



MANAGEMENT SUMMARY

# JUST IMAGINE...

... BECOMING A FULLY DIGITALIZED GLOBAL MARKET LEADER BY 2027

**SIEMENS**

# Just imagine... ...becoming a fully digitalized global market leader by 2027

"People with visions should go to the doctor."

**Former German Chancellor Helmut Schmidt coined this somewhat tongue-in-cheek phrase several decades ago, but our advice today would be that if you have visions, you should come to Siemens and its pharmaceutical team. Why? Because we have all the active ingredients and expertise needed to turn your company into a fully digitalized global market leader by 2027.**

In this future paper, we would like to take you on a journey into doing until we look beyond what is right in front of us. Sluggish innovation and fear of disruption are of course common issues, however, allow us to set out in black and white exactly what we think needs to be done.

In short, through its Digital Enterprise portfolio, Siemens can drive your digital transformation – the seamless integration of automation, software, and cutting-edge technologies. This portfolio covers everything from R&D to the API manufacturing process and secondary processing of pharmaceuticals. However, this transformation is not an end in itself, but rather a means of achieving clear goals – winning the race for a shorter time to market, right-first-time quality, and maximum production flexibility and efficiency.

Just imagine...

... achieving the vision of digitalized pharmaceutical manufacturing in 2027

### Let's start with the basics

Our holistic consulting, implementation, and optimization approach combined with our cutting-edge-technologies made sure your digital transformation was in the best possible hands.

- **Portfolio:** It's 2027 and you have all the tools you need to overcome data silos in both the virtual and real worlds.
- **Consulting:** We kept your digital transformation right on track from the very outset.
- **Implementation:** We rolled out and optimized your factory of the future from the start.
- **Optimization:** Our work hasn't stopped – we are analyzing your operations to deliver continuous improvement.

AI applications related to Big Data are expected to drive up the success rate in research



### Trends and drivers...

When we kicked off your company's transformation in 2021, we identified several trends and drivers. Do you agree with our assessment?

In 2021, the market was growing faster and more globally day by day.

There were many new products and therapies based on biologics, cells & genes, or individualization that were very complex to manufacture. A great deal of uncertainty hung over the world as it pursued change in the face of complex regulations and political circumstances. Generic manufacturing and increased costs for development work and clinical trials also exerted huge pressures. Most notably, the COVID-19 pandemic highlighted the crucial importance of being able to quickly develop and produce vaccines to treat unfamiliar viruses.

These business drivers were key when making strategic choices on an operational level for your business and manufacturing strategy. Flexibility was needed to adapt global networks to changing demand and new products. Speed was key – speed to clinic, speed to build, speed to market, speed to supply. Quality and strategies to manage quality throughout the value chain were very important. What's more, although cost pressures were not as keenly felt in manufacturing, as well as CO<sub>2</sub> reductions in other industries, development costs and global cost efficiency measures were still driving factors at pharmaceutical companies.

### **...translated into digital solutions**

From the manufacturing point of view, these trends and drivers were translated directly into concrete "digital expectations" for your production sites. Technology transfer and improving the flow of information between R&D and manufacturing has long been a challenge, but that has now been addressed thanks to a growing number of electronic systems. Quality data has been gathered online, particularly with regard to continuous manufacturing. Given the sheer volume of data that is readily available, new storage options such as lake and cloud solutions have been deployed. At the same time, there has been a shift towards modular flexible manufacturing concepts. Another piece of the puzzle has been the drive to eliminate paper from your shop floor.

## **THE COMPREHENSIVE DIGITAL PORTFOLIO**

Your manufacturing transformation process was strategically implemented based on the following **three pillars**:

### **Designing and simulating products and processes**

- Mechanistic modelling
- 3D material simulation
- Product lifecycle management
- Quality by design

### **Planning, simulating, and optimizing production**

- Integrated plant engineering
- Operator training
- Plant design and layout
- Machine design

### **Running production efficiently and reliably**

- Electronic batch recording
- Dashboarding
- Automation and control
- Transparent operation and analytics

## THE DIGITAL TWIN

We drove this transformation by applying our concepts of the digital twin based on a closed and continuous loop – the digital twin for the product, production, and performance. As part of the greenfield approach for your production sites, the digital twin of a plant or production system was created during the process and plant design phase.

Siemens gave you a holistic toolset with which to design, simulate, and engineer your process plant.

Based on a Siemens collaboration platform, and with full data integration from design and engineering through to commissioning, we automatically created a digital twin of the automation system in the virtual world. We also generated the automation engineering and PLC code to be used in actual production with minimal effort – saving engineering costs and reducing time to production.

Back in the real world, in 2027, the DCS and MES make sure production runs smoothly, but also help to collect the relevant data to generate a performance twin. This performance twin is generated based on the actual production systems – enriched with IoT data – and allows us to optimize production and preventive/predictive maintenance for critical assets. However, we also use this data to simulate plant operations so we can improve current production or future plant designs.

We made a pledge to facilitate data-based processes for all the stakeholders in the supply chain. However, the real added value came from developing a comprehensive view of the value chain. We achieved the ideal scenario – a standardized database where the necessary information is forwarded to the correct interfaces.

**Did you know?**

**AI applications related to Big Data Analytics, which process both structured and unstructured data, are expected to drive up the success rate in research.**

**The virtualization of clinical studies and the use of cloud and mobile models is revolutionizing study methodologies and reducing both time and errors.**



## THE BIGGER PICTURE

We utilized the latest digital solutions to ensure a seamless transition from lab data and recipes to production, while integrating R&D with process and product development.

Thanks to our advanced digital solutions, you have reaped the benefits of improved process transparency and understanding to achieve right-first-time production in your primary processes.

The key to state-of-the-art secondary processing at your company was flexibility. For example, modular plants and production lines were individually combined for a given product. Another example is continuous manufacturing, which helped reduce lead times while shrinking the equipment footprint. To successfully manage the growing complexity of lines and systems, meet the requirements for quality inspection and documentation, and speed up the release of finished products, we provided a set of coordinated systems and solutions that helped you win the race for flexibility and performance in secondary processing.

We looked at your pharmaceutical processes over the entire lifecycle and beyond system boundaries. This included products, systems, solutions, and services in line with GMP (Good Manufacturing Practice) as well as system maintenance during the operational phase. In this context, data integrity was one very fundamental aspect, spanning everything from entry and recording to the long-term archiving of relevant data.

## THE YEAR IS 2022...

Your digital future starts now!

Our experts are looking forward to supporting you on your journey to becoming a fully digitalized world market leader!