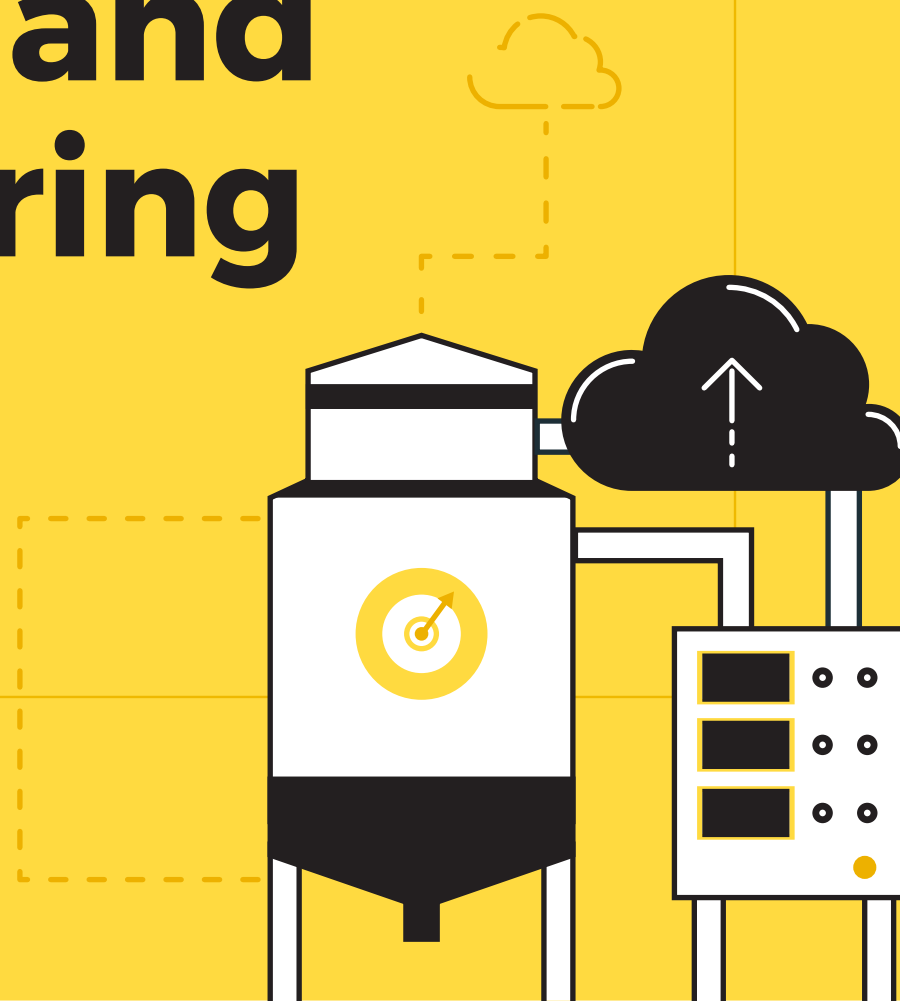


Tech imperatives for biotech and manufacturing

Navigate the future of industry with Action steps and Insights from Innovation Directors



01

What's ahead for biotech and manufacturing

Unexpected resilience and acceleration	3
Disruptive Forces	5
CEO's perspective background	6

04

4 Competitive Advantages

Connectivity and Automatization	18
Great User experience	19
Optimized time-to-market	20
Empowered people who harness data	21

02

4 Common Opportunities

Connected shop-floor	8
Modular & plug-n-play solutions	9
Flexible and scalable hardware and software solutions	10
Strong employee engagement into digital transformation implementation	11

05

Technology Speed 22

03

4 Challenges

Harnessing outdated infrastructure	13
Managing technological debt	14
Establishing business value from data	15
Ensuring security while implementing digital solutions	16

06

Facility of the Future - Digital Transformation Roadmap 23



The exponential growth of digitalization, automation, and AI are fuelling a new wave of **biotech and manufacturing** innovation. This will result in breakthrough products and technologies that fight diseases, improve our health, provide more sustainable food production and tackle global challenges like cleaning pollution.

However, on the journey to fulfill this vision, business leaders need **solid digital partners**. That's why engineers, IT architects, and developers have to become literate in biotech and manufacturing science in order to understand the fundamental shifts underway and seize the vast opportunities. And what's more - **biotechnologists need to build digital technologies awareness in their ecosystem**.

And as that solid partner, we decided to create research to explore and discover opportunities and challenges of biotech and manufacturing companies and their global Innovation Directors.

This report is intended to **explore the sectors' challenges and drivers related to digital transformation**. It also identifies different scenarios for stakeholders to **progress towards continuous bioprocessing**.



Klaudia Kożusznik

Head of Growth
Innovation & Research



Main **highlights** of our research



Digital solutions that support operations **accelerate biotech and biopharma growth**



Improved cybersecurity and data integrity are a must-have



Lab specialists want to **harness emerging technology in a lab** just as they harness it on their iPhones - **as easy as possible**



Biotech and biopharma companies are on the **lookout for modularity and scalability**



Digital transformation touches **organizational and cultural aspects** on top of implementation of new services



Life Science, and Biotech in specific, are the areas with exponential growth potential. Digital technologies play a critical role in the advancement of drug discovery, clinical trials and manufacturing.

