



Culture Reimagined:
How Pharmaceutical Firms Can
Use Data and AI with Confidence



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A sector in the spotlight

COVID-19 has shone an unusually bright spotlight on the pharmaceutical industry. Supply chain disruptions have forced pharmaceutical companies to accelerate production of some drugs, and to slow or stop others. The pandemic has also started to change how the sector thinks about technology.

For example, the consequences of equipment failure during this kind of crisis starkly demonstrate the importance of predictive maintenance. The pandemic has also exposed the importance of resilient supply chain networks. Companies that make the best use of new technologies such as artificial intelligence (AI) and machine learning (ML) are better at managing each of these critical issues. They also find it easier than others to pivot and stay profitable in a crisis.

What are the lessons for the sector from the way these companies adopt and use technologies? That is the question at the heart of this report.

Based on a survey of 300 senior respondents across six countries, our study finds that very few pharma companies – just 13% of our sample – see themselves as having a strong digital culture, and they are benefiting from markedly faster revenue growth than the rest. These leading firms are also ahead in their use of data across drug manufacturing operations.

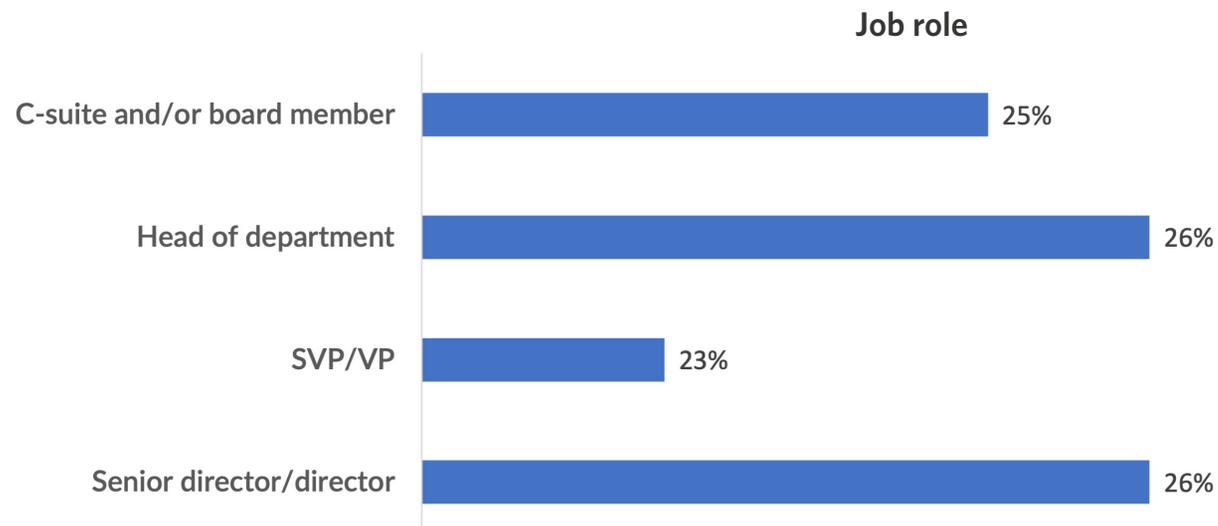
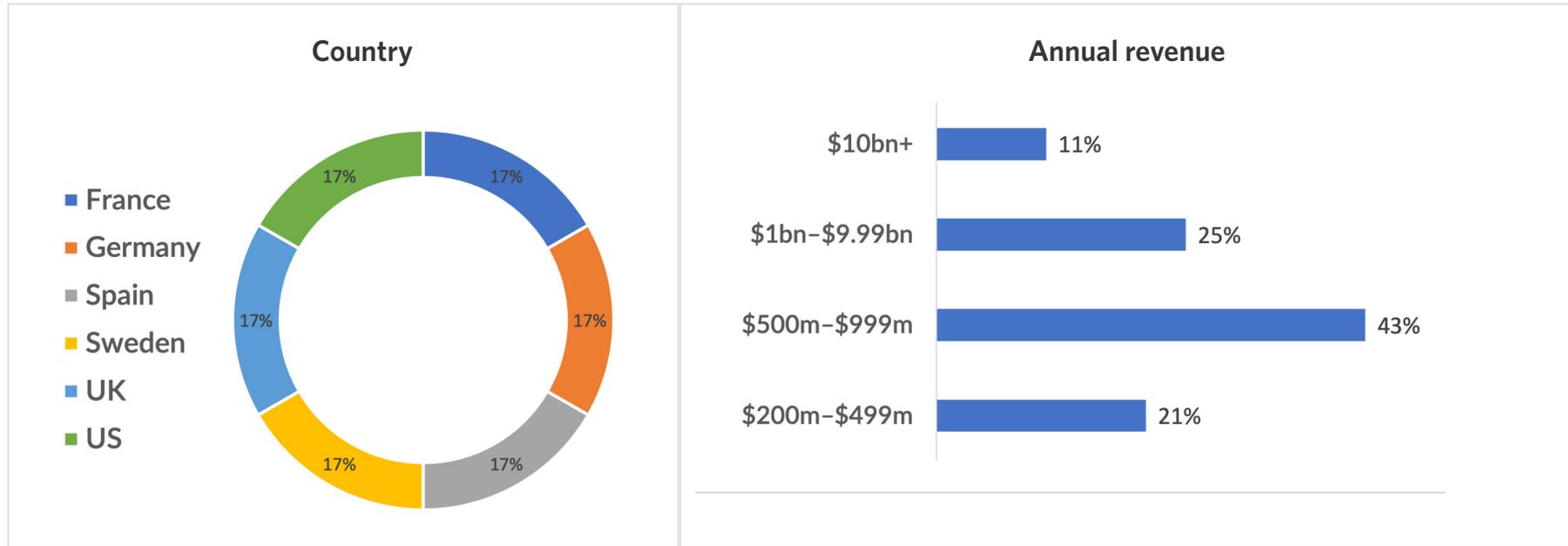
However, many still see room for improvement on technology adoption. Nearly half of these leading organizations even agree that their company's "business decisions are currently less informed than they could be by data

that the company *already holds.*" The same proportion recognize that this inability puts them at a competitive disadvantage.

This report explains what these leading companies are doing differently, finds out what is stopping other firms from emulating them and offers advice on how to break down those barriers. The message from our findings is simple: a strong digital culture helps pharma organizations compete, and the companies that get ahead digitally now will reap the rewards in the coming years and decades.

Demographics

AspenTech, in collaboration with Longitude, a Financial Times company, surveyed 300 senior respondents in the pharmaceutical industry across six countries.



A digital culture gives some businesses a competitive edge

Digital transformation has moved at a slower pace in the pharma manufacturing industry than in the research and development (R&D) of drugs and much more slowly than in other industries such as **telecommunications or high-technology**.

Our study shows that pharma manufacturers do recognize the value of leading-edge technologies such as AI: 50% say that AI can bring value to their organization, for example by reducing time to market. But few have prioritized the development of the kind of strong digital culture that would help them to implement these technologies.

“Traditionally, pharma manufacturers have been moving very slowly and incrementally toward pharma 4.0. It’s an industry that often was not rewarded for going out on a limb and trying something new. The good news is that new guidance from regulatory agencies is encouraging pharma to think differently about how they view compliance in a way that promotes the adoption of valuable technology.”

