Digital Transformation in the Pharmaceutical Industry

5 KEY STUDIES from

- R&D, Manufacturing,
- Analytical Laboratory Tests,
- Quality Control, Change Management

Combine their employees and processes with digital innovation

Pharmaceutical companies are confronted with the evolving expectations of partners, doctors and patients, the need to increase profitability and meet the requirements for quality and safety of manufactured drugs. Success depends on how pharmaceutical companies, through the development and production of effective ingredients and drugs, can support patients' healthy lifestyles. How effective are the revenue growth methodologies used by companies. How to manage a complex business structure and ensure that the company as a whole and its employees act in accordance with rules and regulations on health, safety and environmental requirements.

The solution of these issues is possible by aligning the main strategies of the company in research and development of medical products, generation of clinical evidence, production, marketing, sales, talent management and many others, united in a common corporate strategy. All of these strategies must meet the highest standards of quality and safety, such as **Good Laboratory Practice (GLP)** regulations and **Good Manufacturing Practice (GMP)** regulations, among others.

Below are the main approaches and five key research-based solutions that formed the basis of the Bever Pharm software for digital conversion in pharmaceutical and biotechnological organizations.

*Bever Pharma Software is built on **Microsoft® Dynamics 365** and **Power platforms**, complemented with cloud computing in **Azure**.*

Pharmaceutical Market Challenges

Slower market growth. A QuintilesIMS report demonstrates a market growth drop to single digits, between 6% and 9%, through 2021, in the US, down from a 12% growth in 2015.

Changes and Trends at the top of the chain: patient and people. Population, income, education level, disease patterns or lifestyle change – the whole outlook for an organization or science sector can be affected.

Data Handling, Interpretation and consent. An Econsultancy healthcare marketing report highlighted that the majority of healthcare organisations are unprepared to deal with emerging data sources or to collect high volumes of data. The report shows that 44% of large organisations are not prepared to use their CRM data in marketing campaigns.
www.orientation.agency

Best-in-class companies map stakeholders by constantly taking information from their medical, sales, marketing, and access teams and sharing it across the organization. Develop a strategy for patient access.

Create a single and easy-to-manage digital model of standard operating procedures (SOP)

Automate the delivery of SOP documents to the employee's desktop using optimized routers and

Companies are expanding the model of work with SOPs through the flexible management of SOP documents, including the creation, updating and publication in the organization’s internal network based on configured templates and setting access rules for collaboration between employees.

Process

Using SOP Management System on Dynamics 365 and Power Platform as their SOP records system, pharmaceutical companies promptly provide employees with the necessary instructions to perform the actions necessary at a given time and in a specific situation. A SOP portal allows employee's to quick and easy access to necessary documents and and in time to carry out the prescribed actions to solve any problems that arise.

Using data visualization tools and analytical reporting, managers analyze data on the results of the execution of SOP instructions and, if necessary, make decisions on updating these instructions.

Results

- Created a seamless, automated user's experience in configuring, creating, classification and maintaining SOP documents
- Gained greater visibility into actions, rules, instructions patterns
- Delivered step-by-step operations for understanding the need to perform an actions

Knowledge Management

Easily create SOP documents using various templates, flexibly categorize them in a single consolidated database.

Recognition and Delivery

Get a deeper understanding and step-by-step actions to carry out ongoing work based on the automatic determination of the SOP document and delivering it to your workplace

Data Analysis

Identify and analyze trends data and receive reports based on a wide range of intelligent tools for visualization, monitoring and reporting of data

Maximizing R&D efficiency with insights

Provide your team with more opportunities to accelerate the discovery of new treatments and successfully enter the market

Companies extends their Promoting unhindered cooperation model among members of creative groups scattered across remote research centers and laboratories will allow them to combine different ideas and exchange opinions. This will accelerate the workflows of innovation, clinical development and production, and therefore the fulfillment of our promises to patients. Effective collaboration is a key factor in increasing productivity and accelerating processes.