From Digital Twins of proteins and cells to tools and platforms processing clinical data up to AI based control platforms for manufacturing plants of the future - digital is re-imagining the way Life Science is done today.



Łukasz Paciorkowski
CEO **A4BEE**

Disruptive Forces

Since the Covid-19 pandemic biotech and manufacturing sectors have moved further than they did in the previous 10 years.

When digital disruption and pandemic uncertainty has reached them, new drivers, issues, opportunities, and threats come to life.

Several forces described below have been pushing boundaries and are changing the way the future for those sectors will look like.

Level of intensity: the more vivid colour, the more adequate insight.



CEO's perspective background

In 2020, we conducted in-depth interviews with biotech CEOs to discuss digital transformation in the industry.

At that time, their four main concerns were around competitiveness, people, economic challenges and cybersecurity. One year later, we established a new research project to cover the challenges of Innovation Directors. We feel obliged to bring previous findings so the audience can grasp a clear picture of the situation.

CEOs' Concerns

Result of Biotech CEO Concerns Research Study 2020



Competitiveness

Create new business models
because of disruptive technologies

Developing innovative products
and cultures are a key focus

Competition intensifies



People

Widespread commitment
to cultivating leaders for the future

The #1 priority:
attracting and retaining top talent



Economy

Recession fears reach top of the list

Widespread concern over trade uncertainty

53% of industrial manufacturing CEOs predicted slower growth

CEOs of transportation and logistics, and automotive
predicted slower growth with 61% and 62% respectively

Cybersecurity

Climate change heats up

Common Opportunities

Among main objectives, **biotech & manufacturing executives point at:**



Connected
shop-floor



Plug-n-play & modular
solutions



Flexible and scalable
hardware & software
solutions



Strong employee engagement
into digital transformation
implementation

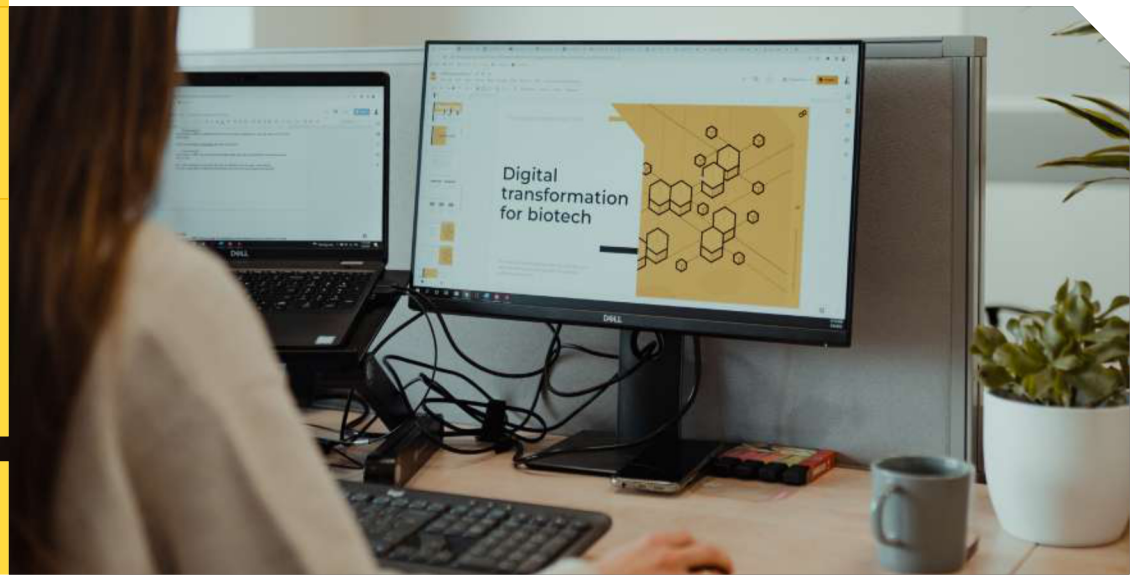
The digital revolution in manufacturing and biotech begins with a synergy of computing power, data analytics, and connectivity approach.

Right now the main objective for those industries is to create facilities of the future powered by modular, scalable and digital solutions.



Biomanufacturing companies such as Amgen, GlaxoSmithKline (GSK), Sanofi Aventis and others, are also working in collaboration with a number of suppliers including Siemens and Emerson to design smart facilities and “paperless plants.” The new “factories of the future” possess instant dashboards and access to all data on the shop floor.

Source: Bioprocess Optimization & Digital Bio-manufacturing: Global Markets





Connected shop-floor

Many manufacturers have already jumped into digital transformation initiatives but... the progression toward Industry 4.0 or 5.0 is slow. They didn't fix the basis by conducting a full connection of the shop floor, sending useful data across the enterprise. **Embracing the new wave of industrial presence is about converging the data from the shop floor with the data from the top floor.**

After that, companies with connected data can build on a layer of AI on top and share insights across the organization.



