

Digital Resiliency

PhRMA member companies are dedicated to researching, developing, and delivering lifesaving and quality of life enhancing innovations for patients. There are a range of ways PhRMA member companies work to bolster digital resiliency, including investments to improve efficiency, flexibility, and productivity of R&D, manufacturing, and logistics processes; reduce costs related to potential shocks or disruptions; and, adapt to changing market conditions.

Understanding Digital Resiliency:

Digital resiliency refers to the capacity for biopharmaceutical companies to use digital tools across all aspects of the drug lifecycle (e.g., R&D, manufacturing, and other corporate functions). An important way that biopharmaceutical companies encourage digital resiliency is through investing in digital innovation and technology to connect, monitor, control, and enhance their business operations—technologies associated with the current digital revolution referred to as “Industry 4.0”. By tracking and synchronizing operational resources, leaders and employees across the industry are empowered with real-time information about business operations, and the ability to adjust to shocks and stressors. Investments in operational resiliency enable productivity enhancements, improve efficiency of corporate R&D and manufacturing processes, reduce risks and costs related to potential disruptions, and adapt to changing market conditions.

The Importance and Objectives of Digital Resiliency

By investing in and implementing digital technologies that lead to more efficient processes, biopharmaceutical companies can improve the resiliency and overall productivity of their operations. A high-level scan of PhRMA member company websites and related publications identifies 29 instances of member company investment in digital technologies that advance digital resiliency.¹ Among these, 27 companies are emphasizing the digitalization of R&D and clinical trial processes, and 23 companies are using digitalization to enhance the resiliency of their manufacturing operations. As a result of these activities, the following impacts are being realized by PhRMA member companies:

Improved operational intelligence: Investments in digitalization and automation to encourage digital resilience provide biopharmaceutical companies with an unprecedented amount of actionable intelligence that can be used to inform and monitor R&D, manufacturing, and other corporate functions.

Stronger global health systems: When faced with disruptions such as the COVID-19 pandemic, biopharmaceutical companies with more resilient operations can quickly, safely, and effectively deliver life-changing treatments and cures in the face of threats and uncertainty.

Prevention of stoppages and disruptions: Digital technologies linked to the equipment in scientific labs or manufacturing facilities can help to inform proactive and predictive maintenance, which can help to prevent costly, wasteful, and potentially dangerous downtime and shutdowns.

Improved risk preparedness: Due to their increased understanding of overall operations, biopharmaceutical companies that are emphasizing resilience are better prepared for risks such as natural disasters, cyber incidents, product shortages, quality problems, or reputational threats.

Digital Resiliency: Examples of PhRMA Members in Action

Notable examples of PhRMA member companies working to encourage digital resilience are highlighted below:

EMBRACING DIGITALIZATION

By embracing digitalization, GSK is optimizing each phase of its vaccine development and production processes.² Working closely with leading companies in digital transformation and technology, GSK has piloted a digital twin to completely simulate the vaccine manufacturing process in real-time, monitor this process closely, anticipate failures, and optimize quality and self-learning. This ultimately allows GSK to accelerate the vaccine manufacturing process and get vaccines to people much faster. In addition to production, GSK is exploring the potential of digital twins to transform the process of vaccine R&D further upstream which could be particularly beneficial earlier in a vaccine project, where the combination of high-throughput experimentation and the twin models would quickly produce the data needed to confirm theories.

CONVERTING MANUFACTURING SITES

Eisai is converting manufacturing sites to automated, remotely controlled operations to shift toward a more resilient production system that is unaffected by emergencies or employee attendance.³ Notable examples of Eisai's investments in innovation include building a digital twin for the drug substance manufacturing process—representing the fusion of reality and virtual space to realize reaction prediction, remote monitoring, and predictive maintenance at manufacturing sites; developing a Continuous Manufacturing system for the formulation process; and, the development of an analysis automation robot, among other efforts.

FOCUSING ON END-TO-END OPERATIONS

Biogen is focusing on the resilience of its end-to-end operations by investing in technology and process improvements to enhance efficiency, reduce costs, and supply the needs of patients.⁴ Thorough business continuity planning and investments in advanced technologies at manufacturing plants provide Biogen with appropriate redundancies, all in an effort to maintain product availability while minimizing environmental impact. For example, Biogen's North Carolina facilities use an innovative process for early-stage clinical products that increases the flexibility and speed of supplying drugs for clinical studies and reduces the environmental impacts of the manufacturing process.