Process

Thanks to cloud computing and collaboration support, research teams can use a wide variety of specialized laboratories to conduct experimental research. This allows them to solve the problem of building the “Laboratory as a Service” within the framework of partnership agreements and thereby expand the capabilities of the developing R&D strategy.

Using modern technologies, employees can now quickly connect to joint projects and interact remotely with colleagues. Remote access systems help manage the entire life cycle of projects and track the status of research and development stages. A computer proactive data analysis of the data provides researchers with valuable information for making the right decisions at every stage of the study.

Tools of artificial intelligence carry out all the necessary calculations, freeing specialists from both routine work and complex time-consuming calculations.

Thanks to data visualization and access to analytical reports, specialists can evaluate processes, identify trends and quickly make the necessary decisions. Now it has become available to simultaneously track the life cycle of several hundred projects, from research, development and production to marketing, supply chain for patient and analysis of application results.

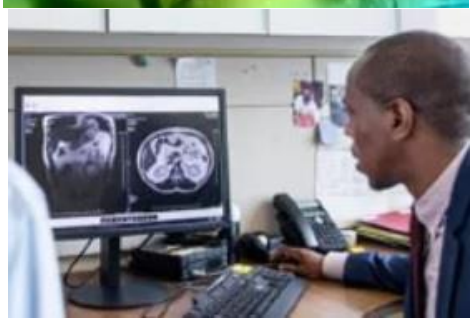
All processes, data and documents are stored centrally in one place using Microsoft Azure Cloud with reliable, secure, global storage and computing services.

Accelerate precision medicine with Microsoft Genomics

Microsoft Azure Cloud meets demanding requirements with reliable, secure, global data storage and computing services

Results

- Created of a single platform for interaction and data exchange between groups of researchers and developers of the pharmaceutical industry
- Delivered real-time of management and simultaneous tracking of a large number of projects and experimental data
- Reached acceleration innovation workflows, clinical development and product manufacturing
- Gained Visualization, automatic data analysis and analytical reporting based on electronic processing of big data
- Given the opportunity to focus on creative operations, rather than on routine, repetitive and lengthy processes



Accelerate scientific innovation

Modernize discovery and manufacturing to advancements. Create value-driven care by rapidly modeling new product development and reducing costs

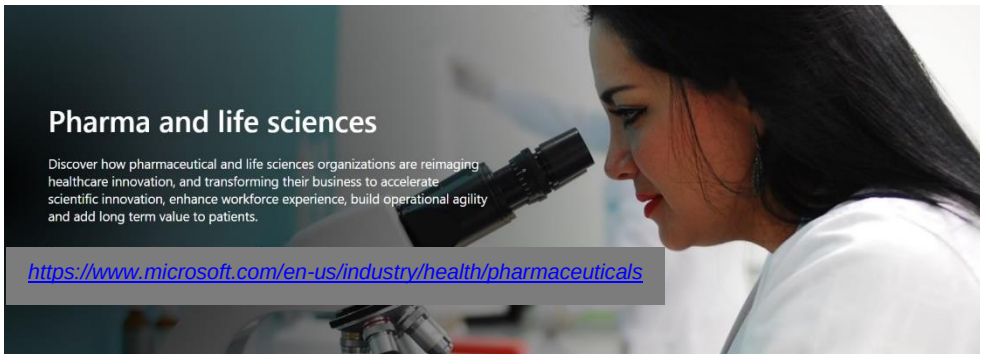
Enhance workforce experience

Optimize digital operations by connecting your people, data, devices and processes to overcome skills gaps, improve communication, digitize workflows, and increase productivity

Build operational agility

Spur life-science innovation without sacrificing compliance, iterate faster, and increase manufacturing productivity to reduce time to market

https://www.microsoft.com/en-us/industry/health/pharmaceuticals



Maximizing the efficiency of production processes and the creation of an electronic production dossier (Main File)

Empower employees to make for productive implementation of production stages, quick detection of deviations, incidents, to take effective measures of response, including corrective and preventive actions.