Because at the end of the day manufacturing starts on the shop floor.

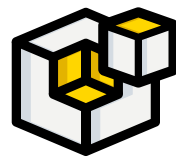
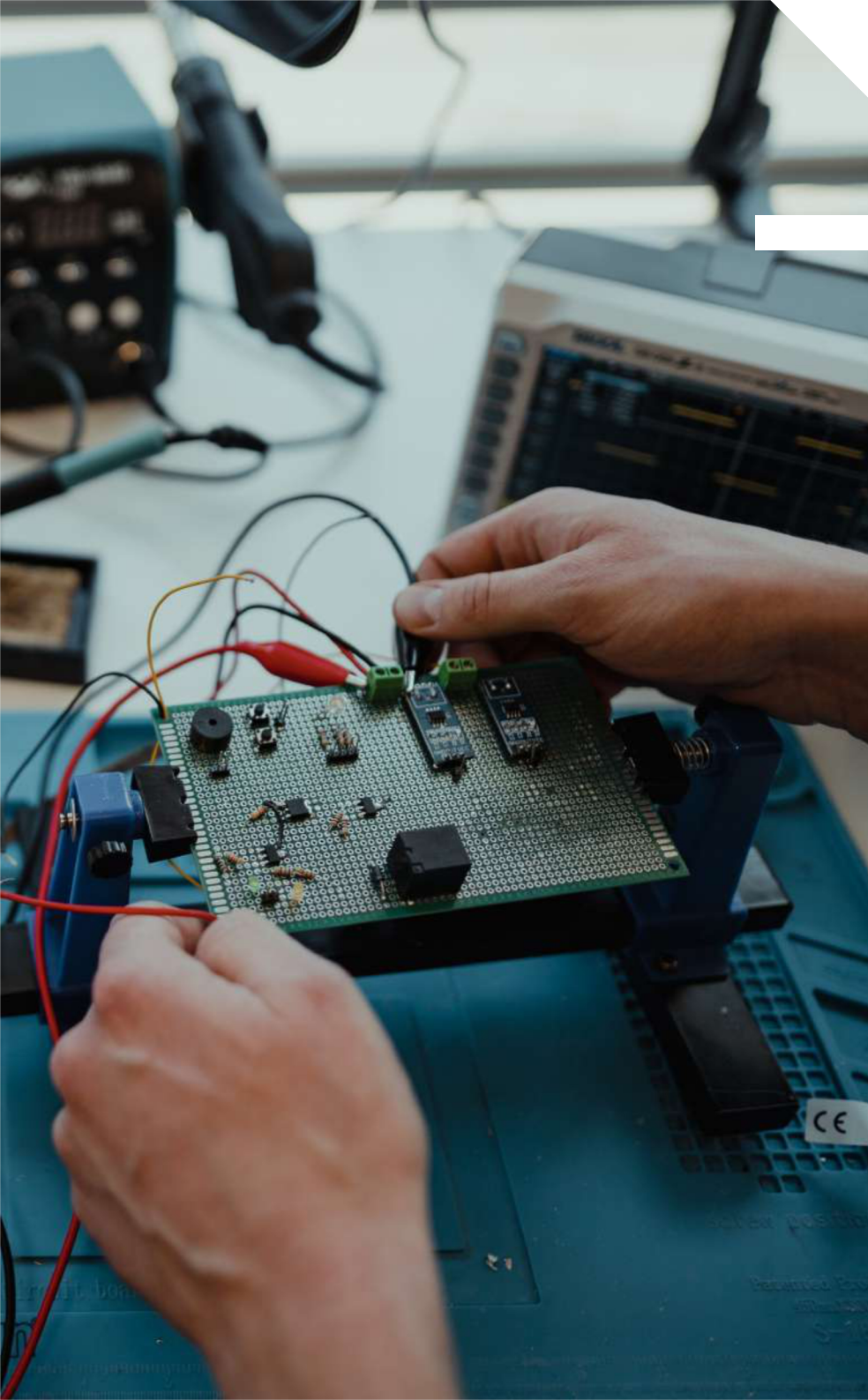


Connected shop-floor - where all systems and devices are connected, and the operator sees everything - is crucial. **When anything goes wrong - we can react immediately.**



dr Łukasz Osuszek
Digital Transformation Manager



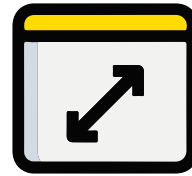


Modular & plug-n-play solutions

Modular hardware and software solutions have to be easy to configure, implement and scale thanks to open standards.

Those solutions can **let laboratory employees make fully automated facilities, respond fast to capacity demands, and deliver products swiftly.**





Flexible and scalable hardware & software solutions

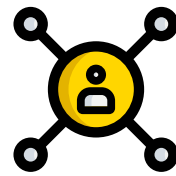
Deciding on the scale of a new facility is a difficult decision and setting up fixed infrastructure won't create scaling opportunities.

That's why production lines should be created in a way that allows reconfiguration with relatively little time, cost and effort to implement and scale new products and methods.

The need for more efficient processes to produce breakthrough therapies is high as never before.

