTech®. He adds that digitalization can also help pharma companies improve their access strategies in remote areas of the world or low- and middle-income countries. Digital technologies are enabling pharma companies to operate more efficiently, improving productivity, time to market and global access to medicine, vaccines and diagnostics. Collectively, smart manufacturing principles are helping to improve the availability of medicines around the world, so patients can have better access to the treatments on which they depend.

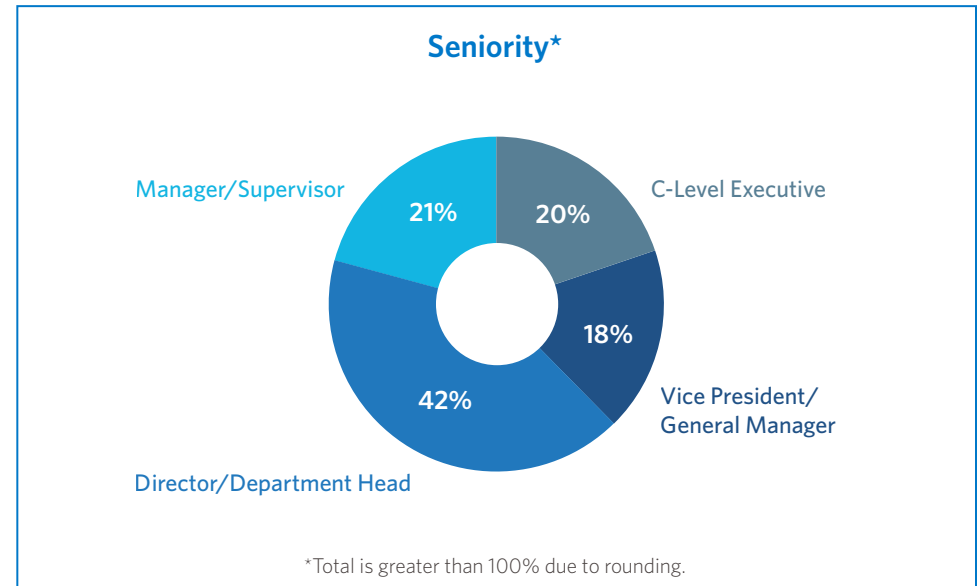
To boost efficiency and productivity while meeting global demand and achieving critical business goals, pharma manufacturers need to fully embrace digital transformation.

The research indicates that pharma firms are prioritizing digitalization to increase operational agility, streamline product innovation, improve regulatory compliance and address areas of cultural digital immaturity.

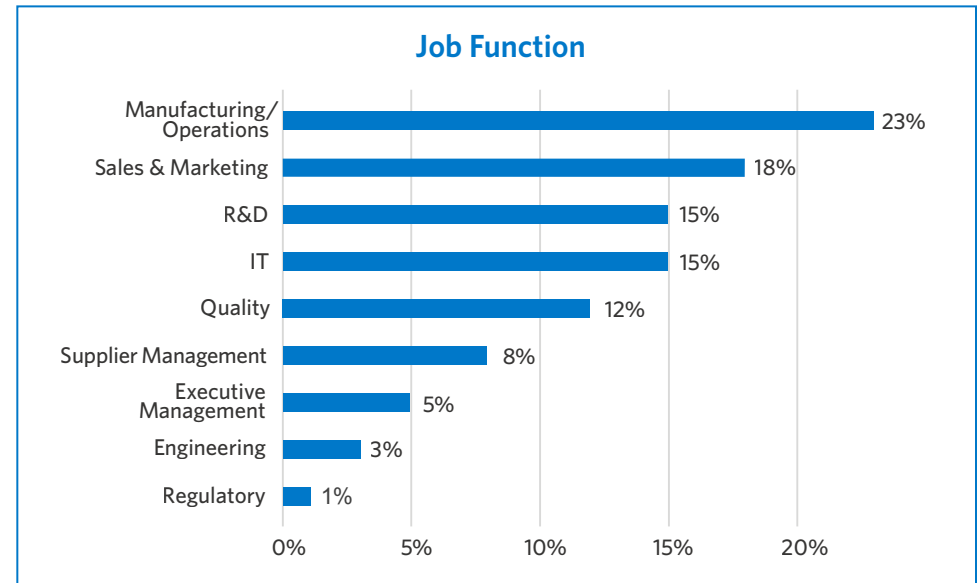
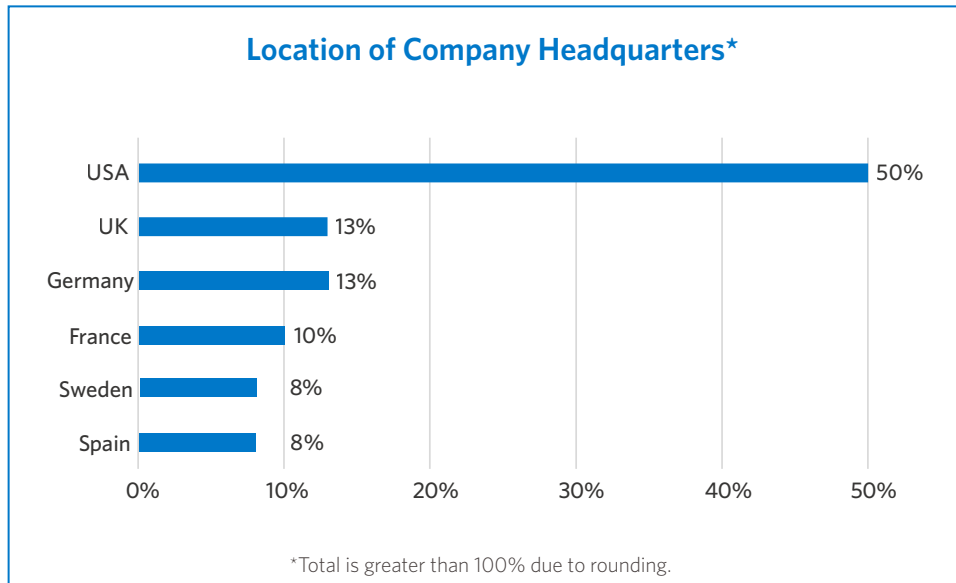


