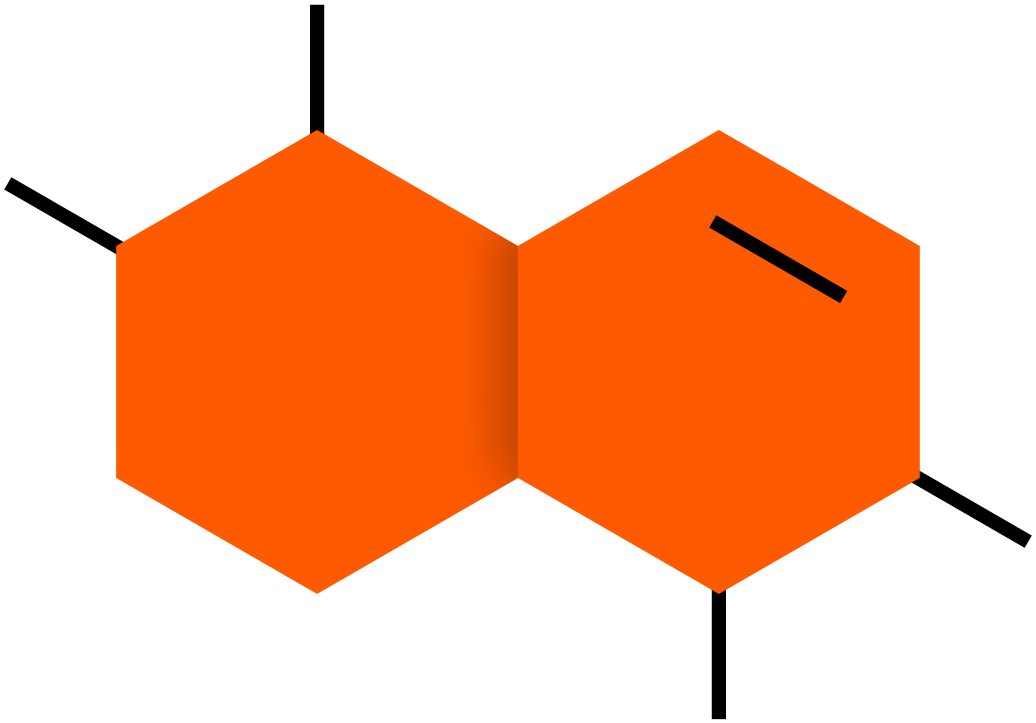
Technical Partner | Natural Innovations Lab

Pharma industry

Technological strategies for building resilience and category security



Billennium

IT for people. People for IT.

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Introduction

The pharmaceutical industry: the current business context

While some will remember the COVID-19 pandemic as a time filled with lockdowns, difficulties, and limitations, for others, it was a period of intensive development and addressing previously unknown challenges. The second group is certainly headed by specialists from the pharmaceutical industry. The sector faced the accelerated pace of work on new vaccines and treatment systems, as well as increased political and social pressure to renounce intellectual property rights due to the pandemic.

Suddenly, the rights that used to stay in the background became a public and eagerly discussed topic of strategic importance for the good of humankind. The situation became even more complex when this issue was combined with the lively discussion around the "loss of exclusivity" with the expiration of patents for many drugs developed in the 1980s and 1990s. It is estimated that over a few years, only a handful of the top 20 pharmaceutical products will face no alternatives on the market, which indicates an increase in competitiveness and price drop.

As Piotr Waszkiewicz emphasizes:

Piotr Waszkiewicz
Chief Financial Officer

> *Many large pharmaceutical companies that have patents for the so-called "blockbuster drugs" expiring soon buy smaller biotechnology companies that already have interesting preparations at an advanced stage of clinical trials in order to maintain steady growth. Note that on average, it takes about a decade and $2.6 billion to develop a drug and release it to the market. Only one in eight potential drugs passes through all stages of clinical trials and obtains approval from authorities such as the FDA.*
> *Large organizations are looking for interesting investment opportunities mainly in areas such as:*
>
> - *broadly understood oncology, e.g., the use of mRNA also in personalized cancer treatments,*
> - *cardiovascular diseases,*
> - *neurodegenerative diseases.*

How will this affect the future of the pharmaceutical industry? This report attempts to answer this question.

The pharmaceutical industry is currently under pressure from the media and politicians around the world. The former eagerly use the drug and vaccine cases as surrogate topics for other news reports. The situation is not made easier by companies from the so-called "big tech" sector joining the race and increasing competitiveness and digital maturity.

In these circumstances, pharmaceutical companies are forced to look for new sources of income. To maintain the current turnover, they increase efficiency to maintain margins or expand into new areas of growth, such as personalized medicine, prevention, or digital health.

Maintaining current margins, in particular, might be a challenge impossible to overcome for at least several reasons. The most important of them is the estimated increase in the volume of people covered by global healthcare systems - according to the OECD, this number will increase from the current 5.5 billion to 6.8 billion in 2030.

