Transition to Digitalization

How to Effectively Digitalize the End-to-End Supply Chain in the Pharmaceutical Industry

ISPE and its members are developing the roadmap to introduce Industry 4.0, also called the Smart Factory, at the pharmaceutical industry as Pharma 4.0 — an operating model that is interconnected, meaning that the digital tools allow for a fully connected network to enable direct communication between all levels in an organization.

Despite the transformational potential of digitalization, the pharma industry has historically been slower than other sectors in adopting digital tools, such as cloud storage, artificial intelligence (AI), machine learning (ML), blockchain, and remote communication technologies, and in making associated changes in workplace culture and strategic priorities. Now, however, the Covid-19 pandemic may be accelerating the pace of change.

What are the digitalization trends in the industry? What is the business case to develop and implement digital tools and digitalization strategies? And how can organizations introduce and use them?

CHEManager asked executives and industry experts to share their views on digitalization trends in the pharmaceutical industry and challenges on the way to realize the sector's digital transformation. We proposed to discuss the following aspects:

- What do you think are the key digitalization trends in the pharmaceutical industry?
- What do you consider to be the most important benefits of digitalization in the pharmaceutical industry?

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- Is your company involved in systematic, ongoing action to digitalize operations?
- At present, digitalization in the pharmaceutical industry is immature. In your view, what are the biggest obstacles that need to be overcome in the digitalization of the sector?
- How would you rate the digital maturity level of your company?

Read the insightful answers of the experts here.

Unlocking Treasures for Unmet Medical Needs

Michelangelo Canzoneri, Global Head of Digital and Data, Healthcare Business, Merck

"Digitalization will enable our industry to streamline its processes, increase speed to market, identify opportunities to reduce costs, and elevate performance."

We have unprecedented amounts of data at our fingertips, yet we're only scratching the surface of its value. To build industry-wide capabilities for deriving genuine and actionable insights from manufacturing data analysis for example is becoming increasingly success-critical in the industry. Some big questions here are 'How is my batch doing?' and 'Has this deviation affected product quality?' In the labs and manufacturing facilities of the future everything will be fully connected, with automated processes and data driven foresights too. Managing knowledge is where digital and data can elevate the connection between R&D and operations. It is not just about accessing and compiling the data. Everyone involved will require access to high qualitative information (re-integration of learnings from all batches) to build process and business excellence.

Secondly, the drive towards more resilient manufacturing. According to an Accenture report, two out of five cyberattacks are now indirect causing the industry tens of billions of US-dollars due to IP theft yearly. Companies in the pharma sector need to look beyond their own four walls to their broader ecosystems. Investing in robust cyber resilience, while bridging the gap between information and operational technology, will be key to prevent, manage, monitor, analyze and predict risks for attacks and intrusions and important to conduct counteractive protocols and report incidents, along with examining and evaluating security strategies and defense.

Digitalization will enable our industry to streamline its processes, increase speed to market, identify opportunities to reduce costs, and elevate performance. And if we continue to evolve and put the patient at the center of everything we do, then we will unlock treasures for unmet medical needs across the digital continuum. This will create opportunities for precision, personalized, and preventative medicine, and deliver tangible benefits to patients faster. Digital is not an end state — it's a journey.

Digital Transformation Journey

Balajikasiram Sundararajan, Chief Digital Officer, ACG

"We strongly believe in digital-enabled transformation. The future is bright. The future is digital."

At ACG, we began our digital transformation journey in 2017 with four broad objectives: How can we use emerging digital technologies to transform manufacturing operations, enhance customer experience, build smart products and services, and create new business models?

We started with projects focused on reducing machine breakdown and enhancing overall equipment efficiency (OEE). Today, 1,000+ machines are connected to our industrial IoT platform streaming more than 30,000 parameters, spanning process data, energy data, machine condition data, alarms, alerts.

What started with OEE enhancement has evolved into a range of digital initiatives powered by technologies, such as industrial IoT, advanced analytics, machine learning, computer vision, mobile robotics, augmented reality, and virtual reality. These digital initiatives have yielded significant benefits in reducing downtime, enhancing OEE, decreasing lead time, reducing defects, optimizing energy consumption, enhancing capacity, improving first pass yield, and much more.

We are also in the process of developing and deploying digital solutions aimed at providing delightful customer experiences across various touchpoints. These include technical services, factory acceptance tests, plant qualification, and product approvals. As a machine builder serving the pharma industry, "Smart Connected Products" is our strategic initiative to make machines smarter using Industrial IoT, edge computing, advanced analytics, and machine learning. These technologies allow us to provide insights to our customers to run the machines better and reduce unplanned breakdowns, enable service teams with insights to perform better field service, and help our design teams to optimize machine design.