About the Research

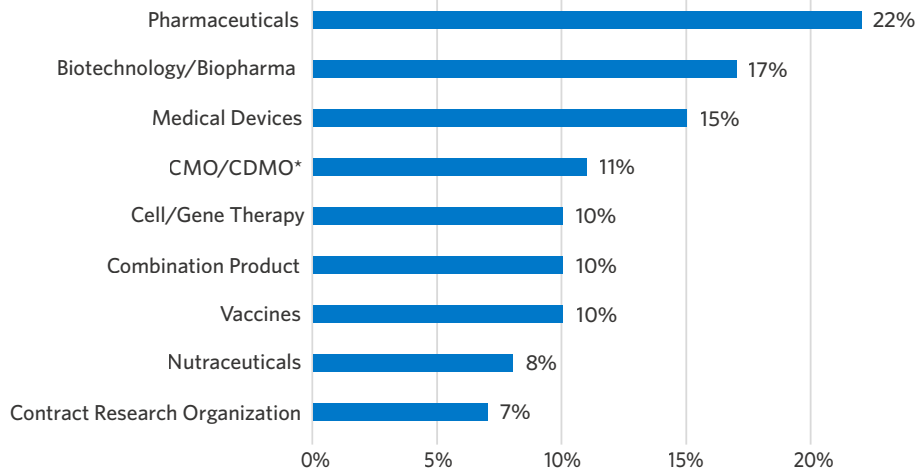
In summer 2022, AspenTech, in collaboration with FT Longitude, a Financial Times group company, surveyed 400 pharma industry professionals with expertise in drug development or manufacturing to get their views on the role of digital transformation and industry trends over the next three to five years.



Demographics

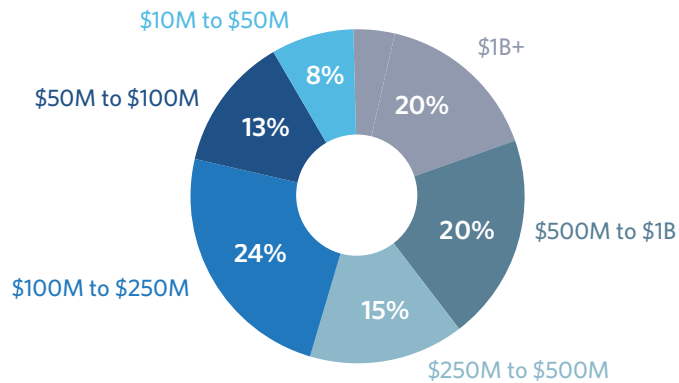


Company Products/Services



*Contract Manufacturing Organization/Contract Development & Manufacturing Organization

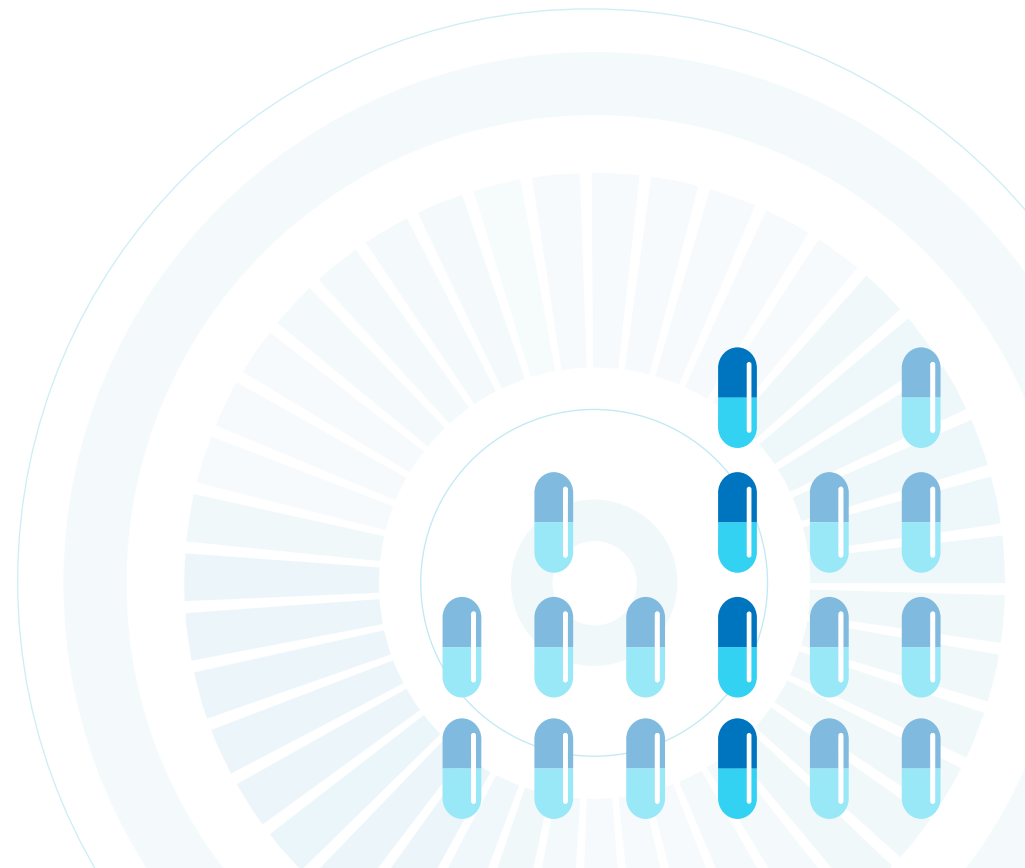
Size of Organization (Total Annual Revenue in US Dollars)