Its new connected manufacturing solution identifies work procedures, deviations, incidents or failures, notifies employees and provides the necessary information, tools and step-by-step instructions for implementation. In this way, an employee can efficiently and timely perform operations, including prescribed corrective and preventive actions (CAPA).

Process

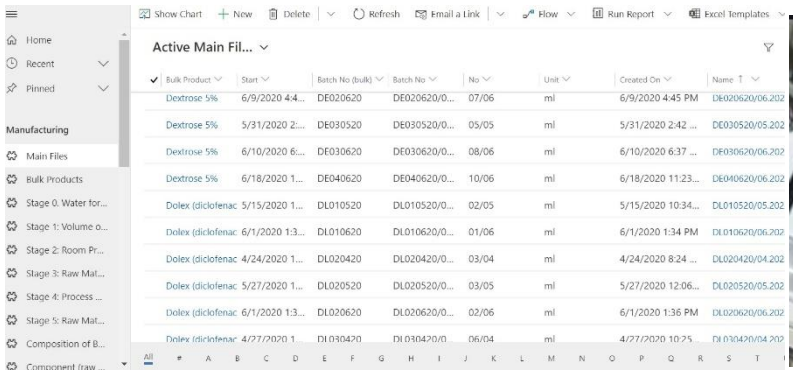
The entire production history, including deviations and corrections, is recorded in the database for further data analysis, generation of analytical reports and documents, such as production dossiers, etc.

The production system generates all the calculated data, such as the composition of the ingredients for the designated production volume, a set of tests and relevant criteria for controlling raw materials, consumables, bulk products and final products. If there are deviations from the set criteria, the system notifies about this and generates the corresponding standard operating procedure.

Results

- Significant reduction in the cost of final products and operating costs.
- Increasing labor productivity
- Quick and easy generation of a production dossier (main file)
- Elimination of human errors
- Transparency of quality control and audit processes.
- Timely and efficient maintenance of production equipment, devices and systems and prevention of their possible failures.

At the same time, based on the analysis of accumulated data, the system makes a recommendation on the most effective corrective or preventive actions.



Quality Management

Microsoft Azure's open, flexible cloud platform with virtually unlimited computing and data storage allows QA professionals to quickly respond to any deviations and take effective measures to correct them according to the CAPA procedure

Now quality and safety managers can easily keep abreast to monitor all processes for compliance with regulatory requirements

Process

BVR QM Solution ensures timely and effective monitoring of compliance with the requirements of standards such as GMP, GLP and others

Now you can formalize the basic concepts of quality management in accordance with GMP in the production of drugs, active pharmaceutical substances and the starting materials used, as well as describe production processes in detail. This will allow you to run multiple applications at the same time to speed up data processing, automatically detect inconsistencies and obtain analytical reports. Thus, now employees can quickly respond to inconsistencies, timely determine the necessary corrective and preventive actions, plan operations, organize their implementation and conduct appropriate assessments of results.

Automation of quality control processes affects the following objects:

Premises, equipment, personnel, methods of sampling ingredients, raw materials, products for sampling, control and testing of intermediate, bulk and finished products. Now the software application will automatically determine the qualitative and quantitative composition of ingredients and materials, the required purity, registration data, proper packaging and proper labeling.