This will result in a reduction in per capita expenditure on healthcare (including drugs) and a decline in the projected stable share of drug expenditure in global healthcare budgets (at around 17%).

That is why it is necessary for pharmaceutical organizations to adapt to changes and follow the rapid development of the technology landscape.

Areas of technological change in the pharmaceutical industry

The changes taking place in the pharmaceutical sector impact the entire value chain - from the development of new drugs to their commercialization.

1 **In the area of drug development, the main directions of changes concern:**

- improving the daily work of scientists,
- technology support in the process of scientific work.

2 **In the area of clinical trials, the changes are expected to impact:**

- improvements in the recruitment of patients for research,
- embedding the research environment in the virtual world,
- collecting data from the real world (Real World Data).

3 **In the area of production and distribution, the key changes occur around:**

- supply chain optimization,
- control and safety of the production and logistics process,
- creating new opportunities thanks to cloud computing and IoT solutions,
- precision medicine influencing production processes.

4 **In the area of drug commercialization, the changes focus on:**

- creating a new business model called "pay for performance,"
- servitization and building experience in the field of medication intake,
- development of e-commerce,
- development of veterinary pharmacy,
- development of tools for building relationships with doctors and sales representatives.

Drug development

1.1 Improving the daily work of scientists

1.2 Support for technology in the process of scientific work

1. Drug development

Discovering new drugs is a time-consuming process characterized by high-risk - only around 1/3 of all pre-clinical projects enter the clinical trial stage. Due to the current pandemic situation, organizations are looking to accelerate and facilitate the work of scientific and research teams, both in the substantive field (for example, searching for appropriate pharmaceutical substances with the desired therapeutic effect) and their daily work.

→ **1/3** of all pre-clinical projects enter the clinical trial stage

1.1 Improving the daily work of scientists

The progressive digitization of the pharmaceutical sector is the result of its adaptation to global trends. The possibility of transferring the workplace to a virtual environment and using new technological solutions mainly concerns project management and cooperation between research centers. Currently, pharmaceutical organizations use universal and easily available technical solutions for these purposes.

At this point, it is worth realizing that the use of Artificial Intelligence methods in various areas may not only significantly increase the organization's competitive advantage but also reduce the number of errors in the automation of selected activities.

Better standardization and acceleration of processes come together with new opportunities for analyzing large data sets and a much broader perspective offered by Big Data. This creates a completely new perspective and undiscovered potential resulting in a visible increase of the conducted and planned research.

Unfortunately, many interesting research projects are not transferred to the production stage because their creators lack the appropriate skills to migrate theoretical solutions to production. In this context, a completely new branch called MLOps deserves attention.

Jan Czuma
Big Data Engineer
& Competence Center Manager

> *The latest achievements in the field of AI allow us to spot diseases on specialized medical images and help in the early detection of faults in devices that are critical for supporting the patient's life, among others. Even though the field of AI has a long history, it is undergoing very dynamic development only now. As a result, a lot of research projects are created, and while sometimes they bring very interesting results, they are often not transferred to the production stage. That is because the people responsible for discovering new AI methods and using them do not have the skills to transfer the solution to production. MLOps comes to the rescue here. Specialists in this field take care of good practices, automation, scaling the solution, and security in the first stages. Thanks to this, the company can enjoy real benefits from its research activities.*

At the moment, most of the leading pharmaceutical organizations use the following technical solutions:

- **collaboration tools** supporting joint safe workplace and knowledge sharing. Mundane things such as remote desktops with strong security features and the ability to manage access to individual data enable efficient collaboration between teams working remotely or in a distributed manner.
- **project management tools,**
- **tools for tracking and estimating working time,**
- **videoconferencing tools,**
- **cloud solutions,** which are appreciated due to their cost-effectiveness. Organizations can set them up and use them in line with their changing needs - and troubleshoot problems faster. The cloud makes data available from any place and device. Teams can also create and recover backups to effectively prevent delays in data transfer.
- **remote access to machines and test results,**
  priceless especially due to the pandemic-induced limitations in the number of people working in one laboratory at the same time.

- **access to data from other institutions:**
  - Creation of Data Lake / Data Mesh for easy access to data generated currently and previously,
  - Intelligent Search that allows searching for data within the organization,
- **ELN** - Electronic Laboratory Notebook, adapted to the scientific field and form of research with the option to share results within the organization.

New solutions bring new challenges. The most important of them are the following:

- **security of remote tools** - especially in the processes of developing new and innovative solutions,
- **stability of connections during collaborative work,**
- **training employees** for a more variable and dynamic work model,
- **smooth workflow** at the intersection of digital work tools and the real world,
- **maintaining the involvement of employees** working remotely and controlling working time.

