Cybersecurity protects clinical trials

The Medicines Manufacturing Innovation Centre in Glasgow, Scotland, is revolutionizing patient care.

The center is led by CPI, a UK-based independent deep tech innovation organization that brings together pharmaceutical giants including GSK and AstraZeneca, the University of Strathclyde, UK Research and Innovation, and more than 25 technology companies to fast-track clinical trial manufacturing. As a result of this collaboration, Siemens technologies – from the digital twin, to industrial automation, to cybersecurity – now ensure seamless digital processes and a secure Digital Enterprise.

Manufacturing medicines for clinical trials is a complex, lengthy and costly process. As the global demand for medicine continues to grow, the pressure is on for the pharma industry to produce in ever-quicker cycles.

The Medicines Manufacturing Innovation Centre was conceived to relieve this pressure. "We operate a model in which the pharmaceutical industry and its supply chain work together to identify and overcome major industry hurdles – or Grand Challenges – to reduce the time, resources and cost of medicines manufacturing – to ultimately deliver benefits to patients," explains Dave Berry, Head of Digital Business Systems, at CPI's Medicines Manufacturing Innovation Centre.

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Industry problems, digital solutions

As a greenfield site, the center is leveraging the potential of the Digital Enterprise to tackle these challenges. Fully integrated best-in-class technology from Siemens was deployed. The digital twin created with Tecnomatix Plant Simulation, for example, allows pharma companies to implement the automation module that they need to conduct tests and avoid bottlenecks. “Modeling allows us to stay within tight specifications,” Berry says. “From a Grand Challenge perspective, we are reducing waste.”

A paperless Opcenter Execution Pharma – a manufacturing execution system (MES), automation and enterprise resource planning system in one – informs personnel how and when to execute each step, likewise speeding up the process to real-time release while ensuring full compliance.

Secure automation

Siemens industrial automation system was applied to all layers, from the demilitarized zone (DMZ) and network, to the MES, down to the control level. The SIMATIC RTLS (real-time location system) tracks materials, cutting down the time needed to locate parts and objects and optimizing inventory. Deploying SIMATIC controllers with integrated security functions and the Totally Integrated Automation (TIA) Portal opens the doors to comprehensive digital automation services and forms the basis of a secure IT/OT (operational technology) environment.

Fully integrated Defense-in-Depth security approach

At Medicines Manufacturing Innovation Centre, where there’s the potential to manufacture clinical trial batches all the way down to the individual level, security is paramount. Protecting personal and company data in this era of cyberattacks is crucial. “Siemens Defense-in-Depth security approach provides comprehensive and extensive protection on three levels – the plant, the network and the system – leading the way to a secure Digital Enterprise,” comments Michael Metzler, Vice President, Horizontal Management Cybersecurity for Digital Industries at Siemens.

A SCALANCE-based security architecture – including SCALANCE W for wireless – was deployed all across the center’s operational technology network. A customizable Mendix-based dashboard allows Qualified Persons (QP) – who are authorized to legally certify medicines to market – to access information quickly and flexibly. The secure, integrated IT/OT network delivers information from the manufacturer back to the QPs, allowing them to legally release a batch in real time.

Compliant with UN and EU standards

Siemens cybersecurity approach complies with both the UN-endorsed IEC 62443 standard and the new NIS 2 EU cybersecurity directive. Siemens Industrial Cybersecurity Services conducted special trainings for the center’s employees to increase awareness.

Optimizing sustainably into the future

With its operations secure, the team at the center can focus on swiftly optimizing. “To improve really quickly, what we have to do is create a lot of waste. By automating and digitalizing processes, we can reduce that waste,” adds Berry. “From a sustainability perspective, what we can't do really very well as an industry yet is look at Scope Three carbon emissions. By creating a bubble where we readily and rapidly understand digitally what's happening in Scope One and Two, it enables us to work out the best methodology for implementing Scope Three within the pharma industry. I’m really excited about working with Siemens to help get that done.”

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