At ACG, we strongly believe in digital-enabled transformation and see great potential in technology for delivering significant value to our customers, our partners, and to ourselves. The future is bright. The future is digital.

Data Science and Analytics Are Key Trends

Viola Meisterling, Digital Officer HPS&GQ, Boehringer Ingelheim

"In today's fast changing world, everyone needs to adapt to succeed."

Health is what we care about. We believe that digitalization helps us to develop new and innovative therapies for patients around the world. Data science and analytics are key trends. With digitalization and automation, the amount of data is constantly increasing. By making better use of data, we can identify patterns and tendencies and transform data into insights and smart decision making. This allows us to optimize our entire value chain. As a result, digitalization helps us to create exciting new opportunities to improve human and animal health.

Digitalization affects almost every aspect of the pharmaceutical value chain. To give you one example: The lead times between the research and development of new compounds and the market launch of the pharmaceutical product will become shorter. Accordingly, manufacturing capacities need to be available faster than in the past. We have created a digital roadmap to be prepared for these developments in operations and supply chain and to actively manage these processes. One example is our project "Real Time Release Testing" (RTRT), which is part of our BI dataland initiative. With RTRT we want to use data in operations to predict product quality and release in real time with minimum risk.

In today's fast changing world, everyone needs to adapt to succeed. We must change the way we think and act today and break out of the existing structures. If you want to be successful with your digital transformation, you need to think and act across the entire end-to-end value chain to achieve more resilience and flexibility.

Standardized Key Quality Systems

Markus Zeitz, Quality Innovation hub lead, Novartis

"Built on the renewed IT landscape an enterprise-wide data lake supported by a solid master data governance will be a key enabler for transformation projects."

For quality, the digital journey will continue to focus on the standardization of key quality systems (e.g. exception handling, change control, document management, batch release, lab systems). These systems will embrace the benefits of cloud computing wherever possible. Built on the renewed IT landscape an enterprise-wide data lake supported by a solid master data governance will be a key enabler for digital transformation projects.

The access to high quality data will be the foundation for transformational projects using state of the art digital tools like machine learning, artificial intelligence, internet of things and block chain. Some of these tools will require investment in new standardized platform applications on the enterprise level. Novartis Quality is embracing operational excellence and playing in all the above-mentioned fields focusing on standardized key quality systems, insight generation based on high quality data and automation of transactions.

At Novartis Quality, we are leveraging data and digital to improve compliance and to increase efficiency at the same time. To be truly transformational and unleash the power of our people we embrace the Novartis values of being a workplace, which inspires curiosity in our employees and allows them to work in an unbossed way.

Seamlessly Integrated Planning across all Disciplines

Andreas Bonhoff, CEO, TTP Group

The planning of all technical projects of TTP Group is based on the building information modeling (BIM) approach. The trend is towards seamlessly integrated planning across all disciplines under one roof. This minimizes replanning efforts as well as costs and enables the creation of a digital twin of the plant. Actually, already part of our daily work.

To meet the BIM requirements for each project and define the scope and benefits, it is necessary to work closely with the client. It is critical that the process is considered as a whole and that the information/data requirements are coordinated and agreed upon by both parties. Through the BIM approach, changes in all phases of the building's life cycle are immediately visible to all parties and the impact is synchronized immediately.

During the construction phases, BIM provides contractors with data information that is shared via cloud data platforms, helping them save both time and money. In addition, construction managers can also track and control the entire construction progress using augmented reality.

"We have systematized the digitalization of processes by deploying specialized teams in the development departments."

At TTP Group, we have systematized the digitalization of processes by deploying specialized teams in the development departments. For example, at Pharmaplan, the Digital Factory department is divided into different areas that are responsible for the development of digitalization — which is unique: Digital Engineering Building, Digital Engineering MEP & Process, and Manufacturing IT & Automation. We use a cloud-based platform called BIM360 as our common BIM data environment, which allows us to share the work with all project participants as well as with our client. It provides not only the data management system, but also all relevant building data that is geometrically visualized as a virtual composite model and stored in a live database. Only in this way, the correct implementation of the BIM database from conception to facility management activities can succeed.

Pharma Industry Faces Specific Challenges

Teresa Minero, Founder & CEO, LifeBee

"Digital transformation is too often perceived to be only about technology. It is not. It is about people and information."