1.2 Support for technology in the process of scientific work

A key area of interest for pharmaceutical companies is data management at the research and development stage. **The drug discovery and development process require not only high efficiency and third-party data sharing solutions** but also predictive and diagnostic analyzes. To this end, organizations take advantage of technologies such as neural networks, Knowledge Graphs, evolutionary algorithms, genetic programming, and VR successfully.

The use of technologically advanced solutions in the process of scientific work meets the specific needs of the pharmaceutical industry. The most popular solutions in this area are:

- **in terms of access to data:**
  - data anonymization in accordance with legal requirements. Unfortunately, most countries lack sufficient legal regulations in this area. Many of the current solutions operate in the shadow economy, and their activities are not entirely clear,
  - availability of data from state laboratories and hospitals. Currently, there are no systems that enable access to data, even for non-profit organizations or state research
- **the use of artificial intelligence and deep learning** for analyzing medical data from multiple sources (laboratories, universities and research institutes, clinical trials, etc.),
- **using deep learning and neural networks to:**
  - predict the molecular properties of chemical compounds and their behavior in the candidate drug (such as absorption, metabolism, etc.);
  - automating tedious and difficult tasks such as distinguishing diseased from healthy cells, pattern recognition, and image segmentation;
  - designing non-existent chemical compounds thanks to the possibility of determining which chemicals will be used in the drug;
  - 3D protein modeling;
- **using algorithms** programmed via genetic programming to generate new ideas for molecules that could be used in treatment,

- **inclusion and anonymization of data from previous clinical trials**, which allows reducing the failure rate of new formulas already at the pre-clinical stage of development,

- **data visualization** used to create the so-called Knowledge Graphs, i.e., graphs that manipulate data and arrange them into a graphical and contextual representation to define, consolidate, and order dependencies and process complexity (e.g., knowledge about chemical compounds in the context of a disease and its variants),

- **creating specialized tools using virtual reality (VR) and augmented reality (AR)** for visualization and teamwork (e.g., for atomic, molecular, and protein visualization),

The most important challenges in this area:

- safe integration with the pharmaceutical company's data ecosystem and external databases,

- combining the needs of all stakeholders in collaborative processes.

Clinical trials

2.1 Improvements in recruiting patients for research

2.2 Embedding the research environment in the virtual world

2.3 Collecting data from the real world

2. Clinical trials

The last months have clearly shown that clinical trials are a key stagein determining:

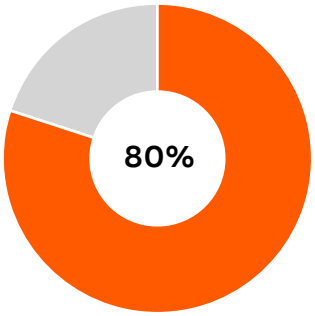
- **drug safety**
  stage I of a clinical trial is carried out on a group of 20 to 100 healthy volunteers; the average duration is 19 months),

- **drug efficiency vs. placebo**
  stage II, reached by 70% of drugs, involves 100-500 sick participants and lasts about 2.5 years on average),

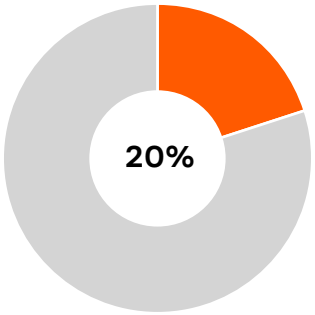
- **dosing and determining the therapy length and nature**
  stage III involving 1000-5000 patients across many locations and lasting approximately 2.5 years on average

Invariably, the greatest challenge is finding and recruiting participants for the study on time - especially in the context of pandemic events. Unfortunately, without enough volunteers, clinical studies have lower statistical power and thus insufficient credibility.

Today, nearly 80% of clinical trials are not completed within the allotted time frame, and 20% of them are delayed by six months or more. The average dropout rate among participants from continuing clinical trials is around 30%.



→ **80%** of clinical trials are not completed within the allotted time frame



→ **20%** of them are delayed by six months or more

2.1 Improvements in recruiting patients for research

Patient recruitment is a key determinant of success in clinical trials. Failure to find participants on time decreases the reliability of the research study and leads to a significant financial loss. The losses are a direct result of slowing down the regulatory approval process and delayed marketing of goods.

It is not surprising that the pharmaceutical industry is intensely looking for solutions to improve the recruitment of patients for research. To better explore both domestic and foreign markets, they use the NLP (Natural Language Processing) technology more and more effectively.

Technological requirements and solutions in the area of patient recruitment for research include:

- **identification of influencer researchers**
  working with influential doctors who can recruit eligible patients for a given study is one of the most effective ways to solve the problem of low recruitment. Data science and natural language processing help to find influencers working in a given field of science (publications, collaborations, workplaces, etc.) to facilitate the recruitment of enough patients for a clinical trial.