- David Leitham, Senior Vice President and General Manager Pharma, AspenTech





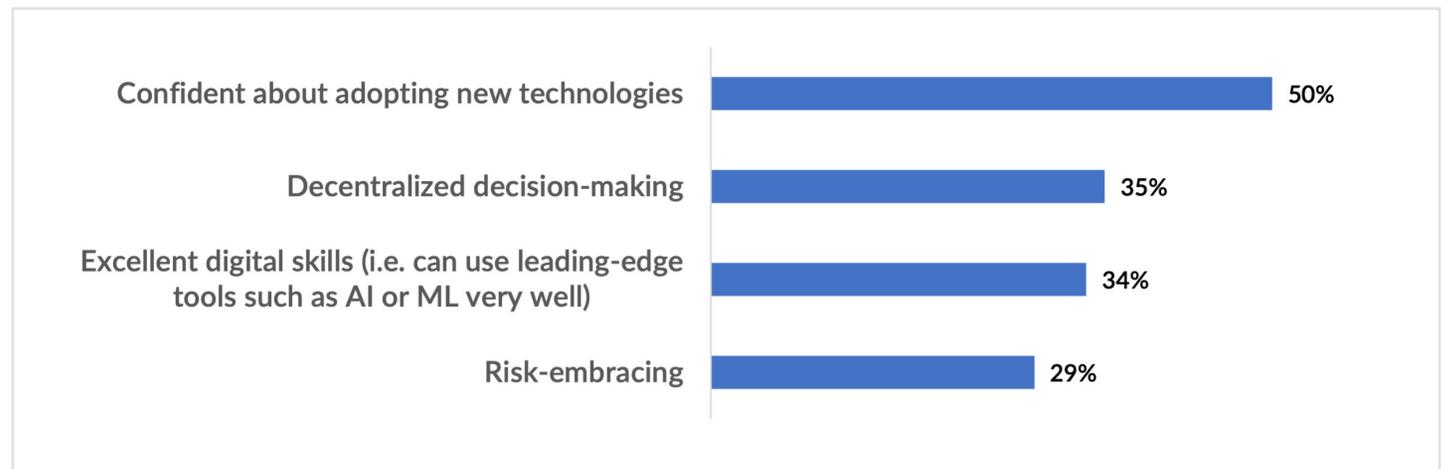
What do we mean by 'strong digital culture'?

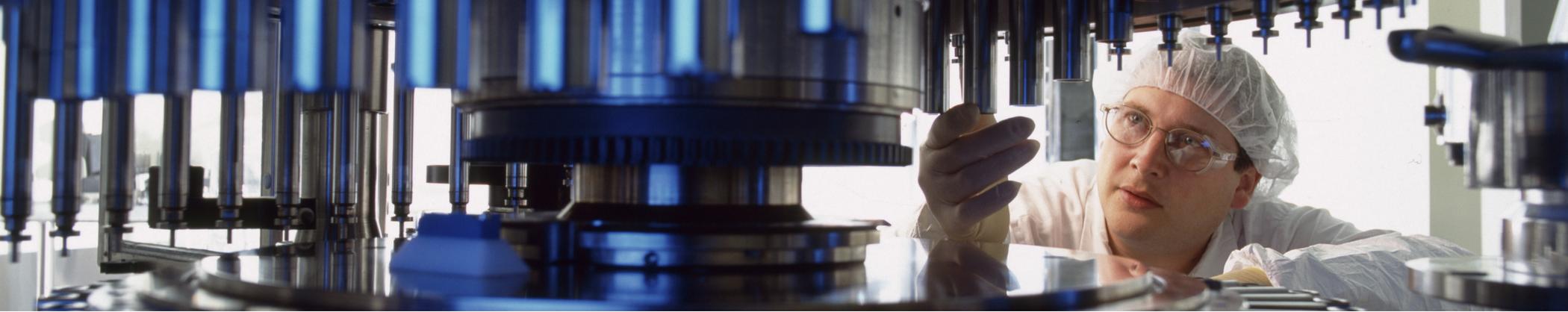
There are four key attributes that we believe can propel organizations' transformation efforts:

1. Confidence in adopting new technologies such as AI
2. Confidence in using these technologies
3. Ability to make decisions quickly and at scale
4. Willingness to take risks

Our study finds that the majority of organizations still have a long way to go on all four. Half describe their company culture and workforce as confident about adopting new technologies, but only 34% rate their digital skills as 'excellent.' And decentralized decision-making, our third attribute, has also been adopted by only a minority of organizations (35%). Perhaps unsurprisingly, of the four attributes, risk-aversion is the area where organizations have most work to do (see Figure 1).

Figure 1. Pharma firms are struggling to embrace risk-taking





Meet the Digital Culture Leaders

A small proportion of firms, however, say they have fostered a strong digital culture. These firms, which we call the 'Digital Culture Leaders,' say they have adopted the first three of the four attributes (see Figure 2).

"Leading organizations stand out for their ability to use data effectively across all aspects of drug manufacture," says Leitham.

And they are already benefiting financially: 48% report revenue increases of more than 5% in the year to February 2021, compared with only 15% of the rest of the firms.

Figure 2. The Digital Culture Leaders are increasing revenues more than other firms

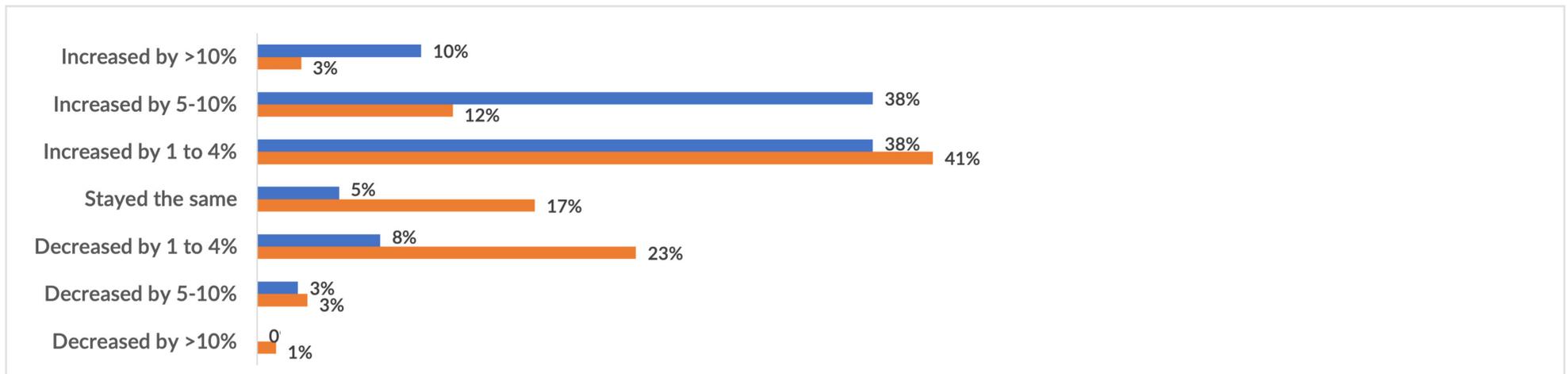


Chart shows revenue change in the past 12 months

So what are the Digital Culture Leaders doing differently that keeps them ahead? We explore this question in the next section.