Even more - the **long-awaited shift to personalized medicines and gene therapies will require the production of small batches and flexible solutions.**





Strong employee engagement into Digital Transformation implementation

Many companies struggle to attract and retain employees with biotech experience and entrepreneurial mindset.

It creates a situation where new technologies or innovation are not welcome in an organization. The new role for the technology partners is to carry out the adaptation process across companies.

As a result of well-conducted adaptation, **digital transformation enables collaboration among employees and improves access to data & intelligence across the organization.**



The crucial thing is to build digital awareness and transform the company culture that allows us to think differently about technology. Thanks to this approach employees at various levels will be able to harness technology.



Tomasz Staszelis
Chief Digital Officer



4 Challenges

Tremendous growth of biotech and manufacturing companies goes hand in hand with **new challenges**.

The main of them occur **among process productivity with the goal to make processes faster and more cost-effective, meet GMP** (good manufacturing practices) and **security compliances, shorten time-to-market, and improve quality**. Others come from the fact that the highly regulated nature of the biopharmaceutical industry has delayed the adoption of new technologies.

Thanks to our responders we extract **4 main challenges**:

Challenge	Business Drivers			
Harnessing outdated infrastructure	Global demand	Emerging markets growth	New products classes for biotech	Cost reduction and processes improvement
Managing manufacturing Technological debt from industry 2.0 and 3.0	Supply chain complexity	Pace of tech development		
Establishing business value from data	Global demand	Cost reduction and processes improvement	Pace of tech development	Scaling flexibility
Ensuring security while implementing digital solutions	Pace of tech development	Scaling flexibility	The need for resilience and dealing with uncertainty	

1

How to harness outdated infrastructure



Challenge

With the high demand for new drugs there is a parallel call to improve production speed, maintain the quality, and... lower the prices. This pressure makes biotech companies keep production efficiency using the sometimes outdated infrastructure.



Expectations

Biotech and manufacturing sector is on the lookout for new connectivity software and hardware that enables them to:



Connect old equipment with modular and vendor-agnostic components like additional probes, sensors, transmitters.



Automatically gather and process data from a few bioreactors.



Empower continuous bioprocessing at upstream and downstream stages to cause cost- effectiveness, reduced timeline, and save lab space.



2

How to **manage** manufacturing **technological debt** from **Industry 2.0 and 3.0**



Challenge

As many companies have already developed roadmaps for digital transformation and some have already started to adopt these digital technologies, some are still clinging to spreadsheets and paper, accumulating manufacturing technology debt that will have to be paid soon.



Expectations

The manufacturing markets are trying to come out of the shackles of traditional set-ups. To win this battle they need to focus on:



Go paperless.

Optimize operations to increase production capacities, flexibility and reduce time to market.

Increase efficiency, **decrease** number of errors, and **improve** productivity.

3

How to **ensure** security while implementing digital solutions



Challenge

In order for biotech companies to harvest the benefits of digital transformation, they need to enforce industrial cyber security. However, data security and privacy are often viewed as significant issues, driven by insufficient internal protections and external regulatory data-protection restrictions. Implementing new digital solutions in this industry involves a careful understanding of its regulatory nature and the biomanufacturing process parameters.



Expectations

While ensuring safety during implementation digital solutions companies expect to:

- ÿ **Acquire** implementation partners that combine an understanding of digital technologies, security, and biotech processes.
- ÿ **Harness** the cloud-based solutions to improve the availability and the quality of data while meeting security and regulatory requirements.
- ÿ **Reduce** security gaps in IoT solutions.

4

How to **establish business value from data**

Challenge

Right now, only a fraction of data from connected devices in laboratories or factories is gathered, processed, and analyzed in real-time due to the limits of technology structures.

We must also bring up the matter of laboratory employees' work efficiency - they spend significant time manually gathering, exploring data, and establishing a correlation among them.



Nowadays, many companies harness data only to analyse the past, but the real **value of data is to predict the future.**



Expectations



Małgorzata Stokrocka

R&D; BD; Quality Director



Biotech companies anticipate harnessing data related to in-process measurements, materials usage, equipment maintenance, or employee records to empower their business and especially to:

- **Combine data stores with “in-real-time” technology and architecture** to enable organizations to develop data platforms and digital twins
- **Harness data to make processes more efficient,** more predictable, and faster.
- Drive innovation thanks to the **advanced analytics and AI-driven capabilities** and the discovery of new relationships in the data.
- Let laboratory specialists **focus more on collaboration, communication, and performance improvement.**
- **Reduce time and costs** of delivery processes.

Main Competitive Advantages

Our interviews with executives suggest that **if the biotech and manufacturing sectors want to maintain their recent strong growth and gain the competitive advantage they will need to address four directions:**



Connectivity



User Experience



Time-to-market



**Empower people
to harness data**



03

04

4 Competitive Advantages

05

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17



Connectivity & Automation

Connected sensors, wearable devices, and monitoring applications. Many companies are already leveraging connectivity.