- **recruiting doctors from a specific area for research**
  social chart analysis combined with natural language processing (NLP) helps pharmaceutical organizations quickly see which doctors are already working as researchers and who can be invited to participate in the study.

- **identification of eligible patients**
  finding suitable patients for research is much easier with the use of machine learning-based software. Scanning electronic medical records (EHRs) and unstructured physician notes speeds up the search for desired phenotypes.

The most important challenges related to the recruitment of research groups are certainly:

- **integration of systems and databases** at the state and EU level,

- **digitization of archival medical documents**, including medical records.

2.2 Embedding the research environment in the virtual world

The decentralization and replacement of traditional clinical trials with remote trials, all the while maintaining continuous patient control, may have a significant impact on the acceleration and success of clinical trials. This form enables organizations to increase the quality and effectiveness of clinical trials, increasing their scale and scope -which is crucial in the context of recruitment. One should not forget about reducing the patient's burden, increasing the involvement and satisfaction of the parties participating in it, and improving the course of clinical trials.

Among the technological needs and solutions related to embedding the research environment in the virtual world, one can find the following:

- **wearables** that is, sensors designed to be swallowed and phone applications that allow faster data collection and decision making. Wearables enable monitoring and control of the health of patients, including those participating in clinical trials, as well as ongoing supervision of such indicators as heart rate, glucose level, movement disorders, concussions, and other medical events.

- **communication solutions**, which allow replacing control hospital visits during the examination through contact with a doctor through audio-video solutions, with the possibility of logging in and contact history.

- **tools for automating the preparation of medical documentation** e.g., voice assistants creating a transcript from a doctor's appointment.

- **automatic language translation tools** enabling direct speech translation from one language to text in another language.

- **cloud solutions** supporting listening and monitoring of networks and social media for feedback during clinical trials.

- **elements increasing the attractiveness of clinical trials** e.g., the use of gamification.

- **tools for collecting feedback from patients** e.g., building a community around the study, keeping journals.

- **tools for analyzing electronic patient records** the analysis of current and past diseases, medications taken, clinical procedures, and treatments builds the foundation for a better understanding of the disease, its causes, symptoms, and consequences.

In turn, the most important challenges related to transferring research to the virtual world include:

- **remote service for patients who prefer traditional contact with doctors,** without access to the internet, etc.,
- **the need to base the solutions used in the field of contact and patient monitoring on the best UX and CX practices** for people/patients with disabilities or the elderly,
- **awareness of the risk of overstimulating the patient** with useless data and/or unwanted messages and reminders,
- **ensuring compliance with emerging and evolving health data security standards.**

2.3 Collecting data from the real world

Real data from registers or electronic medical documentation create the so-called RWE, i.e., real-world evidence. They can supplement data from clinical trials and form a basis for summarizing the effectiveness of therapy in real clinical practice. Thanks to RWE, the pharmaceutical industry can:

- **reduce the cost of research** and validate data from clinical trials in the eyes of sponsors, stakeholders, and recipients,
- **identify people who meet the boundary conditions** for a clinical trial from previously unavailable population groups,
- **monitor the safety** of marketed drugs.

Among the technological needs and solutions in the area of real-world data collection, we can distinguish the following:

- **collecting data from various industries** (e.g., in the field of prevention, diagnostics, healthy lifestyle, etc.) and **various sources** (e.g., social media, data on payment for services, electronic patient data),
- **Use of tools to monitor and collect patient data**, such as digital pills, tracking devices worn by study participants, and sensors and applications designed to provide real-time information.

- **patient engagement**, e.g., through elements of gamification,
- **solutions that create structured datasets** from real-world unstructured data (RWD) to more easily transform them into real-world evidence (RWE).

And what are the most important challenges related to RWE?

- **identification of data** required for tracking and processing,
- **access to medical data and images** in a highly regulated medical environment,
- **ethical and reputation issues** related to patient data management and the accompanying lack of transparency of processes and accountability.

Production and distribution

3.1 Supply chain optimization

3.2 Control and security of the production and logistics process

3.3 Creating new opportunities thanks to cloud and IoT solutions

3.4 Precision medicine influencing production processes

3. Production and distribution

The pharmaceutical sector is constantly under pressure for profitability. This pressure is reflected in the particular focus on operating costs.

Among other things, this focus manifests itself in cutting costs related to infrastructure and the number of employees at the production stage in logistics processes. Progressive robotization, digitization, automation, and more effective management of the work of teams allow reducing financial outlays. But at the same time, organizations also need more precise and industry-specific processes that digitize the supply chain.

3.1 Supply chain optimization

The maturity of technology related to supply chain planning (the so-called SCP) is certainly one of the greatest challenges facing the pharmaceutical industry.

Many pharmaceutical companies have implemented solutions that are limited in scope and do not represent industry best practices. Meanwhile, it is necessary to **create solutions that take into account the needs of all stakeholders in the supply chain**: from recipients, contractors, and purchasing departments, through production, distribution, sales representatives to end customers, i.e., direct recipients.