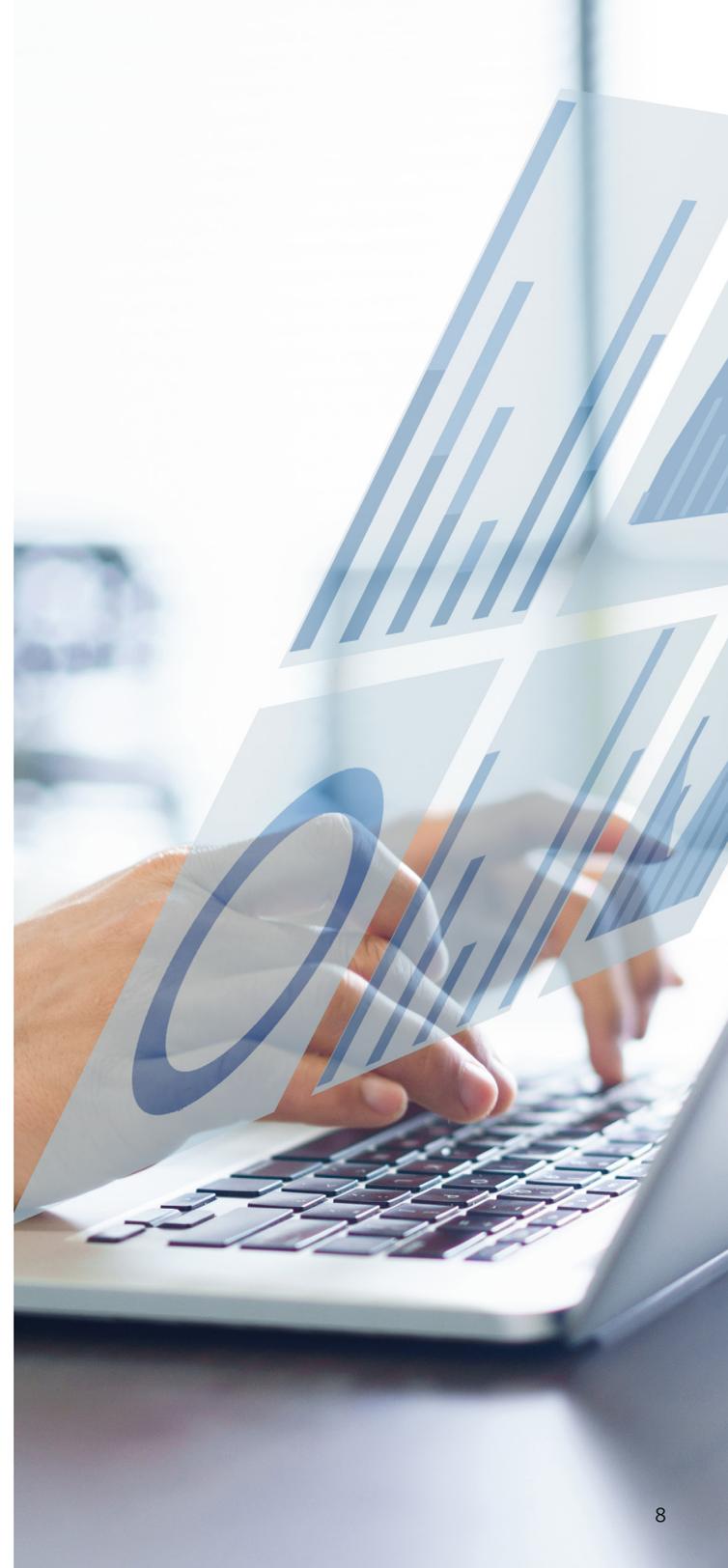
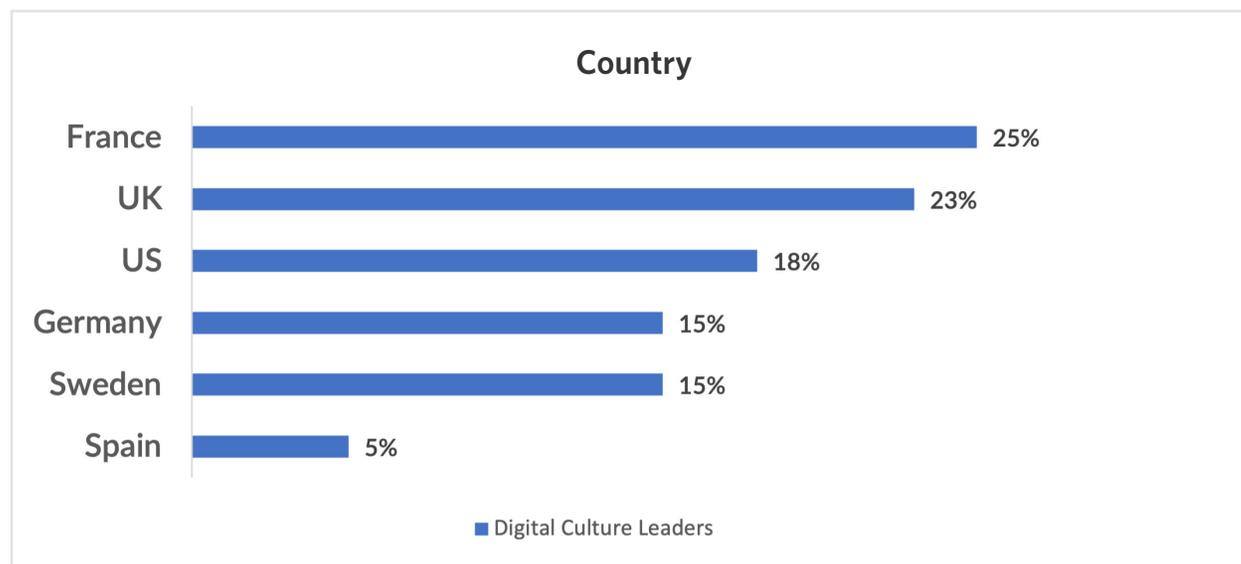
What makes a Digital Culture Leader?

We define the Digital Culture Leaders as pharmaceutical companies that:

- Are confident about adopting new technologies such as AI and ML
- Are already able to use these and other leading-edge tools very well
- Have implemented decentralized decision-making

These leading organizations are most likely to be from France and the UK.

Figure 3. France and the UK are producing the most Digital Culture Leaders



Fast digital transformation is critical in drug manufacturing

The COVID-19 pandemic has disrupted drug manufacturing. The speed of vaccine development and the rollout have changed industry expectations, putting new pressure on manufacturers to deliver faster. But the supply chain has not responded quickly enough to this demand – and not only for vaccines, but also for drugs unrelated to COVID-19. Making sure organizations can predict product demand and adjust output accordingly is important to successful collaboration with supply chain partners. But many companies still coordinate this using basic technology which does not enable centralized scheduling.

To meet new industry expectations, organizations should also implement technologies that facilitate predictive maintenance. Replacing equipment

parts according to a set schedule instead of when they need attention inevitably leads to unnecessary downtime, lost production and inefficiency. None of which pharma organizations can afford at the best of times – let alone during a global healthcare crisis.

Ultimately, the pandemic has all shown that systems that run on more rudimentary IT, such as spreadsheets – and even paper – cannot carry the industry forward.