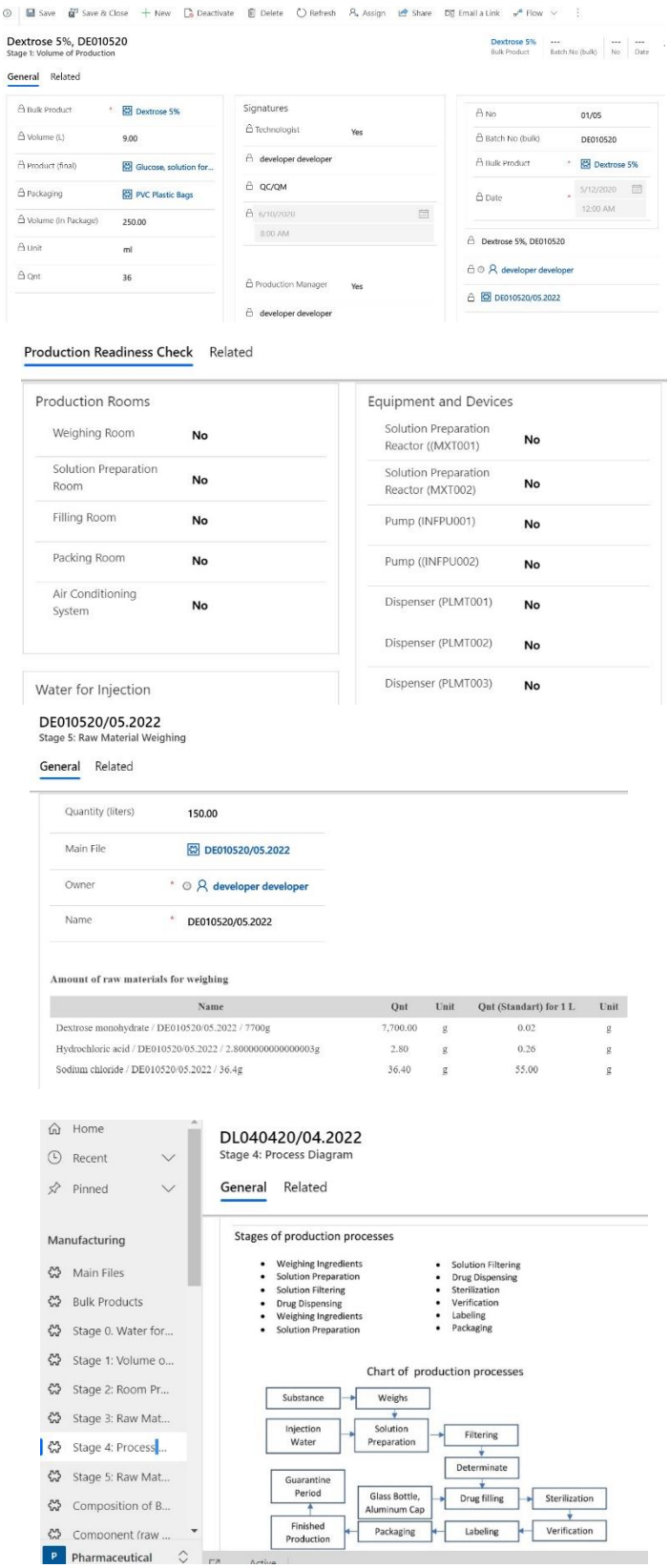
When carrying out the processes, specialists will now receive automatic notification about which objects need to be validated and how to register the corresponding results according to electronic templates.

The software application sequentially determining the necessary actions of employees and providing appropriate templates allows you to easily and quickly record all operations, laboratory tests and production stages.

Hygiene in production	*Qualified personnel*	*Traceability*
complaints and recall	*Quality management*	*Processes transparency*

Results

- A significant reduction in the cost of detecting inconsistencies, research and identification of the root cause of the deviations, determination of the necessary actions according to CAPA, as well as planning, coordination, implementation and monitoring of results
- Reduction of time and other resources by due to automatic data analysis and timely notification of staff about deviations
- Timely identification of adverse trends through the use of artificial intelligence software
- ability to service a large number of processes, procedures, systems, equipment and other facilities for compliance with regulatory requirements of quality and safety
- reduced audit time due to transparency and accessibility to data



Safety, pharmacovigilance

Provide security professionals with smart applications to quickly identify, evaluate, and deepen your understanding of the problem to prevent drug-related adverse effects.

One of the priorities of any pharmaceutical company is the timely identification of previously unknown side effects, risk assessment, and planning actions to improve safety. For this, pharmacovigilance specialists must be provided with accurate and up-to-date information communicated by medical professionals and patients according to the completed Patient Information Sheets (PIL).