Interviews

To complement the quantitative survey effort, interviews were conducted with four thought leaders in the pharma industry:

- Gareth Alford, Innovation and Manufacturing Technology Lead, GSK
- Thomas Bratke, Informatics Head, Technical Operations, Roche
- Michelangelo Canzoneri, Global Head of Group Smart Manufacturing, Merck KGaA, Darmstadt, Germany
- Shalini Sharma, Associate Vice President, Kashiv BioSciences



The Results

Section 1. Digital Transformation Confidence Grows as Pharma Manufacturers Eye Opportunities

The pharmaceutical companies surveyed in our research are eager to transform for the benefit of the patient populations they serve.

Risk aversion has traditionally restrained pharma's appetite for change, but our survey results revealed that is not the case for half of the respondents. Fifty percent say that their digital transformation progress is not being hindered by risk aversion, with just 35 percent saying it is (Figure 1).

These numbers suggest a growth in digital confidence over the past year or at the very least a shift in market perceptions around transformation. In the 2021 research³, **Culture Reimagined: How Pharmaceutical Firms Can Use Data and AI with Confidence**, risk aversion was the top barrier preventing the adoption of artificial intelligence (AI) and machine learning (ML) among digital culture leaders.

To What Extent Do You Agree or Disagree with the Statement, "Our Risk-Averse Company Culture Hinders Our Digital Transformation Progress"?

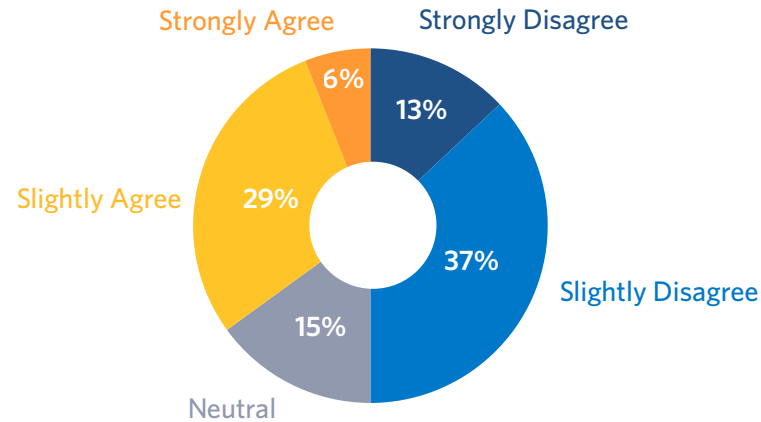


Figure 1. Half say that risk aversion does not impede digital progress.

COVID-19 Accelerated Digital Transformation

The intense pressure of the pandemic accelerated the industry's digital transformation—a trend acknowledged by 74 percent of pharmaceutical professionals in a recent Global Data survey⁴. Within that group, 35 percent believe that the global health emergency fast-tracked pharma's digitalization progress by more than five years.

The disruptions also led to optimization that went beyond digital transformation. With the world looking to the pharma industry for life-saving treatments, many pharma manufacturers were forced to streamline their production processes as much as possible.

"The pandemic pushed us to develop resilience in our core operations, our supply chain and our workforce," says Thomas Bratke, Informatics Head, Technical Operations, Roche.

These productive shifts will continue to prove helpful as pharma companies strive to meet market demands and areas of medical need moving forward.

Cell and Gene Therapies Set to Surge

Sixty percent of respondents expect biologics and cell and gene therapies to continue to be the industry's fastest-growing revenue drivers by 2027 (Figure 2). According to McKinsey & Company, more than 75 cell and gene therapies had been launched globally by the end of 2019, up from fewer than 25 in 2009.⁵ After being valued at \$16 billion in 2020, the cell and gene therapy manufacturing market is expected to more than double by 2030.⁶

Despite only eight percent of respondents recognizing the personalized medicine category as a top revenue growth area, they recognized cell and gene therapies, a highly personalized and targeted type of medicine using one's own genetic material, as the leading revenue driver (31 percent).

"Personalized medicine is a major growth area and a key cause of the digitalization taking place in pharma manufacturing," says Gareth Alford, Innovation and Manufacturing Technology Lead at GSK. "Because we need to adapt the way we operate as an industry."