Most firms expect disruption from the pandemic to continue, but the Digital Culture Leaders expect more disruption than the rest: 80% say their vaccine manufacturing capacity will be significantly impacted, and 73% say the same of their everyday manufacture operations compared with around half of the rest of the sample (see Figure 4).



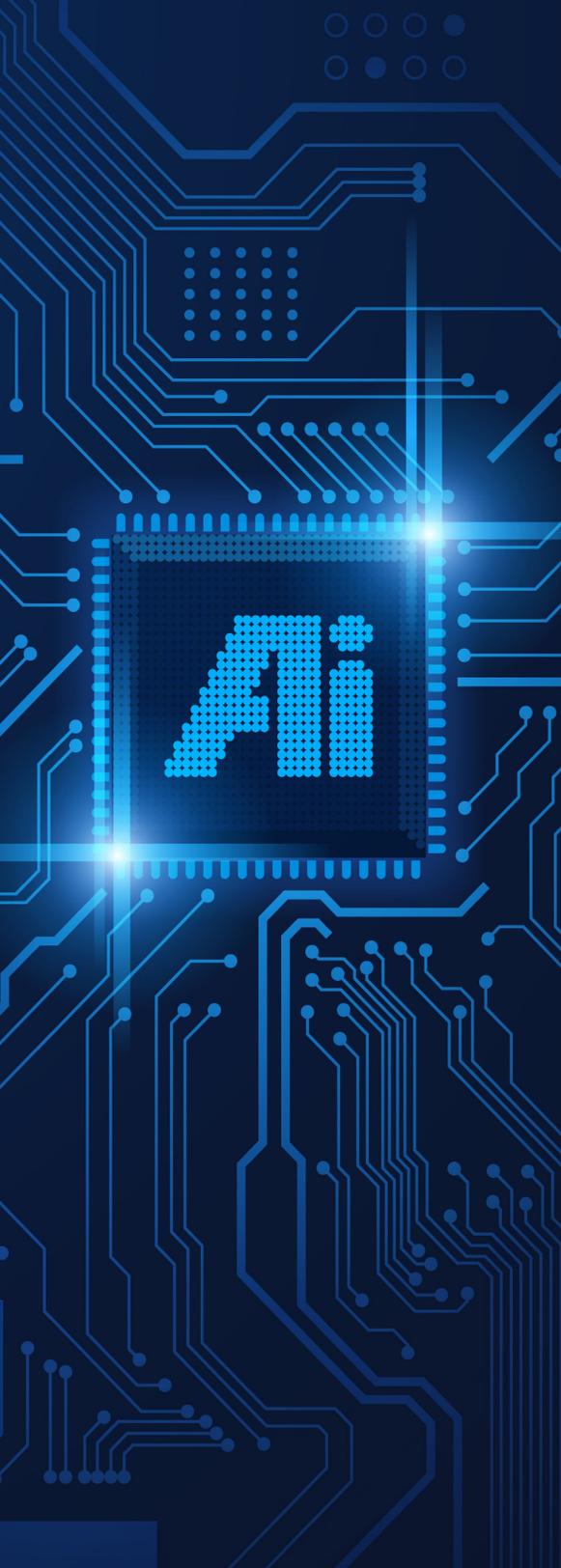


Figure 4. Digital Culture Leaders expect greater disruption in drug manufacture

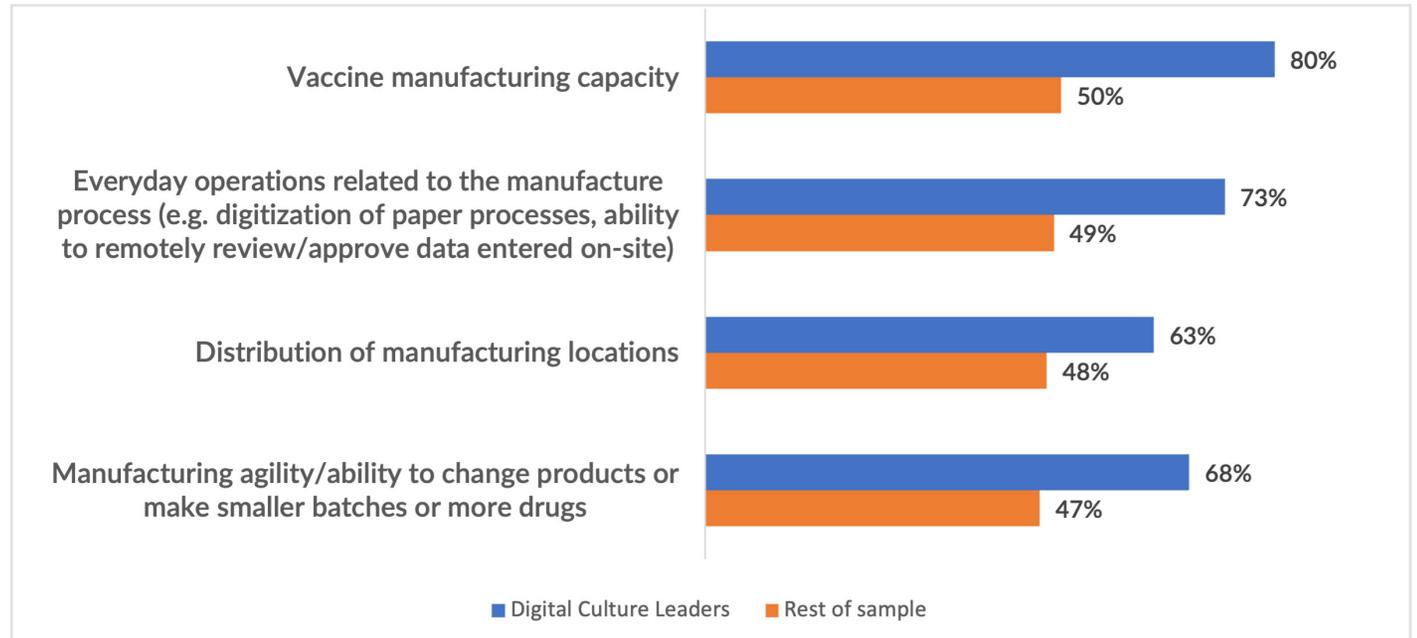


Chart shows percentage of respondents who say that COVID-19 will have an extensive impact on these areas

This expectation of disruption has increased the impetus for technological change and has made leading-edge technologies critical to survival.

The Digital Culture Leaders are more likely than their peers to see digital transformation as critical to success in this complex environment. For instance, 68% say that the pandemic has accelerated their transformation strategies, compared with only 51% of the rest (see Figure 5). Leaders are also more likely than the rest to be increasing the pace and scale of innovation, and to be exploring technologies such as AI in response to the pandemic.



Data is decisive

Data is the thread that runs through an organization's ability to innovate, use AI and ultimately to respond to disruption effectively. Respondents in our survey say that data can deliver value across the entire manufacturing chain.

Two areas stand out where data can deliver most value: predictive maintenance and optimization of product-line capacity. Guaranteeing the security of the manufacturing process ranks third. But the difference between the rest of the areas where data can deliver most value is less pronounced. For instance, our respondents report that data insights are as valuable for addressing non-compliance issues as they are for prediction of product demand and improving time to market. This shows data's critical importance across all drug manufacture operations (see Figure 6).