Technological needs and solutions for the optimization of the supply chain are mainly:

- **solutions supporting placing orders** for end customers / recipients and integrating data in production plants in real time,
- **"multienterprise" solutions**
  because pharmaceutical organizations use many companies as the so-called CMO (Contract Manufacturing Organization) at various levels of the supply chain, they need solutions that allow for planning activities and data exchange taking into account all stakeholders,

- **inventory planning and optimization** inventory levels that are three to five times higher than in other industries are actually standard in most pharmaceutical organizations. This raises the need for tools for advanced inventory and planning to optimize inventory levels and reduce working capital,

- **tools for advanced production planning** modeling the process of its sequencing and optimization within numerous constraints and interdependencies,

- **product durability planning** different requirements as to the shelf life when crossing the border of a given country create the need to visualize and create a production plan taking into account the shelf life,

- he need to create systems for **storing and updating marketing materials for many markets**, including packaging graphics or content on labels, for which archiving is necessary for legal reasons,

- **searching for solutions to plan an increase in demand**, with elements of probability estimation on a global scale due to current tenders,

- **investing in modeling tools in the context of strategic planning** (including those related to regulations) due to the complex legal context and production processes, the pharmaceutical industry requires a lot of time to expand its production plants. This calls for a detailed strategic plan for the next 10-15 years, and modeling facilitates strategic decision-making.

The most important challenges related to the optimization of the supply chain are:

- **the complex nature of planning** that makes it difficult to identify functionality and priorities when investing in planning solutions,

- **the need to integrate with the entire ecosystem** of a pharmaceutical company, taking into account all players in the production and supply chain,

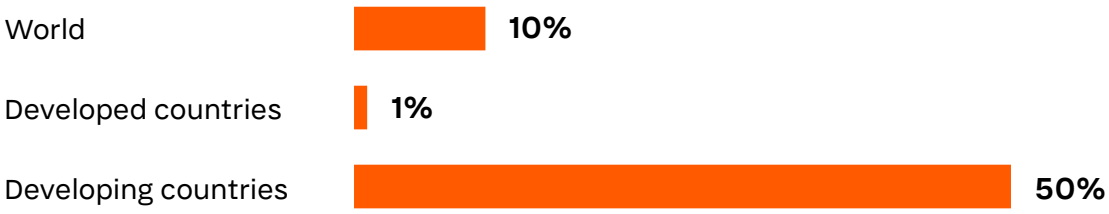
- skillful management of **large amounts of data** and integration with external systems,

- constant **training for staff** on new electronic systems.

3.2 Control and security of the production and logistics process

According to WHO estimates, about 10% of drugs in the world circulation are falsified or counterfeit drugs. In developed countries, this share is about 1% and it is hardly noticeable, but in some developing countries, counterfeit drugs make up 50% of all pharmaceutical products sold online.

Number of falsified or counterfeit medicines



Therefore, quality management has become a pressing need of the pharmaceutical industry. This is especially important due to regulatory and reputational factors. Almost 80% of countries in the world have already introduced mandatory serialization of vaccines and prescription drugs (the EU implemented the Directive on combating drug counterfeiting in February 2019).

Technological needs related to the control and safety of the production and logistics process require a series of specialized solutions, such as:

- **serialization management**
  serialization of vaccines and prescription drugs focuses on obtaining unique serial numbers, assigning them to each batch produced, printing the serial number on the product label in the form of a barcode, and then managing the data to track the product by its serial number.

- **protection against counterfeiting**
  achieved, for example, by combining innovative physical markings on the packaging with a tracking system in logistics based on blockchain technology,

- **enabling easy verification of originality by the end-user**
  (doctor, nurse, patient) and at the level of national distributors, regulators, etc.,

- **improvement of logistics,**
  i.e., Track & Trace, especially in the field of monitoring specific products and meeting delivery dates,

- **quality guarantee based on blockchain**
  i.e., combining the collection of data on the composition and compliance of the production cycle with the declared one and monitoring of production from a single component to the final delivered product,

- **cold-chain logistics**
  consisting in ensuring the appropriate temperature of the product throughout the transport cycle and optimal conditions for its storage, guaranteeing the safety of use.

The most important challenges facing the control and safety zone of the production process are:

- **operational integration of serialization and track & trace** into an already complex production and logistics chain,

- **storage and security of serial data,**

- **increase in operating costs,**

- **high cost of blockchain technology.**

3.3 Creating new opportunities thanks to cloud and IoT solutions

The fact that we live in a time of digital transformation has had a direct and indirect impact on virtually all spheres of our life and business. On a daily basis - consciously or not - we use devices that fit into the IoT concept. The Internet of Things, developed more and more often as "Intelligence of Things," is already helping doctors and patients. Over time, it will certainly have a massive impact on the pharmaceutical industry.