The next step is to **embody industrial automation thanks to cloud solutions.** **The synergy between smart OT, IT, and lab devices with automation leads to a high level of efficiency, allowing technology to do repetitive tasks for us.**

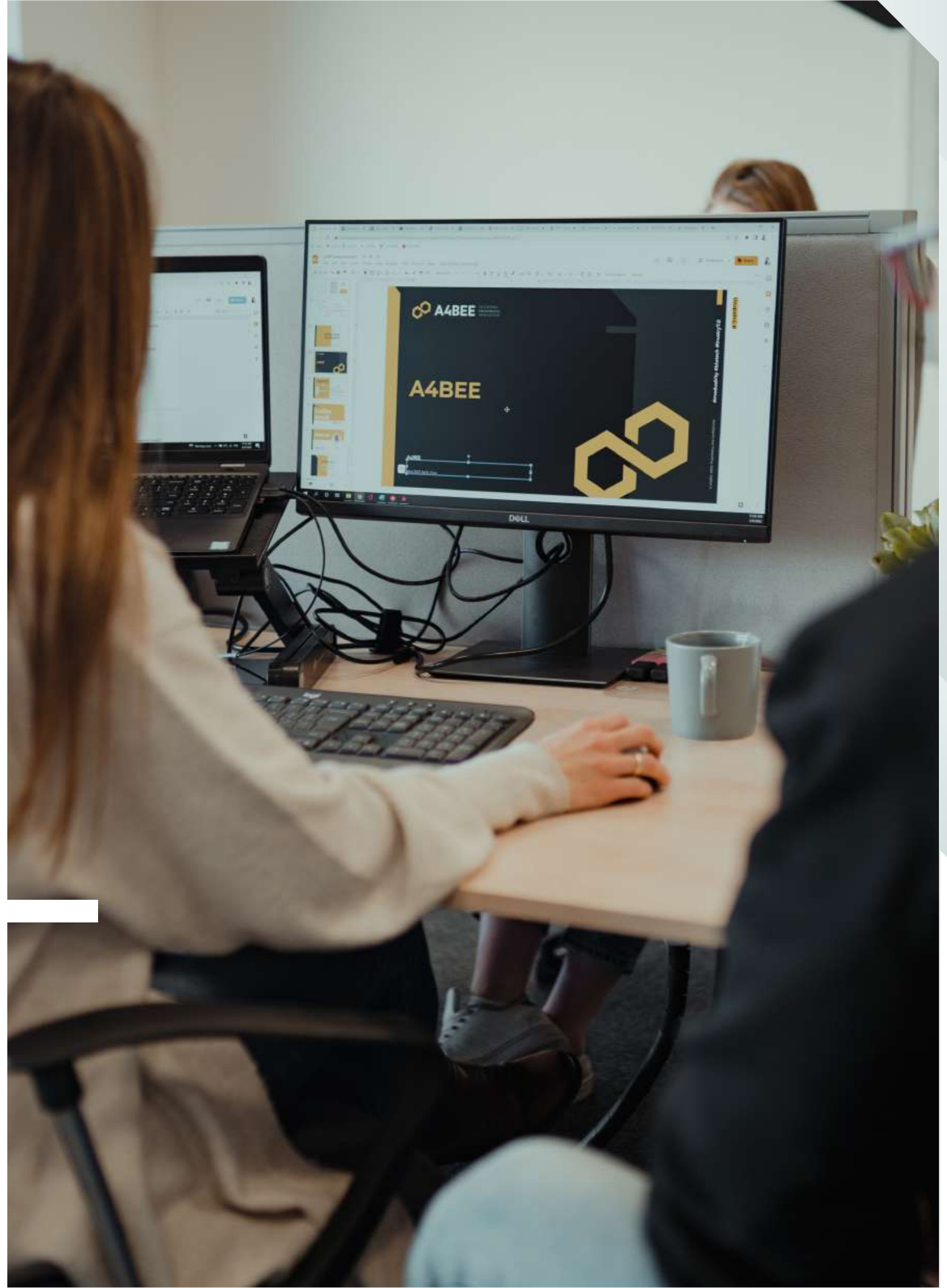




Great User Experience

When using OT, IT, and lab devices' software, you can get the impression that they are technology-center, not user-center made. A lot of companies understand that **bad UX and UI can cause confusion, human errors, and decrease work efficiency.**

A high-quality user experience supported with data visualization is crucial. It lets human users who work with control systems and machines to **make data visuals more comprehensive, reduce cognitive load, and make better-informed decisions.**