Figure 5. Digital transformation and technologies such as AI will be key to addressing disruption in drug manufacture

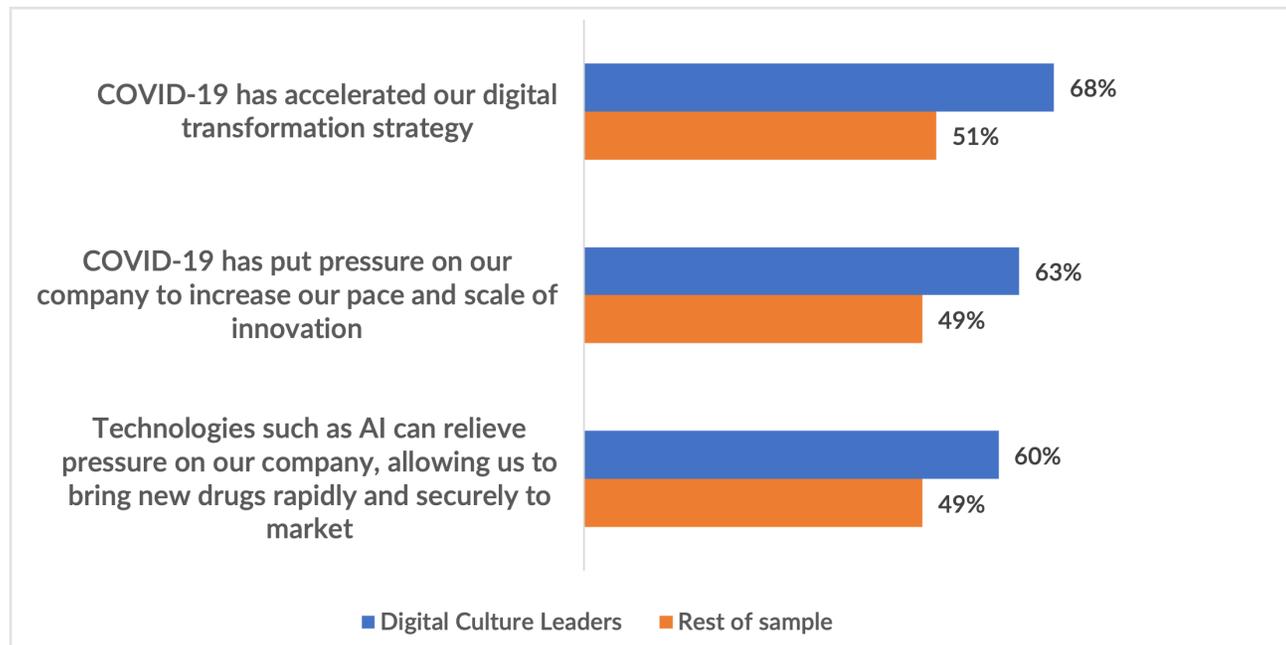


Chart shows percentage of respondents who agree with these statements

Figure 6. Data is essential across the entire manufacturing chain

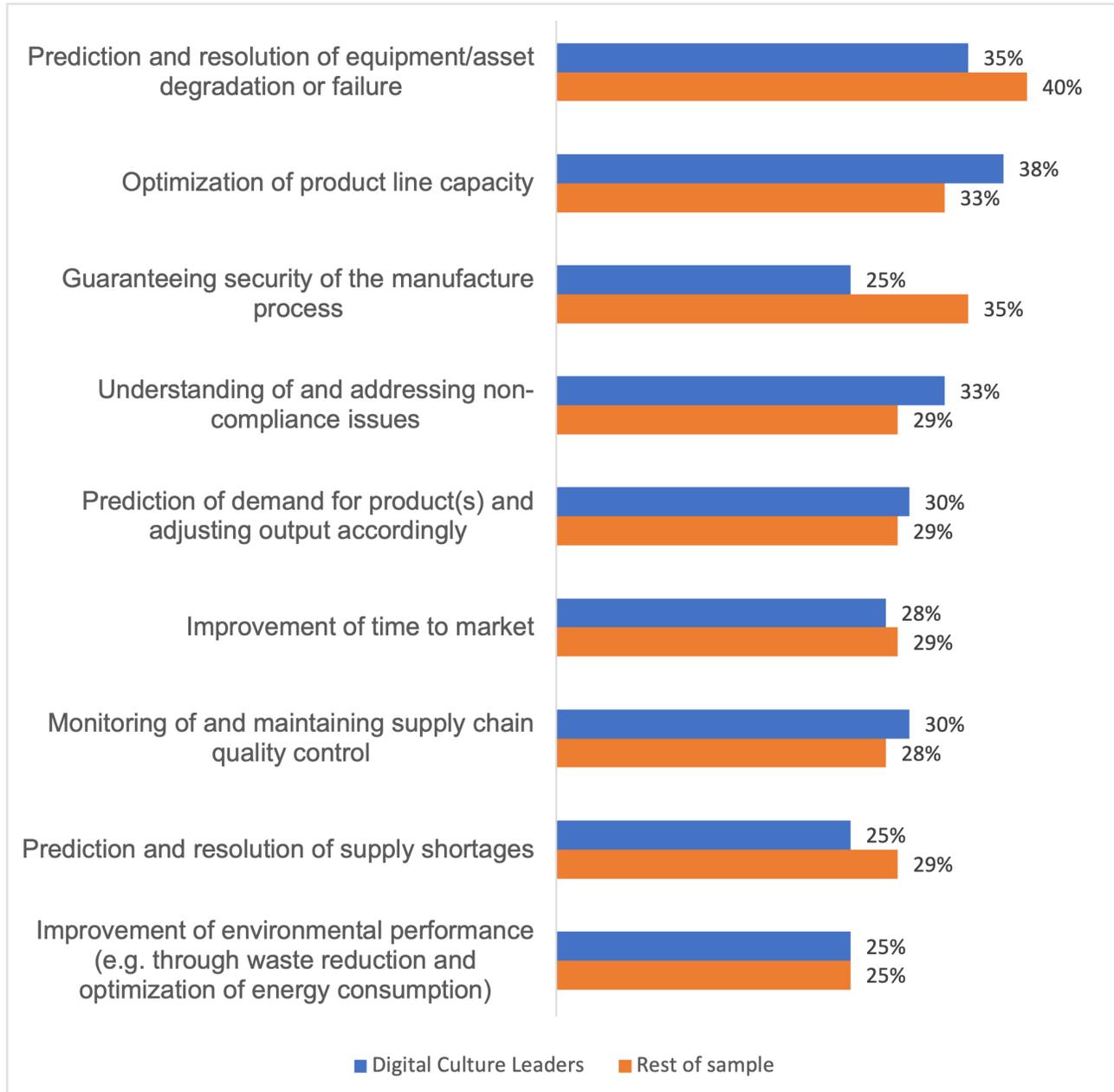


Chart shows percentage of respondents reporting the following are areas in drug manufacture where data can deliver value