IoT capabilities have influenced the traditional production and distribution chain to the extent that pharmaceutical companies are forced to improve and modernize conventional processes. The implementation of new technologies in pharmaceutical companies means, inter alia, better quality control as cloud solutions favor better aggregation of data from multiple sources and facilitate decision-making. This is how they create more flexible production and distribution models.

Maciej Skuratowski
Azure Architect

> *Remember that data from IoT devices is irrelevant without proper analysis. But thanks to this data and modern cloud solutions, we can forecast when a given device may experience a failure or detect anomalies, among many other examples. Personally, I hope that IoT solutions and intelligent cloud increasingly support us in the process of creating products or services that are friendly to people and our planet.*

The technological needs and measures applied in the field of cloud and IoT solutions include:

- **methods to improve production efficiency and utilize plant downtime** real-time exchange of information enables pharmaceutical manufacturers to ensure that drugs are produced when patients need them most. It also allows organizations to optimize the production cycle to order,
- **real-time monitoring and visualization of critical variables on the production line** (such as temperature or pressure),
- **predictive analysis in production and warehouse plants** real-time data collected with IoT sensors can be used to correlate the effects of many variables, including temperature and drug ingredients, along with predicting production trends with statistical precision,
- **use of AR on production lines** thanks to advanced technology, technicians and line operators can increase productivity by suggesting tasks, sequences, proportions, and settings in real time,
- **cloud solutions** that allow for the aggregation of large amounts of data and improve decision-making processes.

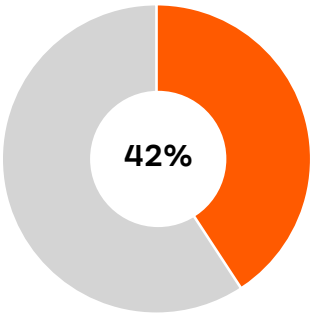
As in every area, the use of cloud solutions and IoT presents challenges.
The biggest ones are:

- **standardization of standards** throughout the production line and across different plants,

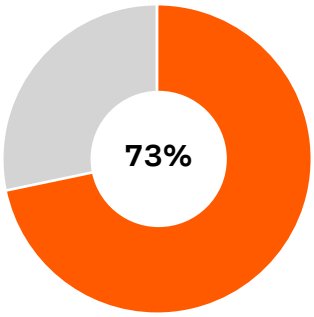
- **complexity of solutions** resulting from various needs of products manufactured in the plant,
- **compliance requirement** - for regulatory reasons, not all data can be stored in the cloud (for example, serial numbers),
- **ensuring the highest quality and security of cloud services.**

3.4 Precision medicine influencing production processes

Precision medicine is a new approach to the treatment and prevention of disease that takes into account the individual variability of each person's genes, environment, and lifestyle. We understand more and more how the human body reacts to drugs, which, together with advanced manufacturing methods such as additive manufacturing, makes personalized medicine a reality. It is estimated that 42% of all drugs included in the current plans of pharmaceutical companies are personalized drugs (in oncology, it is about 73%).



→ **42%** of all drugs are personalized drugs



→ **about 73%** of drugs in oncology are personalized drugs

Technological needs and solutions in the field of precision medicine include:

- **natural language processing (NLP)**
  NLP processing plays a key role in the development of precision medicine. This technology allows pharmaceutical companies to isolate phenotypic factors from electronic health records and to identify variants of the disease,

- **solutions for dynamic production management** (e.g., preparation of small batches for precision medicine), as well as thanks to single-use technology (reduction of downtime, increased efficiency, elimination of complex works such as cleaning and validation between production stages),

- **3D printer software for drug formulation and the creation of personalized tablets** good examples are, for example, polypills (multi-drug tablets), personalized dosage forms or sustained release of a drug,

- **cooperation of pharmaceutical companies with food producers**
  such cooperation enables the creation of nutrigenomic food, i.e. food adjusted to the needs and health condition of a particular patient.

The most important challenges related to precision medicine include:

- **collecting data** on specific needs and the growing dynamics and complexity of production processes, as well as cost-intensive production in small batches.

Drug commercialization

4.1 New "pay for performance" business model

4.2 Servitization and building experience in the field of drug intake

4.3 Development of e-commerce

4.4 Development of veterinary pharmacy

4.5 Development of tools for building relationships with doctors and sales representatives

4. Drug commercialization

Due to the growing awareness of patients about the costs of treatment, greater budgetary pressure from payers, and the increasingly important prophylaxis, there is **a paradigm shift in healthcare**. Until now, the main emphasis was located in the therapy itself. Now, the emphasis has shifted to its effects.

This, in turn, generates the need for new business models, such as performance-based contracting and payments, and the creation of ecosystems that support patients and doctors.

Organizations are also constantly looking for additional sources of income and expanding services.