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4 Competitive Advantages

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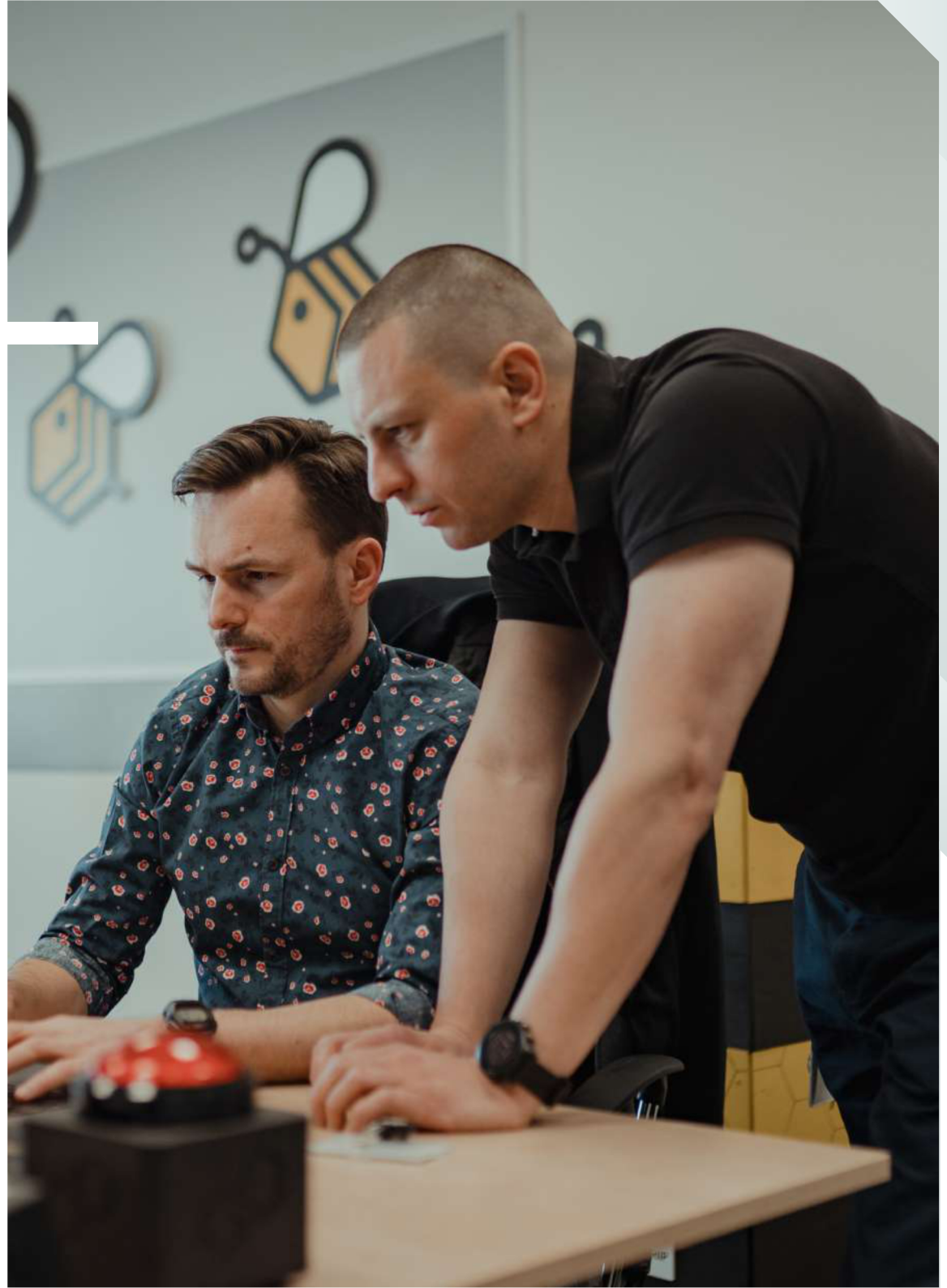


Optimized time-to-market

Improving commercial and development execution is a crowning achievement for executives. Of course, the highly regulated markets can't tolerate the quick release of products that compromise on quality or safety.

However, a lot of companies have already developed tactics to move towards and keep it in mind. Some of them improve the pace and quality of drug research by using **small batches thanks to modular hardware with single-use technology.** Others invest in systems connectivity and integrate all areas of production. 

At the top of that, to increase time to market speed companies benefit from **scalable cloud platforms** that allow them to **add not only new functions or capabilities but also enable collaboration** between external distributed teams if needed.



03

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4 Competitive Advantages

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Empowered people who harness data

The unpleasant truth is that there is much more ready to use data than talent. The winners in the disruptive digital battle will be the companies who will have the ability to **expand internal or external talent pools.**