Pharma 4.0 embodies the same characteristics of Industry 4.0, but there is an extra dimension in its complexity: compliance with regulations for patients benefit. The Patients are waiting at the end of our supply chain for a medicine that must be more and more effective, safe, promptly available at sustainable costs. We must assure this with Pharma 4.0.

From what we find in ISPE, and also in my company LifeBee, we must underline that digital transformation is too often perceived to be only about technology. It is not. It is about people and information. The main benefit is to empower human beings with the right information at the right time, in order to act and make the best decisions, at every level in the organization, from the line operator to the lab analyst, to the supervisor, to the QA, to the CEO, up to the regulators. In pharma there is also an additional complexity: information needs to be managed in full "data integrity".

Regarding challenges specific to Pharma 4.0, they were deeply analyzed in a workshop in 2020, held at the ISPE European Pharma 4.0 conference. Results were clustered in six key topics as follows: 1. Compliance: the need to assure the company of the alignment between 4.0 and regulatory guidance; 2. Economics: costs of a 4.0 program versus the tangible value; 3. Knowledge: a wide spectrum of information on the 4.0 initiative must be shared with management and personnel from the outset; 4. Organization: the company organization will need to change — cut the silos — to benefit from and manage the 4.0 perspective; 5. Competencies: questions from management about workforce 4.0 features and workers' potential resistance to change; 6. Strategy: many companies have developed 4.0 pilots and projects, but there is a lack of a mid to long term strategy, with a definition of business targets and a sound road map.

The benefits are undoubtedly far more important for our patients compared to the complexity of challenges. Let's start the Pharma 4.0 journey!

Enormously Transformable Buildings

Rino Woyczyk, Head of Life Sciences, Drees & Sommer

"Modular digital construction planning offers maximum user orientation via defined modules that can be quickly exchanged as needed."

For construction projects in the life sciences segment, with its stringent safety, speed and flexibility requirements, two approaches are particularly promising when it comes to digitalization: modular construction and building information modeling (BIM). Linking these two methods forms a powerful digital duo that allows, amongst other things, faster, more reliable and more cost-effective realization of production buildings and labs.

The key to efficient modularization is the digitalization of the design using a BIM model, a process whereby a "digital twin" of the building is created. The building model is consistently modular. Recurring spaces and structures are only modelled once and stored as catalogue models. Examples of such modules are the furnishing modules for user-defined expansions, such as laboratory units, offices and meeting rooms, cloakrooms and kitchens, including their entire development and all of their technical equipment.

Modules from the catalogue are added to the project model according to user preferences. The result is a building design that is developed like a product. The components can be put together according to the customer's wishes within a coordinated set of rules, and the planning becomes more or less a configuration.

The innovative modular planning approach in combination with a complete digital representation of the building is opening up new dimensions. The buildings of the new pRED research center in Basel, most of which are equipped with laboratories, are set up using this method, and the requirements are very high, due to the necessary laboratory installations and especially the demand for flexibility in the buildings.

Modular digital construction planning offers maximum user orientation via defined modules that can be quickly exchanged as needed. It allows for the quick conversion of labs instead of new construction or renovation. Even in highly customized architecture, the digital duo leads to economical construction and operation and reduces the planning effort as possible errors are already identifiable in the "digital twin". Thus, it enables a proverbial "quantum leap" towards enormously transformable buildings, perfectly tailored to a particular use and produced to the highest quality standards.

Significant Market Advantages

Ferdinand Biermann, Head of business unit Life Sciences Engineering, Fraunhofer Institute for Production Technology IPT

Digitization and networking are the central development concepts of production in the sense of 'Industrie 4.0'. For manufacturing pharmaceutical companies, these modernizations result in significant market advantages: One is that powerful systems for obtaining and evaluating process and product data in real time provide valuable information that can be used for optimization. Additionally, they facilitate compliance with regulatory requirements — from Good Manufacturing Practice (GMP) to EU directives on serialization and anti-counterfeiting. Furthermore, process chains can be organized more agile through digitization and networking. This results in a new level of flexibility that prepares pharmaceutical manufacturers for the challenges of the personalized medicine of the future. The modernization and development of production processes and process chains according to 'Industrie 4.0' is a core competence of the Fraunhofer IPT: Together with our partners, we develop individual solution concepts for the establishment of new technologies as well as for networking and adaptive design of production in pharma companies.

"Process chains can be organized more agile through digitization and networking."