4.1 New "pay for performance" business model

For the past few years, we have witnessed the rise of the Pay-For-Performance model, which is gaining importance with the increasing pressure of payers' budgets - in the EU of countries and patients, and insurance companies in the USA.

As part of such cooperation, the price for a drug is correlated with its individual effectiveness and the resulting economic benefits, e.g., lowering the price of further treatment.

Of course, the Pay-For-Performance model brings technological needs and solutions such as:

- **the growing need to collect and analyze real-world data** (RWD) to validate the effects of medication,
- **Being aware of the cost and complexity of tracking patient outcomes** for pay-for-performance contracts, the costs of tracking individual patients' health outcomes may often outweigh the benefits of this solution. This, in turn, means that the number of such forms of cooperation is still relatively small (for example, in the USA), but it will certainly gain in importance along with the increasingly cheaper technology.

The most important challenges related to the new business model are:

- **monitoring results and collecting data in real time,**
- **increase in operating costs for pharmaceutical companies.**

4.2 Servitization and building experience in the field of drug intake

Some changes in the pharmaceutical industry are driven by consumer practices. The growing awareness of patients who want to understand their treatment better and participate in it more actively paved the way for the development of the "around the pill" strategy.

This concept aims to transform the drug experience and improve it by offering additional services. Rather than just developing and selling drugs, pharmaceutical companies now focus on delivering digital devices and health applications to improve the customer experience. The idea of providing a complete medical package is also partly dictated by the need to look for new sources of income.

Technological needs and solutions in this area:

- **patient involvement in research related to service design,**
- **adjusting UX and CX to difficult audiences**, such as children, people with disabilities, etc.,
- **establishing contact with third parties** cooperation with technology suppliers, startups, incubators, public health centers, and fitness clubs dealing with healthy nutrition is very helpful,
- **creating and implementing solutions to support the patient** and encourage them to regularly adhere to the prescribed therapy/drug regime.
  Patient education, drug delivery, monitoring and counseling, physiotherapy, nutritional advice, mentoring, and health management consultancy are very important here,
- **solutions collecting feedback from patients covered by the therapy.**

The most important challenges in the area of servitization and building experience in the field of drug intake are:

- **designing services and products** with a good understanding of the real needs and habits of patients,
- **federalization** - the need to fit into the existing healthcare ecosystem (also, from the perspective of usability, solutions for doctors from various companies),
- **achieving the required return on investment**, i.e., demonstrating the value of additional services,
- **the proliferation of legal and regulatory obligations** is also related to the service ecosystem, not just the drugs themselves.

4.3 Development of e-commerce

The market for selling drugs over the internet is constantly growing, and online drug purchases are becoming safer. In this context, legal changes enabling the mail-order sale of prescription drugs seem inevitable. In Poland, the shipment of prescription drugs - currently only possible in the case of a patient's disability - seems to be the missing link in the creation of a fully remote treatment process.

Its creation is justified because patients appreciate online medical consultations and efficient e-prescription systems more and more.
Proper identification of both the person ordering and receiving the ordered products is only a matter of using the right IT solutions.

However, the role of the pharmacist remains a contentious issue in the entire virtual purchasing process.

Wojciech Spoz
Natural Innovations Lab
Technology Management Consultant

> *Currently, when the vast majority of drugs sold are ready-made ones, the role of the pharmacist is most often limited to administering the drug from the shelf, reminding the patient about the dosage, and processing payments.*

> *Sometimes, the pharmacist helps to find substitutes for drugs. A well-designed online service could provide all of that. Interactive, tailored to the needs of specific patient information about drugs, chat, voice, or video conversation with a pharmacist would be perfect here. The introduction of the sale of drugs over the internet does not have to mean that pharmacists will no longer be needed in these processes. Thanks to this, their support may be more available also after the transaction is completed because patients may still have doubts and questions at the time of payment.*

The development of e-commerce in the pharmaceutical industry is also followed by technological needs and solutions in this area:

- **e-commerce platforms for pharmacies**

- **specialized e-commerce stores** dealing with a specific healthcare area, offering additional services, such as medical and specialist consultations. This will be necessary, especially in areas where discretion is important, such as sexual health, mental health, male hair loss, or contraception,

- **systems for confirming the patient's identity** (e-ID, trusted profile, patient card) and their medical condition,

- **the possibility of filling the prescription completely via the internet** in Poland, such a solution is currently possible through medical teleconsultations, combined with the delivery of a prescription drug to the indicated address (the clinic mediates in the purchase of a prescription after prior patient identification),

- **the role of a professional pharmacist in patient education** Since online shopping lacks the knowledge and opportunities for patients to ask questions about the dosage, order of taking medications, or the best substitutes, it is desirable for e-pharmacies to offer easy access to a pharmacist and the possibility of consultations preventing self-treatment.

