Distributed Control System Facilitates Expansion for New Drugs Produced by Contract Manufacturing Organization

Large Contract Manufacturing Organization relies on flexible Distributed Control System to quickly ramp up production of both a COVID-19 treatment and a vaccine under EUA

Combatting the pandemic has highlighted the importance of the partnership between biopharma organizations and the contract manufacturing organizations (CMOs) that must flexibly handle outsourced production, which can come suddenly and often must quickly be ramped up.

For example, to meet the urgent need for COVID-19 related therapies and vaccines early in the pandemic, Thermo Fisher Scientific, a world leader in serving science with annual revenue of approximately $35 billion, had to expand its manufacturing capacity quickly and dramatically at its Greenville, North Carolina plant to meet urgent demand.

Thermo Fisher offers a comprehensive range of industry-leading services for small and large molecule product portfolios, including drug substance and drug product development, viral vector and cGMP plasmid manufacturing, clinical trial services, and commercial-scale manufacturing and packaging.

At the plant, the expansion involved adding a whole new production suite and safeguarding quality. Enabling sufficient production flexibility was also required.

NovaTech
AUTOMATION

As production rapidly increased and other pharmaceuticals were added to the manufacturing lineup, production changes at the plant would be inevitable.

The expansion includes a new 130,000-square-foot facility for sterile drug development and commercial manufacturing of critical medicines, therapies, and vaccines expected to be operational by 2022, according to a recent www.wraltechwire.com article.

As part of the expansion, the plant has added to and upgraded its existing Distributed Control System (DCS) to accommodate the production of two vital pharmaceuticals during the pandemic: first, the antiviral drug Veklury® (remdesivir) FDA approved for the treatment of patients with COVID-19 requiring hospitalization, and then a vaccine authorized under EUA, the Moderna COVID-19 Vaccine.
In this effort, a robust DCS is critical. A DCS is a hub of a CMO's production, conveying, and handling of pharmaceutical products. The DCS's user interface brings all the data collected from production equipment and the controller's process and presents it in a highly "human factored" manner for an operator, generating trends, alarms, etc.

In late 2020 ramping up production of the antiviral drug for those hospitalized due to the pandemic was crucial, according to Chris Gepfert, Regional Sales & MSR Channel Manager at NovaTech LLC Process Division which specializes in DCS systems and continuous control system architecture. Gepfert was involved with DCS implementation at the Greenville plant. He notes that this entailed adding a new production line, including on-site construction, and required FDA testing.

According to Gepfert, NovaTech was fully aware of the urgency of the project. He says,

"With the constrained supply chain, it was difficult to meet the tight timeline, but we prioritized the effort to make all required deadlines."

"For CMOs, the need to quickly produce various vaccines or therapeutics and then ramp up volume can occur rather suddenly today, so we were on standby and ready to implement the system architecture necessary for increased production," he adds. "When there can be a new project or a new contract awarded from week to week, the DCS system must be flexible enough to accommodate whatever is needed quickly, whether new I/O equipment cabinets, new process control modules, or new services."

In the Greenville plant's case, the CMO already successfully used NovaTech's D/3® DCS, and it was decided to utilize it in the new suite expansions. The system can display real-time process information in a complete high-performance graphical human-machine interface (HMI). Custom graphics, built using dynamic objects from an extensive library, make it easy for the operator to control the process, enter information, and interact with sequence programs.

The CMO and NovaTech collaborated to provide the needed flexibility for the new suite expansions, according to Gepfert. He says, "They do a lot internally, and we have our engineers full-time on-site to offer immediate support as well."

When a critical, high-volume vaccine contract was awarded to the CMO, the plant's DCS system was robust and flexible enough to handle the added production.

According to a recent CNBC.com article, "Moderna said Thermo Fisher's commercial manufacturing site in Greenville, North Carolina will be used to provide fill/finish manufacturing services and supply packaging for hundreds of millions of doses of the vaccine."

Gepfert points out that for high-volume production of this sort, CMOs often require automation today to increase production and minimize the need for operator involvement while reducing potential error.

In this regard, to implement plant automation at the plant, the DCS utilizes a modern I/O system, the 8000 series platform, a remote I/O family native that is highly integrated with the D/3 System. The combination facilitates greater automation with better diagnostics, troubleshooting, and asset management capability.

The system, in fact, enables significant batch process control and automation, using the Sequence and Batch Language (SABL) that the D/3 controllers utilize and an S88-based layered batch management package called FlexBatch.

"The pandemic has upended routine CMO production planning, so a DCS must be flexible and capable enough to make any required changes to vaccine and therapeutic manufacture rapidly and easily," concludes Gepfert. "Having the right DCS system in place and working with a supportive vendor is crucial today for CMOs to respond as quickly as the market requires."

For more information, visit the NovaTech website, **www.novatechautomation.com** or call (844) 668-2832.

NovaTech
AUTOMATION