The Pharma Industry's Vision for Digital Transformation

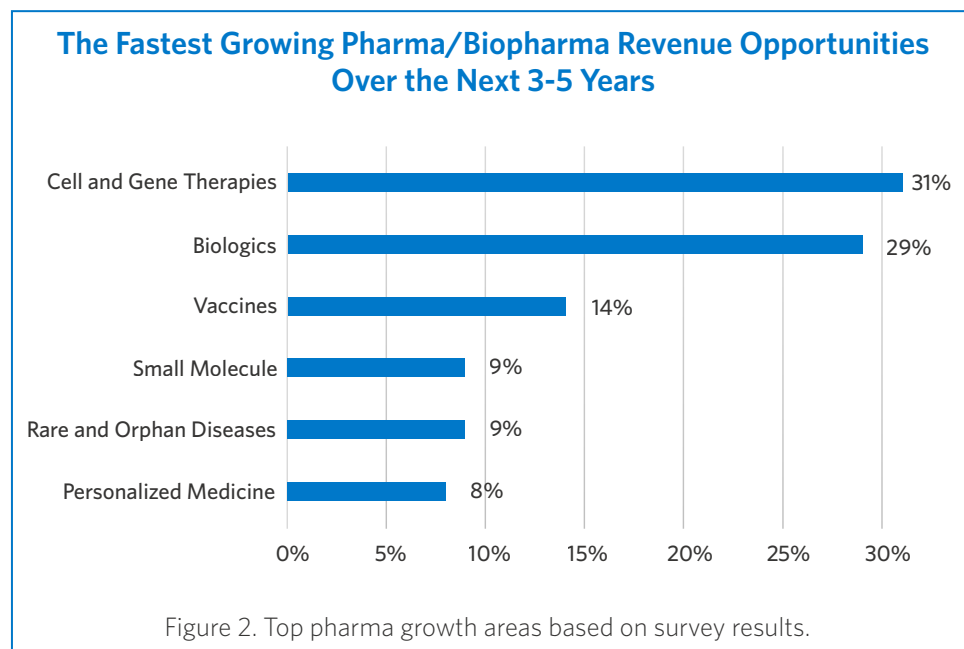
According to respondents, ISPE's Pharma 4.0™ initiative and Industry 4.0/5.0 are the frameworks that best represent the future of digital transformation in pharma, with Pharma 4.0 resonating more in Europe and Industry 4.0/5.0 frameworks resonating more in the United States.

"Personalized medicine is a major growth area and a key cause of the digitalization taking place in pharma manufacturing because we need to adapt the way we operate as an industry."

— Gareth Alford, Innovation and Manufacturing Technology Lead at GSK



“The industry is acknowledging the fact that we need to cater to very different demographics around the world,” he adds. “This awareness is rooted in the application of genetics in early drug discovery. We are seeing a need for a higher degree of personalization for certain molecules.”



Biologics Are a Key Growth Area

Biologics (therapeutics derived from living organisms) have proven to be highly effective for the treatment of a wide variety of diseases. They are also extremely profitable due to the high cost per treatment and are on track to become one of the pharma industry’s fastest growing revenue generators, as indicated by the results. In fact, forecasts suggest that global biologics sales could outpace small molecule sales by 2027.⁷

Shalini Sharma, Associate Vice President at Kashiv BioSciences, agrees that biologics as well as cell and gene therapies, are the future of pharma manufacturing and hold a lot of untapped potential.

Sharma notes that the caution from regulatory authorities to date has indeed slowed down biologics development timelines, however, it has placed pressure on developers to make sure quality and safety are optimized. She adds, “I do see a major shift where development timelines are shrinking and that’s because past submissions and approvals are helping regulatory authorities understand this segment much better.”

To fast-track development timelines and get medicines into the hands of patients more quickly, pharma manufacturers are launching digital transformation initiatives to streamline product innovation—the second highest priority for respondents’ digital transformation strategies (Figure 3). These programs need digital technologies that can minimize risks, boost agility and foster transparency in therapy development and manufacturing.



Section 2. Top Obstacles to Overcome

As pharma companies tap into transformation momentum and newer medical advances like cell and gene therapies, respondents identify four main hurdles to using technology to fully capitalize on revenue growth drivers while enhancing access to medicine.

1. Cultural Immaturity Holds Businesses Back

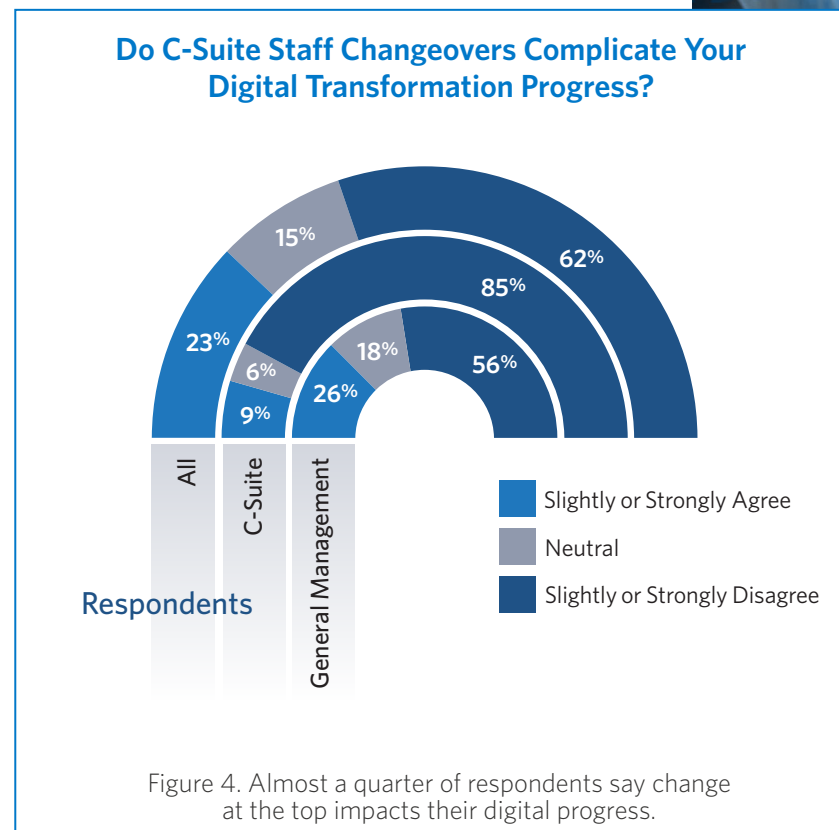
Although the industry is progressing its digitalization mindset, more than one in three pharma businesses are still struggling with an element of risk aversion at their company (Figure 1). Also, nearly one in four pharma companies that responded agree (19% slightly agree, 4% strongly agree) that C-suite changeovers complicate their organization's digital transformation progress (Figure 4).