- **solutions allowing recipients to check the authenticity of the serial number and developing other ways to authenticate the authenticity of the drug** it is necessary to further improve and modify Track & Trace solutions to make them readable for the end customer (e.g., code allowing the consumer to see live video from the production line of a given drug or archival from the production of a given batch).

The most important challenges related to the development of e-commerce revolve around:

- **selling products directly to end customers,** which means cooperation of pharmaceutical companies with marketplaces such as Amazon or AliExpress,
- **increasing price competition and easy price comparison,**
- **monitoring the production and logistics process** to check the conditions of storage and transport of drugs (e.g., temperature).

4.4 Development of veterinary pharmacy

The development of the pharmaceutical market for animals (veterinary pharmaceuticals and feed additives) has in the past been dictated by the breeding of production animals and an increase in the demand for meat. Currently, the key factor of development is the growing number of pets around the world. The increasing awareness of pet owners and greater detection of diseases in animals shape the requirements and expectations of the pharmaceutical market.

As pet ownership transformed, technological needs and solutions in the field of veterinary pharmacy development now include:

- **wearables for pets and farm animals** monitoring and analyzing health data at the stage of therapy and clinical trials,
- **hardware and software for administering drugs to animals** (e.g., an insulin collar),
- **solutions from veterinary clinics for patients and pet owners** following human counterparts, a patient card, an archive of test results and diagnoses, communication with a doctor via chat, online consultations with a veterinarian, or reminders about visits and vaccinations work well in the case of animals,
- **solutions for veterinary clinics building a relationship with a pharmaceutical company** knowledge bases, webinars, veterinary consultations, reminders, and information on drug administration allows building loyalty between the pharmaceutical company and the veterinary clinic,
- **solutions for sales representatives to build relationships with veterinary clinics.**

4.5 Development of tools for building relationships with doctors and sales representatives

Looking globally at the direction of change, progressing digitization, and cloud solutions, it becomes clear that pharmaceutical companies need solutions that improve the work of sales and marketing departments and allow sales representatives to build relationships with doctors, nurses, pharmacy owners, and pharmacists.

The key technological needs and solutions in this area are:

- **CRM customer management solutions** combined with a planner, appointment schedule, VoIP, and other digital technology solutions that enable pharmaceutical representatives to organize communication with doctors better,
- **the ability to track sales of various pharmaceutical products** and enable easy contact, access, and input of data while working in the field (e.g., using mobile applications),
- **drug ordering systems for hospitals and pharmacies,**
- **platforms for building relationships between sales representatives and doctors/owners/pharmacy managers,**
- **multi-channel marketing automation systems.**

In turn, the most important and greatest challenges are:

- **a multitude of systems used by recipients**, e.g., hospitals, pharmacies, clinics, veterinary clinics,
- **connecting these systems to the entire production and logistics chain.**

Strategic priorities of the pharmaceutical industry

It's clear that the healthcare and pharmaceutical industries face many different challenges. The ongoing Covid-19 pandemic makes things even more difficult, as focusing on fighting the Sars-Cov-2 virus could cost us millions of underdiagnosed and untreated patients.

Hospitals, clinics, and pharmaceutical companies should be prepared for the unprecedented demand for pharmaceutical and medical solutions in the coming years. Such a situation will prioritize the conscious "players" focused on the effectiveness of their solutions and the operational excellence of internal processes ensured by the use of advanced technologies.

The most pressing topics that largely herald the transformation of the entire industry's backend are the improvement of drug quality and safety, the flexibility of production and distribution processes, and the transition of pharmaceutical production towards industry 4.0.

Digitization is also a keyword in connection with the end-users (doctors, pharmacists, patients). Patient data management to improve drug effectiveness, entering the area of services provided to both the medical sector and end patients, increasing the effectiveness of clinical trials - these are the key issues that make up the ecosystem undergoing a profound transformation. Tools such as natural language processing (NLP), AI, and cloud-based solutions are powerful weapons in this area.

The Covid-19 pandemic is still here, and the scenarios it creates are extremely dynamic and difficult to predict. We need to remember that new, equally dangerous variants of the virus are constantly appearing, and scientists predict the high probability of further pandemics. That is why profound changes in the pharmaceutical industry seem inevitable, especially given that they affect entire business models.

Development method:

This report is based on qualitative studies with participation of pharmaceutical industry representatives. Expert interviews were complemented by an analysis of found materials and data.

Bibliography

2021 global life sciences outlook, Deloitte 2021

Digital transformation for life sciences, Avenga 2021

Digitization, automation, and online testing: Embracing smart quality control, McKinsey 2021

10 Must-Have Supply Chain Planning Capabilities for Pharmaceutical Companies, Gartner 2021

The Pharmaceutical Industry in Figures, EFPIA 2020

Biopharma leaders prioritize R&D, technological transformation, and global market presence, Deloitte 2020

Driving the future of health, PwC 2019

Life sciences 2025 - managing disruptions to gain competitive advantage, EY 2017

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