Leading firms are exploiting their data

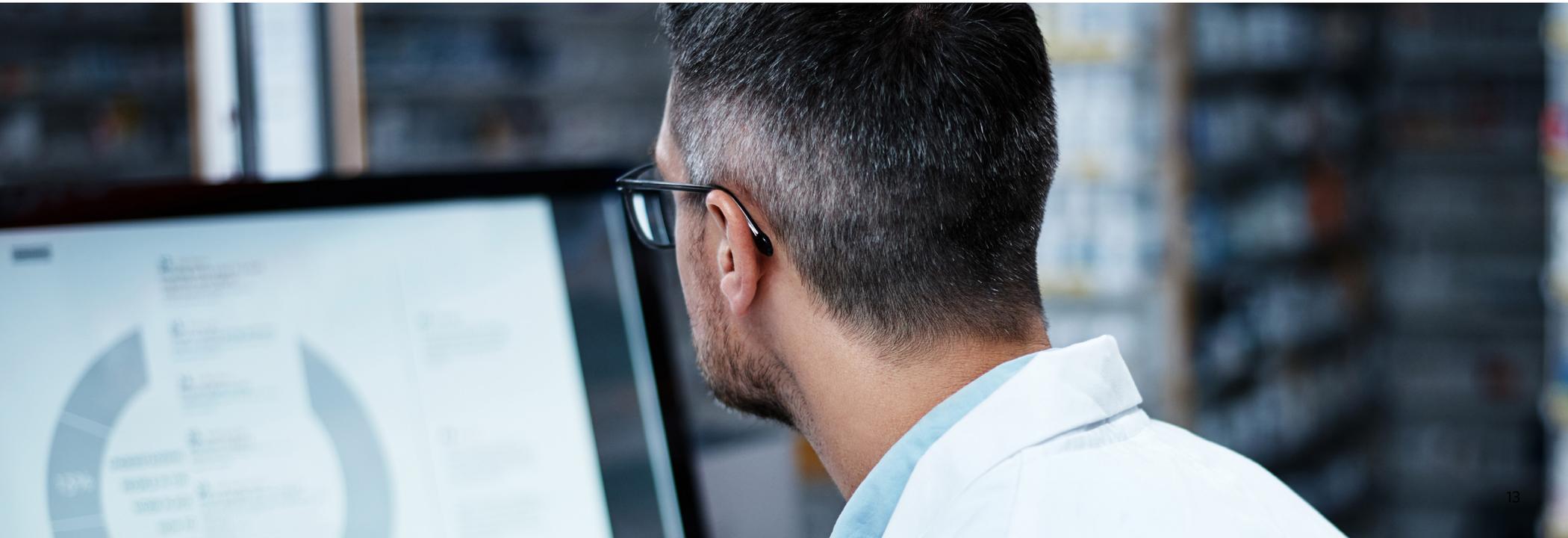
So just how effective are organizations at using data for drug manufacturing?

Many organizations understand the value of data in theory, but admit they struggle to make the most of it in practice. Nearly half (48%) of all respondents, including leading organizations, say their inability to generate and use data insights puts them at a competitive disadvantage. The same proportion admit that their business decisions are currently less informed by data than they could be. There is clearly much room for improvement here – for the leading organizations as well as everyone else.

However, even though the Digital Culture Leaders recognize that they could do better, our survey shows that these organizations are currently more effective than the rest at using data.

For instance, they have a greater capability to use data to predict product demand and adjust output accordingly, monitor and maintain supply chain quality control and address non-compliance issues. This might explain why these leaders expect to see more change across the manufacturing chain: they have a better sense of what data can do.

48% say “our inability to generate and use insights from our data puts us at a competitive disadvantage”





Q1. How effective is your company at utilizing data in the drug manufacturing process for the following purposes?
 Chart shows the results of the Digital Culture Leaders.

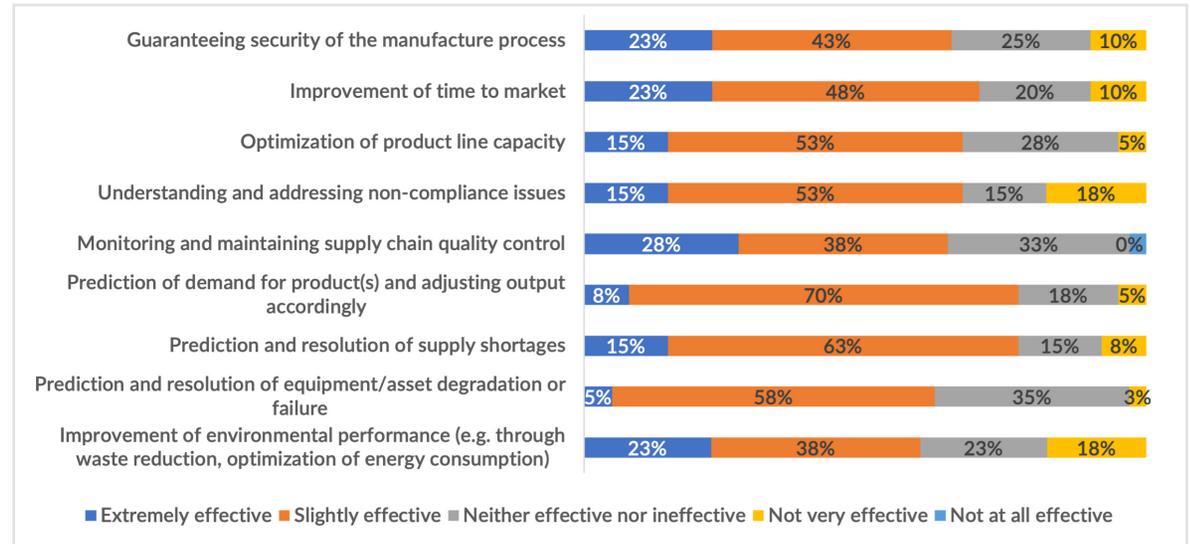


Figure 7. Leaders are tapping into the value of data

Q1. How effective is your company at utilizing data in the drug manufacturing process for the following purposes?
 Chart shows the results of the rest of the sample. Chart shows the results of the Digital Culture Leaders.