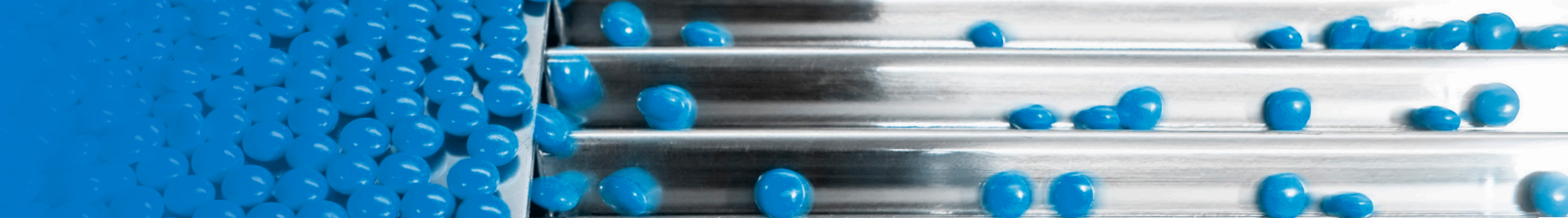
General management professionals (those below C-level) are 17 percent more likely to acknowledge the disruption of C-suite turnover than C-level professionals themselves (9 percent). C-suite changeovers can have significant impact across the enterprise, often resulting in adjustments in company structure, staff roles and strategic priorities.

Outside of just the C-suite, many respondents say they need to continually develop their

cultural maturity around tech adoption. In fact, addressing this challenge is one of the top digital transformation goals for the industry, based on the survey (Figure 3).

The need for more cultural maturity was especially pronounced for US respondents who ranked it among their top two strategic goals, whereas it falls just outside the top five goals of European firms.





In her experience, Sharma has seen cultural immaturity around tech adoption result in skepticism. She says, “At least in the case of biologics, there are so many operations where personnel and scientists have a mindset that in order to decide next steps, they have to personally monitor the process while it’s running and make individual calls based on the data.”

Sharma adds that the solution stems from achieving acceptance from R&D groups working at pilot scale for new technology and artificial intelligence tools making process decisions with people. “There is always collaboration between the development groups and the manufacturing groups,” she says. “The more the development group trusts a technology, the easier it will be for teams in commercial manufacturing setups to fully rely on those systems.”

Without maturity and acceptance around technology adoption, pharma manufacturing sites may face some challenges when scaling up digital transformation pilots and assessing enterprise-wide value. This could result in missed opportunities for improved operational excellence and cost savings, benefiting both manufacturers and patients.

2. Current Manufacturing Plants Lack Sufficient Agility

To make the most of the industry’s fastest-growing revenue opportunities and improve patient access to medicine and health outcomes, pharma manufacturers understand that they need to change the way they operate. Biologics and personalized medicines like cell and gene therapies can be

more unpredictable and complicated to manufacture than traditional therapeutics. In many cases, they are designed and developed for small patient populations—even for a single patient in some cases⁸. These small volume production requirements are incompatible with traditional manufacturing models that revolve around high volume blockbuster drugs, which may be few and far between in the future.

As a result, pharma manufacturing plants will need to flex to deliver varied therapy modalities. GSK’s Gareth Alford says, “We all need agility within our manufacturing environments. The notion of building a facility to produce one or two products that remain the same for 15 years is outdated.”

Manufacturing plants need to be able to accommodate a variety of product formulation processes, streamline inventory and shorten lead times. But the trend toward smaller production volumes raises concerns around cost management. Pharma businesses will need to prioritize operational agility techniques that generate new cost efficiencies.

3. Data Silos Threaten Productivity Levels

Data silos directly impede cross-functional collaboration for a sizable proportion of the survey respondents (48 percent). However, the largest pharma businesses (\$1B+ USD) are more likely to say that data silos interfere with internal collaboration efforts (53 percent). See Figure 5.





A Company's Size Can Impact Its Impression of Data Silos

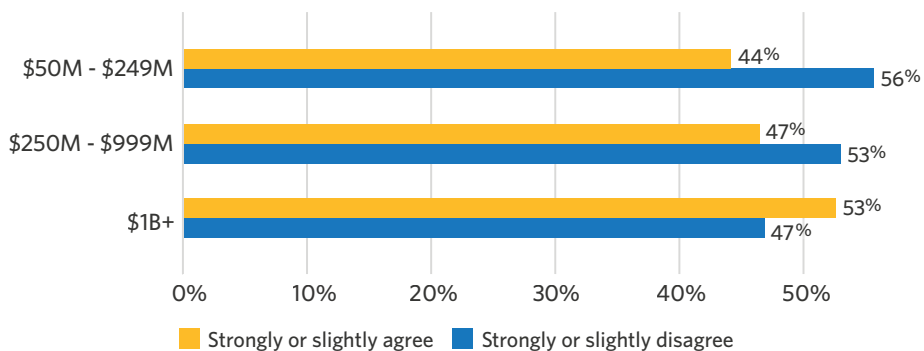


Figure 5. The largest companies agree that silos disrupt collaboration.

