ALZHEIMER’S TREATMENT BECOMES AFFORDABLE WITH THE PI SYSTEM

Biogen is a leading developer of drug therapies for neurological and neurodegenerative diseases. Headquartered in Cambridge, MA, for nearly 40 years, the Biogen team has worked to combat the effects of diseases such as MS, Alzheimer’s and spinal muscular atrophy. Biogen is in the process of rolling out its Aducanumab drug, which is designed to treat the symptoms of Alzheimer’s. Phase 1b results noted that the drug significantly slowed the decline in Alzheimer’s patients, giving hope to the over 25 million people around the world who suffer from the disease.

A NEXT GENERATION MANUFACTURING PROCESS

While Biogen has made significant progress in the fight against Alzheimer’s, it’s goal is to treat one million more patients by 2020. To do so, the drug needed to become more affordable, and affordability starts with production. With a long-term goal of reducing its biologics manufacturing process by 80 percent and cutting costs from $10,000 per gram to $100-150 per gram, the team created a Next Generation Manufacturing plan for its Solothurn, Switzerland facility. Comprised of two cells and four bioreactors, the modular facility is designed to expand to manage additional Aducanumab production. However, the current process needed to be honed, and with the help of the PI System, it became possible.

To drastically increase output and reduce costs, Biogen needed to minimize screening time for raw materials while still maintaining quality, implement process and quality controls, as well as predictive models for consistency assessment. “When we look at our current processes… although we’ve worked really hard to optimize them, we still have some challenges, right?” said Tim Alosi, head of the Global Data Analytics team, during the 2017 OSIsoft User’s Conference in London. “…with next gen manufacturing, our goals bring together some of these initiatives and enable them with strong, integrated IT systems.”

CHALLENGE:
Deliver new Alzheimer’s drug, Aducanumab, affordably to 1 million patients by 2020

SOLUTION:
Next Generation Manufacturing facility with operational data available in real time

BENEFIT:
Expect to reduce time waiting for test results 50%, batch exceptions 70%, and batch review time 78%
Biogen had a goal of cutting testing time in half through advanced process control. By moving its testing process onto the plant floor and in real-time, and for any tests that could not be done at the line, reduce the testing time, the team produced quality Aducanumab faster than ever before. "How can we bring these sorts of technologies right down to the shop floor so that decisions can be made in real-time to affect the process, right?" said Alosi. "So, if you have to wait two-to-three days for a lab result, then it's real hard to have a positive impact on a purification process when, three days later, you're two steps beyond where you were." With the need for adjustable processes to meet these new testing goals, Biogen deployed its BES Integrated Solution. Comprised of 58 different interfaces, including the PI System, the technology ecosystem is designed to provide real-time visibility and context needed to implement advanced process controls and predictive modeling.

**THE BIOGEN EXECUTION SYSTEM INTEGRATED SOLUTION**

Using the PI System, Biogen now has both asset and temporal context data with Asset Framework and Event Frames. "It is becoming incredibly important — and the key element here is that context — it's not just time series data but, it's the time series data coupled with the manufacturing context that enables these different applications," said Alosi. With PI System data, events are created at a source system level, exposed, and stored in the PI System in real-time. Using Alarms or Notifications, a real-time report is generated for quality or process issues and a workflow sent to the supervisor. Often, the issue can be addressed prior to the batch moving to the next step rather than scrapping a batch if there was an error in the production process. With this real-time review by exception process, Biogen can now adjust the manufacturing process in real-time, allowing the company to reduce manufacturing costs, increase yield, and ultimately expand production efforts. Thanks to the PI System, Alzheimer’s patients everywhere will have access to an affordable solution.

**REAL-TIME REVIEW BY EXCEPTION**

**Real-time Review:** Using PI System data, Biogen can review the manufacturing data and correct any errors or issues before moving on to the next stage.

For more information about Biogen and the PI System, watch the full presentation [here](http://www.osisoft.com/Presentations/Next-Generation-Biologics-Manufacturing--Delivering-the-Vision).

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Alosi, Tim. “Next Generation Biologics Manufacturing: Delivering the Vision”

Our goal here with the OSIsoft PI System is really to turn it into the central point of information driving some of our really key, data-rich applications and work processes.”

— Tim Alosi, Head of Global Data Analytics Team, Biogen

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