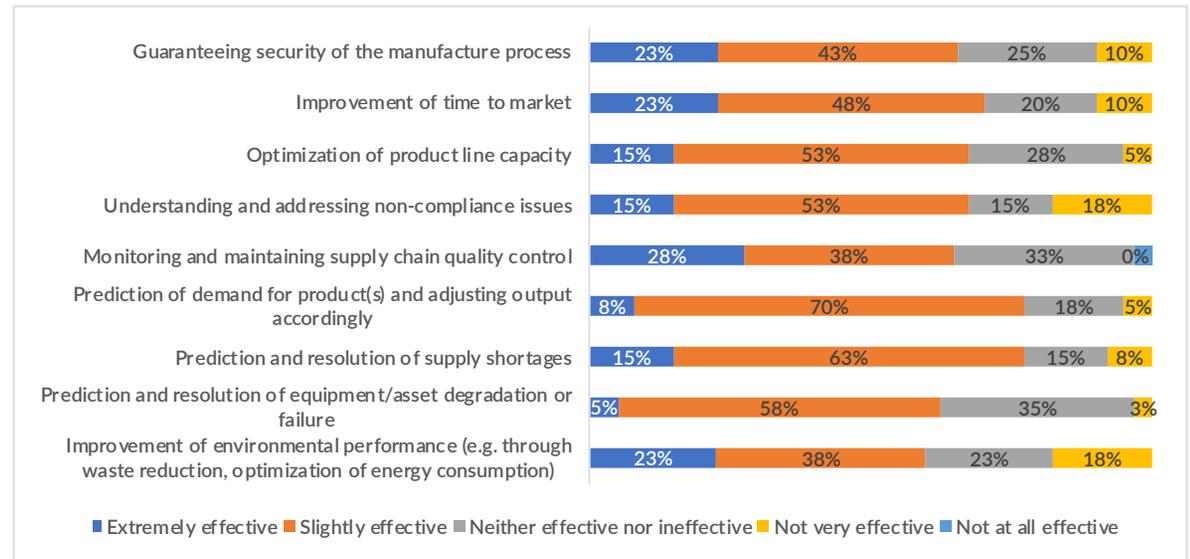


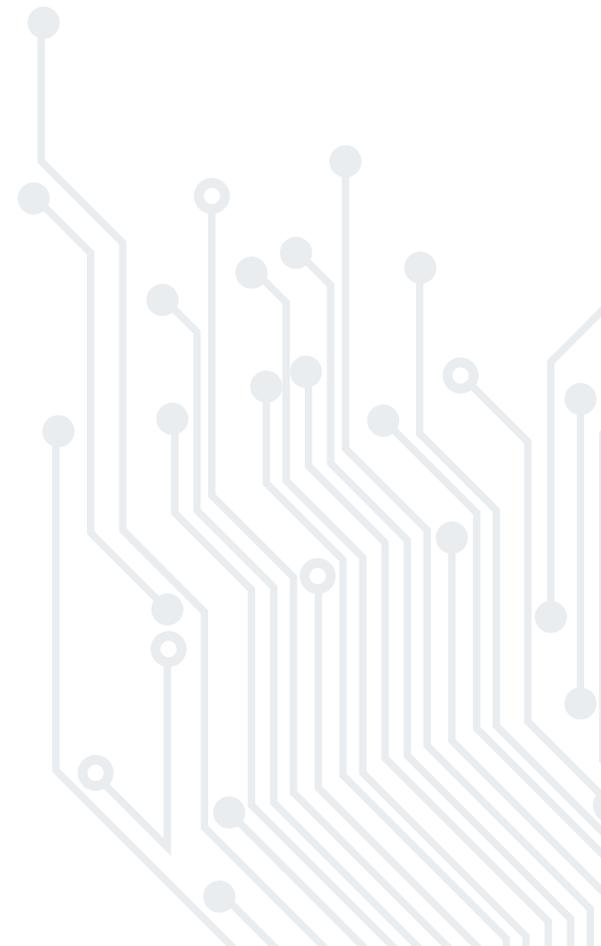
Figure 8. Most organizations are only at most slightly effective at using data

How to use data: Real-time quality assurance

There has long been discussion within the pharmaceutical industry about using data to improve the process of creating drug substances, the activity of bioreactors and other parts of a production line. Conducting analytics and quality assessments and making closed loop adjustments and improvements within defined guard rails - in real time - is an enticing prospect. But until recently, it has been very expensive to do in practice.

That is changing. Improvements in spectroscopy have made it affordable to produce actionable data on a batch mid-production. This data can be gathered without interfering with the reaction and is robust enough to inform decisions about what should change. This process opens the possibility of getting good data earlier: rather than manufacturing a product then testing it rigorously to assess its effectiveness, manufacturers would get data during the process.

“The next challenge is to build in this capability from the start,” says AspenTech’s David Leitham. “You might have to invest to install sensors and put in the software upfront, but long term it will prevent errors in production and create digital evidence, and that all helps to release the batch faster.” Leitham expects the use of solutions like this to increase in the coming years.





How to use data: Predictive maintenance

Traditionally, equipment maintenance has been scheduled at regular intervals, which means that production must be stopped, and delay is built into the system.

With predictive maintenance, manufacturers receive data from sensors about when individual components need attention, which means they can then replace or repair them promptly. This reduces unplanned downtime, delays and inefficiencies.

Companies with a strong digital culture are better at using data to predict and resolve this kind of equipment degradation or failure. In our survey, 63% of the Digital Culture Leaders say they are either effective or very effective at this, compared with 50% of the rest of the sample.

“One of the reasons predictive maintenance is so popular as a first foray into more advanced technology is because it is unlikely to need regulatory approval. Adopting it does not mean having to revalidate the whole line,” says AspenTech’s David Leitham. “After all, companies using it have not violated what they said to the regulator about how the line would run – they are just getting extra help from technology.”

And although the technology might be sophisticated, it does not need data science expertise to manage it – existing staff can be trained to do this.

How to use data: Supply chain network scheduling

Supply scheduling continues to be one of the biggest challenges for pharmaceuticals manufacturers. Making sure that you can get the products you need at the time you need it is a critical success factor.

But scheduling can be difficult when you are dealing with many suppliers, in many parts of the world, who are supplying a variety of different products in different ways to different locations. Manufacturers therefore need to be able to keep track of supply chains and inputs.

Some companies, however, still use rudimentary tools to try to juggle all the information. One contract manufacturing organization put in place a new scheduling solution just before the pandemic. “Before, they were using spreadsheets to keep track of what they expected to get, and when,” says AspenTech’s David Leitham. “But centrally, they did not know when the various labs or manufacturers would provide products.”

By switching to a single dedicated system, the organization was able to coordinate the variables more smoothly, and have visibility over what was arriving when, centrally, enabling easier and better decision-making. This was particularly important because the demands of the pandemic required the company to switch production temporarily.

“Demand for certain medications skyrocketed, while others dropped through the floor,” says Leitham. “By putting all the data into one system, when demand for their products shifted, they had an idea of what was going to be available to them, so they could make better decisions about how they were going to use their plant that day. They were able to see everything together.”

Leitham predicts that in the coming months and years, the Digital Culture Leaders will start using AI and ML for other purposes – to reduce unused factory and asset space, for instance. This would be vital, as a surprising proportion of the organizations we surveyed – 42% – say they are currently maintaining such space even though they might never need it.



AI is key to deriving value from data, so what is stopping its adoption?

Our survey shows that the Digital Culture Leaders are more likely to see the value of AI: 60% say that technologies such as AI can relieve pressure on their companies, allowing them to bring new drugs rapidly and securely to market, compared with 49% of the rest of organizations surveyed.

60% of Digital Culture Leaders say that “technologies such as AI can relieve pressure on our company, allowing us to bring new drugs rapidly and securely to market”





However, Digital Culture Leaders and the rest still face four significant challenges to adopting AI and ML.

1. Data silos and structures

For many companies, unlocking value from AI starts with breaking down data silos and implementing consistent data structures across the organization (see Figure 9). This is a big problem, because without access to data from different operations and the supply chain, manufacturers will not be able to predict product shortages or improve time to production and market.

2. Lack of an overarching strategy

At present, 55% of the Digital Culture Leaders and 48% of the rest say that investment in AI and ML in their company is driven at the function level or below and lacks an overarching strategy. Four in 10 of the leaders and the rest even recognize that this will hurt their company competitively, agreeing that manufacturers that do not learn the lessons of AI and ML adoption in other industries will face severe financial trouble within two years.

3. Lack of skills and leadership support

With their strong digital culture, the leaders in our study are much less likely to say they lack the skills or leadership support to use AI solution - only 10 and 13% say this respectively. But this is a major barrier for 3 in 10 of the rest of the sample.

4. A change-averse culture

For the Digital Culture Leaders there is a much a bigger challenge that they need to tackle first: their organization's approach to risk.