Information silos are often created by lack of connectivity between data sources across departments, which hinder efficiencies across the product lifecycle. This is especially true when scaling up from drug design to commercial manufacture and then again when moving from production to quality assurance release.

Poorly managed scale-ups can harm product efficacy and quality, which can have wider business impacts. "If there is an impact on product quality this can be managed manually by rejecting any batches with quality issues," says Sharma. "The main issue here is that you will be wasting a lot of money. Failure of batches, issues with business continuity and the commercial viability of a product or a process, will come at a cost to an organization."

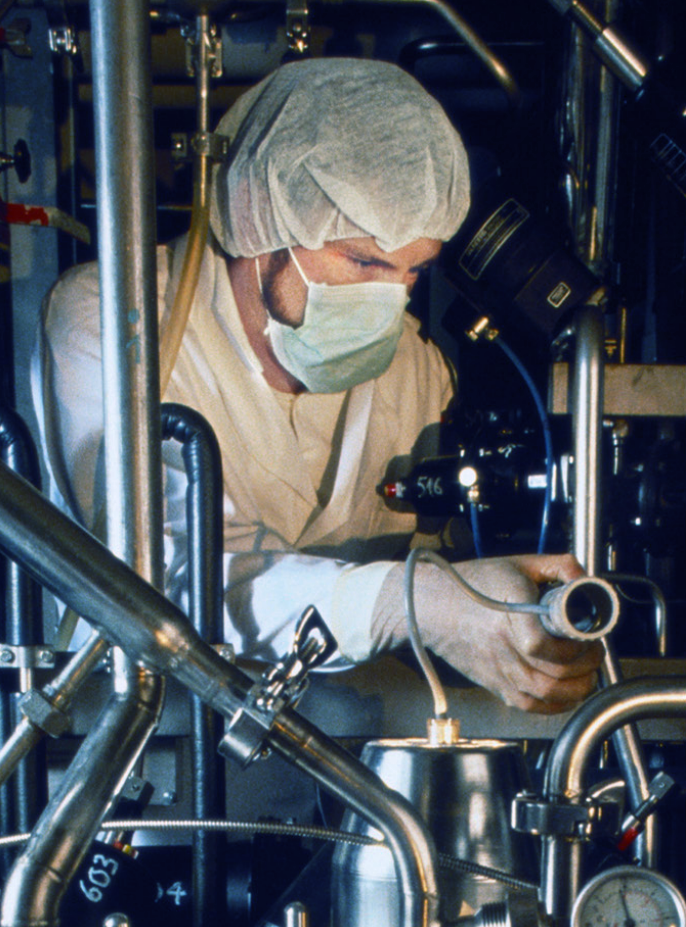
4. Regulations Can Slow Down Digitalization

Technologies used in the production of medicines need to be FDA Title 21 CFR Part 11 or EU Annex 11 compliant and validated in accordance with the company's SOPs. Adopting new technologies for an existing procedure, no matter the potential benefit, can be arduous and costly, and is one of the perceived barriers to digital transformation for some companies.

In our research, 54 percent of respondents feel that regulations are undermining their digital transformation ambitions. However, a large proportion (46 percent) say that regulations do not undermine their digital transformation initiatives, and improving regulatory compliance was among the top reasons for pursuing digital transformation. This indicates that attitudes towards regulations are mixed. Biopharma manufacturers are one of the most likely sectors to say that regulations interfere with digital transformation progress.

Gareth Alford oversees GSK's external collaborations with governments and extended industry partners to spark conversations around how innovation ambitions interact with regulatory frameworks. "These collaborative environments provide opportunities to iteratively de-risk elements through the development innovation process," he says. "Interactive discussions can build confidence and open up a dialogue with regulators around compliance and opportunities for innovation."





Section 3. The Journey to Smarter Manufacturing

To overcome the challenges discussed and meet market demands, pharma companies are prioritizing initiatives focused on operational agility and efficiency. These factors will be critical for manufacturing plants of the future as they strive to accommodate a range of treatment modalities and smaller batch sizes. Improving tech-enabled agility and efficiency by upgrading capabilities in manufacturing plants is crucial for supporting patient access to all medicines, especially highly personalized treatments.

With this in mind, Michelangelo Canzoneri, Global Head of Group Smart Manufacturing, Merck KGaA Darmstadt, Germany, explains that technologies will play a vital part in the future of pharma manufacturing. “Imagine you produce one drug per patient. It brings up questions around how we release manufactured batches of medicines. We have the potential to leverage smart automation, advanced robotics and AI enabled systems. Smart manufacturing is firmly at the heart of our fourth industrial revolution and enables the next generation of healthcare products.”

“...Smart manufacturing is firmly at the heart of our fourth industrial revolution and enables the next generation of healthcare products.”

— Michelangelo Canzoneri, Global Head of Group Smart Manufacturing, Merck KGaA Darmstadt, Germany

What Are the Three Most Important Steps Your Company Is Taking to Improve Operational Agility and Keep Up with Market Demands Over the Next 3-5 Years?