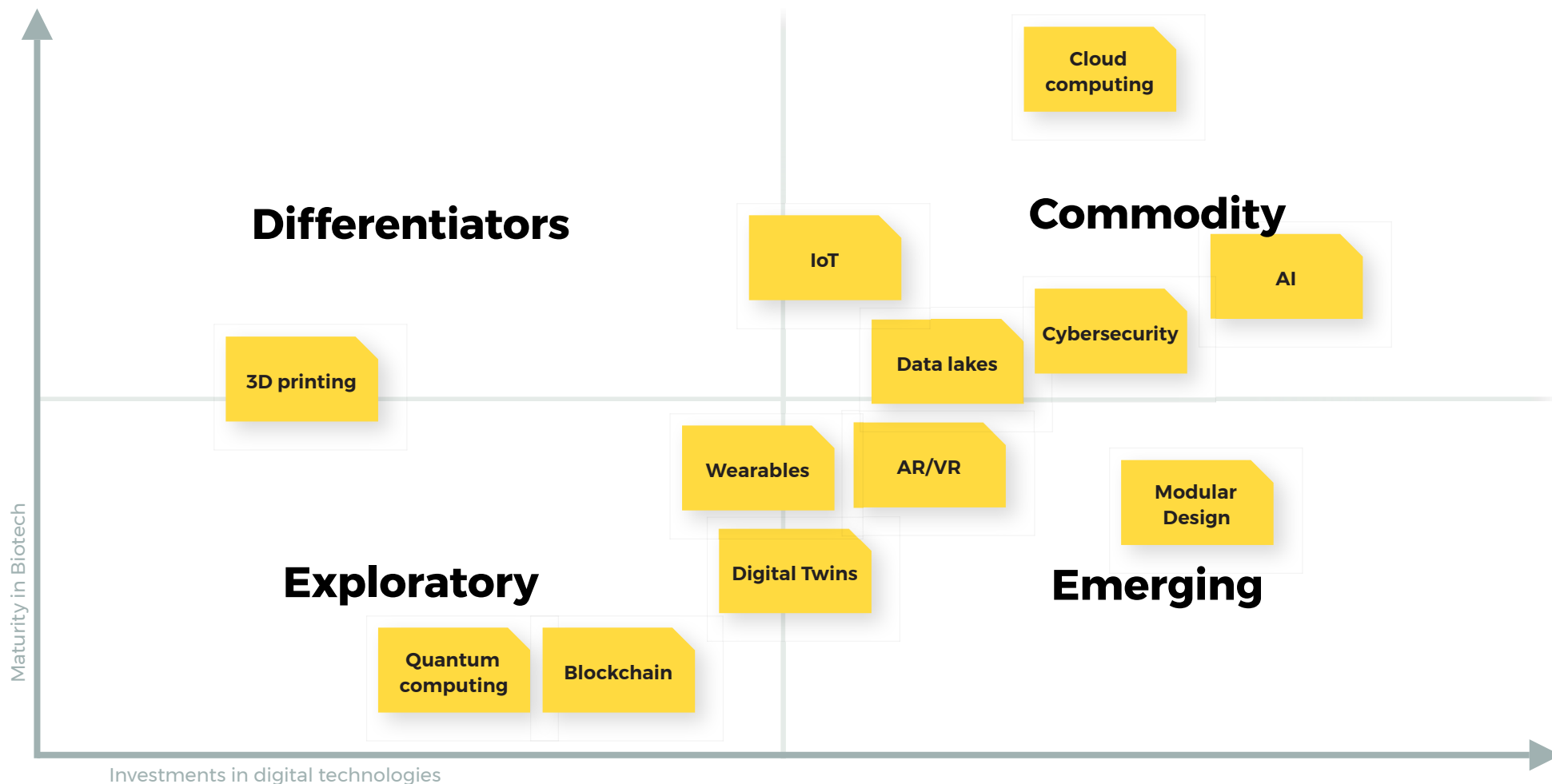
To take full advantage of the data, companies have to face a critical question: **„How to enable people with analytical skills to work with data?“** They will have to **empower employees with data and analytical skills** or find trusted external partners who won't only be able to deliver meaningful innovation but also work closely with in-house teams.



Technology Speed

Certain digital technologies like Cloud, AI, Data Lakes, 3D printing, and AR/VR solutions are widely adopted and implemented in biotech and manufacturing operations.

They make improvements in plant operations, quality control, and supply management as well. Those new technologies will define the sector's pioneers. We've already seen many companies embody at least some of them, with many more beginning the journey to do so.