Process

During clinical trials or PIL data processing, **the Bever Risk Management software** helps the researcher to perform the following actions in sequence:

- collection and analysis of data on adverse events
- classification of cause and effect relationships
- research and safety assessment
- Reporting to regulatory authorities on the acceptability of a safety profile and drug efficacy.

New reports of adverse events using machine learning software and processing a large number of parameters automatically possible root causes are identified, the degree of possible risks is classified and evaluated. These studies are valuable for decision making and further action, as they provide data in a less controlled environment for patient use of drugs.



DATA COLLECTION AND VERIFICATION ACKNOWLEDGEMENT

DUPLICATE SEARCH TRIAGE DATA ENTRY CASE

REACTION DESCRIPTION CODING OF DRUGS ASSESSMENT

Results

- making optimal decisions based on data to ensure drug safety, reduce side effects and possible risks
- reduction of current costs for the implementation of internal processes associated with the planning and implementation of measures aimed at improving the safety of treatment and recovery of patients
- increased efficiency by automating processes to prevent possible adverse events and various risks
- Using automated tools to optimize operations, identify trends and patterns, allocate resources, and improve patient health outcomes.

https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview

Get a comprehensive understanding

Make each interaction point more relevant and responsive with a proactive, data-based understanding of the root causes of complaints

Solve problems

make decisions yourself with the help of intelligent data processing and visualization tools Dynamics 365 AI +Power Platform + Azure

Streamline research processes

Gain a deeper understanding of your patients and doctors by combining relationships, processes and data between applications

Innovative digital technologies for business transformation in pharmaceutical and biomedical organizations

Make your team work productively with the help of digital transfomation on Microsoft Dynamics 365 + Power Platform + Azure and other innovative technologies.

With the help of a suite of smart business applications **Bever Pharm** on **Dynamics 365** platform allows companies to conduct their business and get high results thanks to predictive analysis based on artificial intelligence. Using the flexibility and scalability of **Power Platform** and **AI**, companies get an extensible and customizable solution suitable for any process automation scenario. Discover Pharma and life sciences solutions to enable personalized patient experiences, accelerate innovation, and improve operational outcomes within a secure and compliant environment.

Power BI

Connect to hundreds of data sources, set up dashboards for data visualization and analysis, receive real-time analytical reporting using the Power BI

Power Apps

Using Power Apps Portals, give remote colleagues and partners access to data collaboration based on a flexible authentication model and access rights to protect sensitive data.

AI Builder

Building learning models based on AI Builder allows employees to use artificial intelligence applications, better understand data, easily analyze large amounts of information and make decisions quickly.

Power Agents

Microsoft Power Virtual Agents increase employee team satisfaction, lower support costs, and increase productivity with AI capabilities. Empower your employees with an easy-to-use solution for creating and managing virtual agents and bots.

Power Automate

The introduction of the Power Automate system allowed employees to automate the execution of processes and provided the ability to seamlessly create intelligent automated flows. Thus, employees freed themselves from routine repetitive work and are now more focused on creative work.

The Bever Pharm Software has been validated and fully complies with accepted GMP and CAPA standards. Bever Pharm solves an important task by connecting people, processes, technologies and data to implement modern digital transformation capabilities. One of the main approaches at the core of Bever Farm is a commitment to standardizing solutions that play an important role in ensuring the technological compatibility, security and scalability required for modern intelligence systems.

Bever's solution is built on flexible Microsoft platforms Dynamics 365 + Power BI + Azure, that allow you to develop and implement innovative industry solutions based on the foundation of Microsoft, combining best-in-class technology and deep industry experience. No other technology provider offers a comparable, comprehensive portfolio, or an open and flexible approach.

Bever represents a unique perspective for the implementation of digital transformation in all aspects of the manufacturing organization, namely, changing ways to optimize operations, expanding the capabilities of employees, transforming the research, development, production and delivery to the market of products and services to meet the needs of patients, doctors and partners.

BEVER

At the poles of real solutions

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