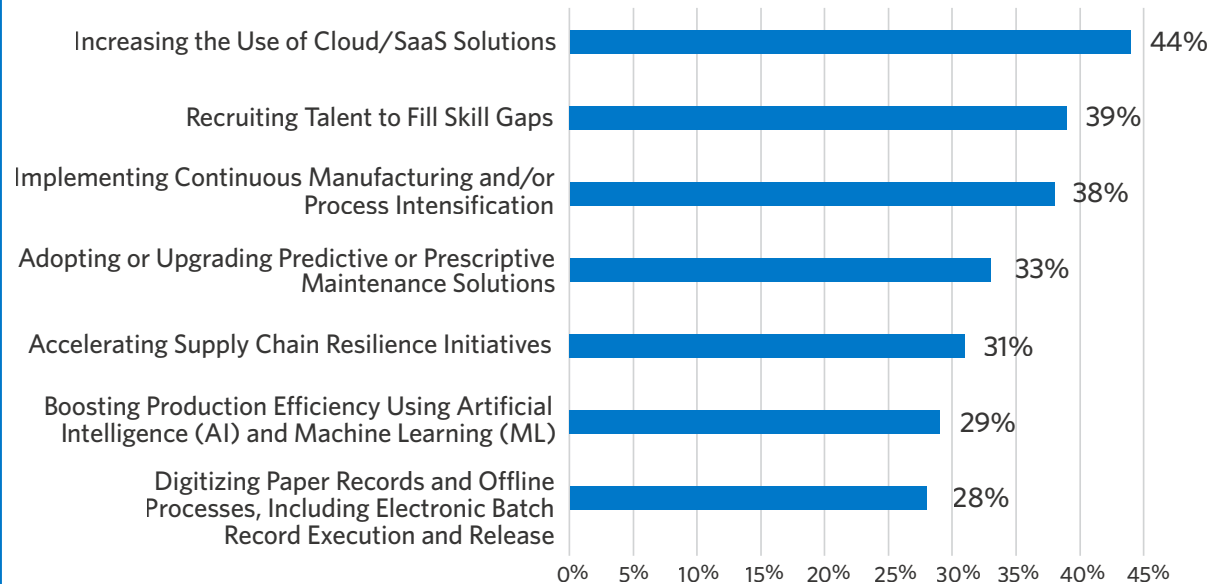


Figure 6. Respondents are most likely to prioritize cloud/SaaS solutions.

Learnings

The survey findings surfaced six key initiatives and recommendations to boost operational agility and efficiency levels as well as create smarter manufacturing workflows and functionalities.

1. Explore Cloud and Software-as-a-Service

Survey respondents cited increasing their use of cloud and software-as-a-service (SaaS) solutions as the most important step they are taking to improve operational agility in the next 3-5 years (Figure 6).

These deployments afford greater data access, visibility across departments and among partners, and enable more informed data analysis and decision-making.

“Cloud and SaaS systems represent a great opportunity to access and store data at scale in a much easier way than in the past,” says Roche’s Thomas Bratke. “For instance, factory data produced on a daily basis can become globally available to contribute to wider capabilities and use cases.”

2. Accelerate Implementation of Continuous Manufacturing

Respondents are also prioritizing continuous manufacturing to enhance operational agility.

Studies within the US show that, compared with the batch framework that is widely used in the pharmaceutical industry, continuous manufacturing processes could accelerate medicine production timelines by as much as eight months.⁹

The same study found that the acceleration in time-to-market from continuous manufacturing could translate into millions of dollars in early revenue benefits.⁹ In addition, continuous production frees up floor space, facilitating more production lines in a given footprint.

However, pharmaceuticals lags behind many other manufacturing industries in its use of continuous production processes.

“Hypothetically, all the individual technologies exist for pharma companies to have continuous manufacturing processes end-to-end,” says GSK’s Gareth Alford. “A key challenge, from a compliance point of view, comes in knitting those platforms together.”

He adds that industry-wide collaboration will be vital for accelerating the accessibility of continuous manufacturing in pharma. “As an industry we need to come together so we can build consensus collaboratively.”

3. Prepare for Ongoing Talent Gaps

Based on the survey’s findings, pharma businesses say that in addition to Cloud/SaaS and continuous manufacturing, recruiting talent to fill the skills gaps is in their top three priorities for improving operational agility. In the US, recruiting to fill talent gaps is the number one digital transformation priority for pharma businesses.

But unlike many other industries¹⁰, not every pharma company is having difficulty finding the talent they need. According to our respondents: 41 percent are not struggling to secure and retain the talent they need, and 39 percent say they are (Figure 7).

However, difficulties around filling skills gaps in pharma are expected to intensify. As pharma modernizes, demand for new skillsets will grow, especially around data science. “As data engineering and data science move from innovation models into scaled rollouts, the issue of skills gaps will grow,” says Bratke. “If pharma manufacturers really want to put data to work at [a high] scale, they will encounter a different dimension on the skills they need versus when models were conducted on an innovation level.”

Automating high-volume, low-complexity tasks gives manufacturers additional capacity, which helps them upskill employees to deliver more value.

Automation makes it easier for pharma businesses to replace missing capabilities. Automating high-volume, low-complexity tasks gives manufacturers additional capacity, which helps them upskill employees to deliver more value.

To What Degree Do You Agree or Disagree with the Statement: “We Are Struggling to Secure and Retain the Right Expertise, Such as Data Science Talent?”