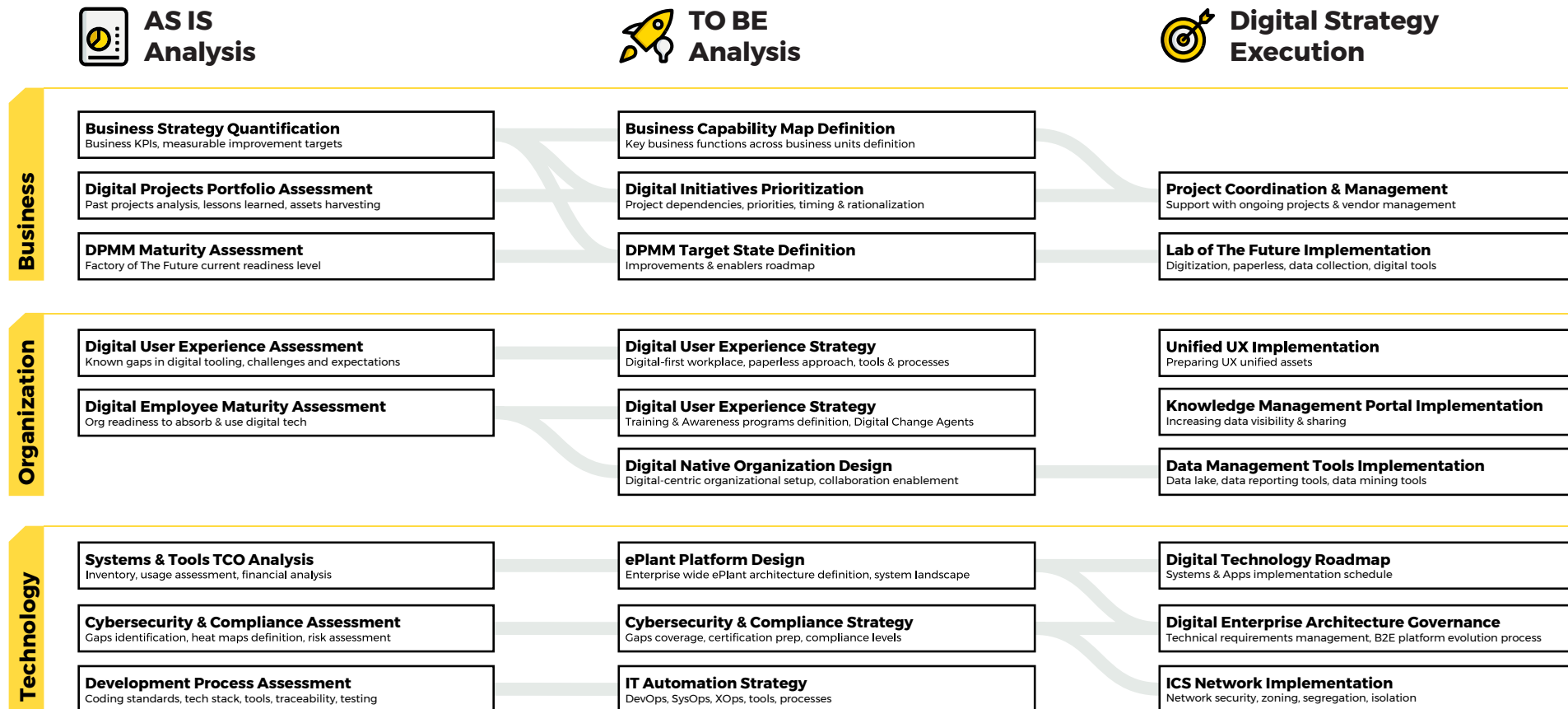


Next Steps

Digital Transformation Roadmap for the Facility of the Future

We believe that digital transformation is not a sprint nor a marathon. It's an interdisciplinary triathlon. Companies need to keep a keen eye on the business, organization, and technological development to shape the future of the facilities.

The 3 phases approach will ensure sustainable implementation and harnessing of digital transformation. To answer challenges and opportunities listed on previous pages, biotech and manufacturing companies should consider the roadmap below as a starting point to explore their way toward the facility of the future.





Conclusion

The digital transformation in manufacturing began with merging manufacturing engineering with digital technology. The integration of monitoring, analytics, and new computational capabilities, as well as artificial intelligence, robotics, and automation, is changing the way the evolution of manufacturing processes takes place.

The concept of digital transformation in manufacturing is not new to industries such as automotive, aerospace and defense, and consumer goods, but for the pharmaceutical industry, digital manufacturing is starting.

A key challenge for the manufacturing and even more for biotech industry is the broad regulatory landscape in which it operates.

The need for rigorous compliance and validation, strict technical record keeping, product tracking, and supply chain connectivity are all issues that are lagging the adoption of digitization in those sectors.

The pandemic challenged convictions about how to reach digital transformation goals. Telemedicine went from its pre-pandemic infancy, to mainstream in a matter of weeks.

Enterprises have been pushed by the pandemic to understand the opportunities that technology can offer them.

This trend has been particularly visible in manufacturing companies, as the advantages of automation to limit the number of people working in close proximity while decreasing the number of people needed to create a product are huge. The need to solve manufacturing problems spurred companies to start or make further progress in the digital transformation process.

Digital technologies were key to the success of the rapid development and launch of COVID-19 vaccines, facilitating collaboration between companies, even across national borders.

Digital transformation comes with some caveats, such as the need to ensure that attention to quality, monitoring, and management does not falter with virtualization.

The most important one: we've learned how to become more antifragile. We've learned how to deal with uncertainty. Change, challenges, risk - have become a matter of course rather than excuses.

Authors



**Karolina
Marzantowicz**

Technology & biotech
expertise advisor
**Chief of Growth,
Board Member**



**Klaudia
Kożusznik**

Report author
Head of Growth



**Iwona
Ignąć**

Research & analytics
Research Lab Leader

Methodology

The research brought together innovation directors from global companies who shared their perspectives on the current state of their industry.

- Method:** In-depth interview supported by analyses of third-party research
- Participants:** Directors / Heads of Innovation in international biotech and manufacturing companies

hello@a4bee.com
www.a4bee.com



USA
A4BEE New York
244 Fifth Avenue, Suite 2646,
New York, NY 10001

EUROPE
A4BEE HQ in Wrocław
Muchoborska 8
54-424 Wrocław

A4BEE Warsaw
Żurawia 45
00-680 Warsaw

**A4BEE is a technology company
deeply committed to support
biotech, pharma, and manufacturing sectors.**

We work closely with global players to shape winning strategies, implement new digital solutions and harness the power of connectivity, flexibility, and modularity. We support them at every stage of their digital transformation journey while solving real-world problems.



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