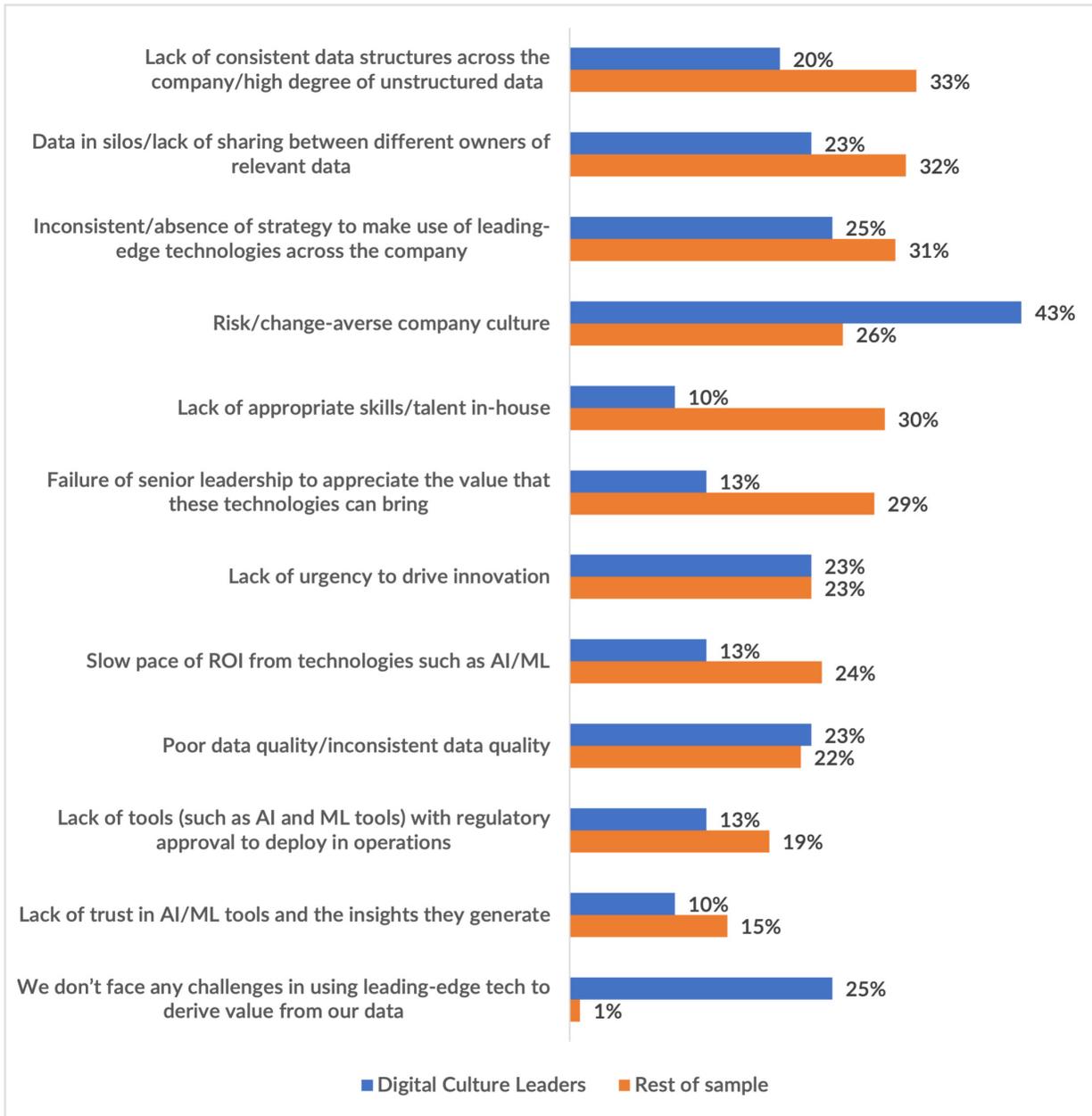
The risk-reward ratio often deters many pharmaceutical firms from adopting leading-edge technologies such as AI. If a suggested innovation might speed up production, but it introduces a small new risk of the company being cited by an auditor, not adopting it is the sensible and common approach. The penalty of a temporary shutdown is normally more threatening than the enticement of the efficiency gain.

However, this is often due to a lack of awareness about this technology and what it can do. “Introducing AI doesn’t necessarily mean you will have to change your existing validated processes. For instance, predictive maintenance can be deployed to supplement your committed processes around device maintenance and calibration,” says Leitham. “But not enough firms know that.” As a result, many perceive greater risk in adoption than there actually is.

“Introducing AI doesn’t necessarily mean you will have to change your existing validated processes. For instance, predictive maintenance can be deployed to supplement your committed processes around device maintenance and calibration. But not enough firms know that.”

- David Leitham, Senior Vice President and General Manager Pharma, AspenTech

Figure 9. Risk aversion is a major barrier to using AI for the Digital Culture Leaders



Q3. What are the biggest barriers your company is facing to using leading edge technologies such as artificial intelligence (AI) and machine learning (ML) to derive value from your data?



Four steps to adaptability, resilience and lasting success

“There is no shortage of smarter, better ways for pharma companies to use technology,” says Leitham. “Best of all, these solutions are available now, they are being adopted, and they are helping companies get ahead.”

So how can organizations make the most of these solutions, get value from their data, and drive their digital transformation strategies forward?

1. Reimagine your culture

The Digital Culture Leaders’ superior financial performance and ability to use data illustrates the importance of a strong digital culture. Promote digital literacy throughout the organization and empower everyone to be a decision-maker, and you will derive greater value from your data and existing technology solutions. It will also encourage confidence in your organization’s adoption of other emerging technologies.

2. Develop an overarching digital transformation strategy

A strategic approach to digital transformation is a must. With a transformation strategy, rather than ad hoc decisions, you can adopt technologies such as AI more consistently and use data more effectively. It will also allow you to think holistically about the value that data can add across all aspects of drug manufacture.

3. Get leadership support

Without leadership buy-in, you will struggle to create the right culture and develop a digital transformation strategy. If your leaders understand the value of data and emerging technologies not just for R&D but also for drug manufacture, they will be able to lead the company successfully in the aftermath of COVID-19’s supply chain and distribution disruption.

4. Collaborate with strategic vendors

You do not need years of expertise in innovation and implementation of AI or ML to adopt these technologies. With strategic vendors as partners, you can seek advice on the solutions that will enable you to analyze data and draw conclusions from it without having to learn any new technical skills. “I call that productization,” says Leitham. “Leading organizations tend to look for products that put the information together in such a way that it can be used by management as a whole.”

The disruption brought about in the supply of and demand for drugs has shown us that the ability to collect and use data about processes is the key to adaptability, and this in turn is the key to organizational resilience. Our Digital Culture Leaders offer a blueprint, and those organizations that emulate them in the coming years will thrive.





About Aspen Technology

Aspen Technology (AspenTech) is a global leader in asset optimization software. Its solutions address complex, industrial environments where it is critical to optimize the asset design, operation and maintenance lifecycle. AspenTech uniquely combines decades of process modeling expertise with artificial intelligence. Its purpose-built software platform automates knowledge work and builds sustainable competitive advantage by delivering high returns over the entire asset lifecycle. As a result, companies in capital-intensive industries can maximize uptime and push the limits of performance, running their assets safer, greener, longer and faster.

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