LEVERAGING AUGMENTED AND VIRTUAL REALITY TECHNOLOGIES

Novo Nordisk is leveraging augmented and virtual reality technologies (AR/VR) to improve processes at manufacturing facilities, blending the real world with the virtual and leading to an increase in efficiency, a more flexible workforce, and faster training of new employees.⁵ Using VR headsets, augmented/mixed reality allows users to move around and operate in the physical world, but with a virtual layer on top. The augmented instructions guide users throughout the process they are performing, which is particularly useful for employees performing complex tasks on production lines or for training purposes. Instead of reading a traditional 2D instruction, the employee can put on the device and get an "augmented" instruction, with 3D animations in the surroundings of the actual equipment at a production line. Augmented instructions also involve a platform that is run on the backend that helps to trigger workflows and configure, manage, and automate processes. This allows Novo Nordisk to apply augmented instructions in compliance with the strict requirements imposed on the biopharmaceutical industry.

DIGITALIZATION THROUGHOUT THE VALUE CHAIN

Astellas is implementing digital transformation throughout the value chain—including R&D, manufacturing, commercial and marketing, and other corporate functions.⁶

To maintain and improve upon the rigorous production processes necessary to provide a stable supply of high-quality biopharmaceuticals to patients, Astellas independently developed DAIMON, a state-of-the-art data mining system. This advanced data mining system for manufacturing incorporates three types of monitoring: univariate, cause and effect and regression, and multivariate. Significant time reductions in data analysis can be achieved through the appropriate operation of these three monitoring types, according to the volume of data and the complexity of the analysis. DAIMON's strength lies in a continuous cycle of knowledge acquisition, and through this cycle, it is possible to promptly react to quality or production trouble and prevent such troubles in advance, thereby realizing a high manufacturing level and a stable supply of biopharmaceutical products.

DEVELOPING PARTNERSHIPS

Eli Lilly and Company has developed partnerships between their Information Technology (IT) and Operational Technology (OT) domains, helping drive the company's global serialization program.⁷ This enabled the company to steward a global solution to providing regulatory-mandated traceability for all final product units by integrating vision systems, high-speed control, event management systems and Enterprise Resource Planning (ERP) systems. Through this collaboration, Eli Lilly and Company also developed an understanding of industrial cybersecurity risks, with a plan to mitigate immediate risks and an ongoing strategy for best-available protection.

DIGITALIZED SOLUTIONS

Boehringer Ingelheim is using digitalized solutions to implement globally efficient processes with standardized software solutions.⁸ In recent years, BI has successfully supported and implemented global digitalization projects such as the collection of environmental data and electronic signature solutions for environmental, health, and safety audit systems. This digitalization approach enables BI to rationalize their activities throughout the world, and to reduce expenditures without suffering quality or performance losses.

1 TEconomy Partners Analysis of PhRMA Member Companies

2 GSK, "Digital twin: using advanced technology to accelerate vaccine development."

See: <https://www.gsk.com/en-gb/behind-the-science-magazine/digital-twin-using-advanced-technology-to-accelerate-vaccine-development/>

3 Eisai, "Value Creation Report 2022: Empowering people to live their lives to the fullest." See: <https://www.eisai.com/ir/library/annual/pdf/epdf2022vcr.pdf>

4 Biogen, "2021 Year in Review: Our commitment to corporate responsibility."

See: https://www.biogen.com/content/dam/corporate/en_us/YIR-2021/Biogen-YearInReview-2021.pdf

5 Novo Nordisk, "Augmented Instructions."

See: <https://www.novonordisk.com/partnering-and-open-innovation/digital-innovation-hub/augmented-instructions.html>

6 Astellas, "Innovation in Manufacturing." See: https://www.astellas.com/en/stories/dx_strategy_series_vol.4

7 Rockwell Automation and Eli Lilly and Company, "Building Resilience in Pharma and Biologic Manufacturing."

See: <https://www.rockwellautomation.com/en-id/company/news/blogs/resilience-in-bio-pharma.html>

8 Boehringer Ingelheim, "Digital Innovation."

See: <https://www.boehringer-ingelheim.com/science-innovation/human-health-innovation/digital-innovation-our-digital-pipeline-only-growing>