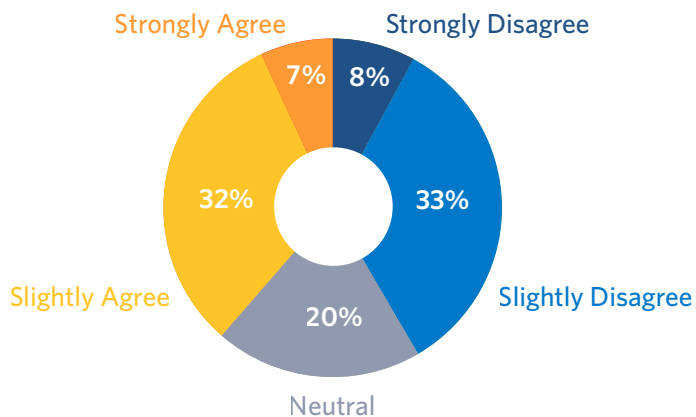


Figure 7. Pharma companies are nearly split on whether there’s a skills gap.

4. Don’t Neglect AI

Less than one in three respondents (29 percent) plan to prioritize boosting production efficiency with AI and ML, leaving the majority of pharma businesses at risk of overlooking their importance (Figure 6).

The larger pharma businesses in the research—those with over \$1B USD in annual revenue—rank AI as one of their top three digital transformation priorities. Also, US pharma businesses are more likely to prioritize AI than European firms. This difference could be related to the differences in data laws operating within the two regions, with the EU having more stringent data protection regulations.¹¹

As access to computing power advances, and data integration and integrity improve, pharma manufacturers should consider expanding their applications of AI and ML. For example, ML and AI-powered predictive maintenance is playing a key part in drug manufacturing. Predictive maintenance, which was recognized by respondents as the fourth highest priority to achieve operational agility, enables process engineers to proactively manage the health of their operations by receiving advanced alerts of impending equipment breakdowns to preempt and avoid production downtime.

5. Break Down Data Silos

To improve sharing of data between departments, companies can build on the growing appetite for digital transformation and enable team members to be involved in different stages across the product lifecycle. “At GSK, we are constantly striving to achieve closer alignment between those that generate the data and those that consume it,” says Alford.

Silos between functions can degrade overall data output. For instance, factory staff may be less comfortable with the work required to generate data and data scientists can lose meaningful, contextual data when they do not communicate with frontline employees.

“Data insights need to be connected across functions in the value chain,” says Michelangelo Canzoneri, Global Head of Group Smart Manufacturing, Merck, KGaA Darmstadt, Germany. “Data doesn’t only generate information and wisdom on individual tasks but can scale across other tasks in the production life-cycle.”

Alford agrees. “We have had to acknowledge that some stakeholder groups don’t necessarily have the same priorities or communication styles, even though they are dealing with the same processes,” he says. He then goes on to explain that the answer is to upskill team members where possible and ensure you have allocated employees who are focused on helping key departments overcome communication hurdles.

6. Minimize the Impact of C-suite Changeovers

The impact of C-suite changeovers often impact all aspects of a business and can materialize as adjustments in company structure, staff roles and shifts in strategic priorities.

To maintain digitalization momentum in the face of C-suite changeovers, digital transformation leaders must strive to achieve alignment with senior leadership, especially with newer members of the team. Presenting clearly defined strategies and progress against KPIs will be crucial for maintaining buy-in from C-level executives. Pharma manufacturers should seek out technology providers that are willing to partner with them to support these business cases by quantifying the ROI that their services generate.

Key Takeaways

Our research indicates that the pharmaceutical industry is prioritizing operational agility and efficiency to take advantage of opportunities such as biologics and cell/gene therapies in the next five years. Recent macro trends and market conditions have resulted in a higher level of understanding by pharma manufacturers of the need to improve cultural maturity around tech adoption, thereby reinforcing the importance of digital transformation as an enabler.



Manufacturers continue to digitalize and improve the operational agility needed to deliver quality medicines quickly, including to areas of the world that are traditionally underserved. The demand for new employee skillsets will grow as well. As companies develop plans for hiring new talent, there will be a great need for professionals with data science proficiency as this skillset will play a crucial role in pharma's future.

Michelangelo Canzoneri, Global Head of Group Smart Manufacturing, Merck KGaA Darmstadt, Germany explains: "Digital transformation is a fundamental element of business evolution. It's an enabler of next generation data-based business models and an additional contributor in helping to reduce cost and time to market, while continuing to deliver high quality products to our customers."

"To fully capitalize on these opportunities requires more than just having access to all data," he adds. "The answer lies in contextualizing this data to gain information and knowledge, aiming to generate insights at scale and create descriptive and predictive models from it. Leveraging data in order to fully understand the design space of manufacturing processes of each

product, such as process parameters, quality attributes, raw materials, technologies, suppliers, ensures this intelligence informs our ways of working."

Conclusion

To overcome supply chain challenges, product inconsistencies and long development timelines, pharma manufacturers must continue to prioritize operational agility. Doing so will help them seize new revenue opportunities, such as biologics and cell and gene therapies, while achieving critical pharma goals: boosting efficiency and productivity, delivering innovation and improving access to medicine and patient quality of life. It's become increasingly evident that advancing digital transformation and implementing an integrated, robust digital strategy are (and will continue to be) key enablers of operational excellence for pharma companies.

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About Aspen Technology

Aspen Technology, Inc. (NASDAQ: AZPN) is a global software leader helping industries at the forefront of the world’s dual challenge meet the increasing demand for resources from a rapidly growing population in a profitable and sustainable manner. AspenTech solutions address complex environments where it is critical to optimize the asset design, operation and maintenance lifecycle. Through our unique combination of deep domain expertise and innovation, customers in capital intensive industries can run their assets safer, greener, longer and faster to improve their operational excellence.

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