

Helping Customers with 21 CFR Part 11

Software Provides FDA Compliance for Pharma, Along with Speed and Flexibility

Snapdragon Chemistry is a leader in developing continuous-flow chemistry solutions for the discovery and production of active pharmaceutical ingredients, intermediates, and materials. The company is based just outside Boston, and its customers discover and manufacture pharmaceuticals, animal care products, materials, and other fine chemicals.

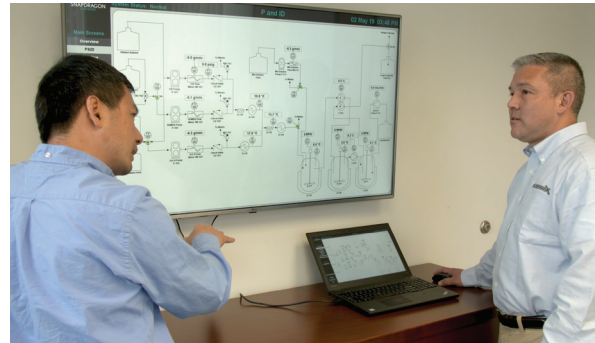
Snapdragon recently adopted a new system for supervisory control and data acquisition (SCADA), and is leveraging that system to help its customers comply with requirements from the United States Food & Drug Administration (FDA). The FDA's Title 21 of the Code of Federal Regulations Part 11 (21 CFR Part 11) establishes rules for the use of electronic records and signatures, covering confidentiality, integrity, authentication, and more.

For its new SCADA system, Snapdragon worked with system integrator NeoMatrix, which deployed Ignition by Inductive Automation®. Ignition is an industrial application platform with tools for building solutions in SCADA, human-machine interface (HMI), and the Industrial Internet of Things (IIoT).

“When we were approached on this project, we chose Ignition because of the features it had that were already aligned with 21 CFR Part 11,” said Danny Haskell, chief operating officer of NeoMatrix. “That includes the audit log, the Active Directory security support, and the Reporting Module, which allows us to create batch records as well as audit trail reports. We also like Ignition a lot because it can transform into any customer architecture.”

Regulatory Compliance and More

“When NeoMatrix showed us the Ignition software — and the interface and the flexibility and the



Snapdragon Chemistry uses Ignition for FDA compliance, faster development, and much more.

on-demand data we could get from that system — it really became the go-to system for us,” said Matt Bio, president and CEO of Snapdragon. “And we’re planning to grow with that system.”

Ignition helps Snapdragon turn cutting-edge laboratory technologies into manufacturing technologies very quickly. NeoMatrix's Ignition application provides Snapdragon with 21 CFR Part 11 compliance, full control, audit log, reports, trending, alarm management, and security management. “We gave Snapdragon the ability to view trend history and access to all of the process data, and we also provided the ability to view all events,” said Haskell. “And we utilized Ignition’s reporting capabilities to create batch reports — an official record that a customer can use as needed.”

The pharmaceutical industry has become more complex in recent years, and the need for robust technology has increased. Snapdragon is responding to that and is always intent on providing better, faster service to its customers.

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– David Ford
Director of Chemistry, Snapdragon Chemistry

“We chose Ignition because it allowed us to meet the requirements in 21 CFR Part 11 while also providing a great deal of flexibility,” said David Ford, director of chemistry at Snapdragon. “As we work with our customers to design these systems to meet their requirements, our customers are very impressed with the flexibility that we offer them — both in terms of changing the software, and in terms of the integration with their existing plant systems.”

Snapdragon’s continuous-flow technology helps reduce the number of transformations required to synthesize a given molecule, and to improve the efficiency of those transformations. “In pharmaceutical development, the target compound changes all the time,” said Bio. “Ninety-five percent of the compounds that enter development never make it to the end. So having a system that allows us to change from one product or one process to another without having to reinvent the wheel every time — that’s really important, and Ignition provides that flexibility for us.”

Rapid Development

“A big challenge with this project was the timeline,” said Eric Fang, chief scientific officer for Snapdragon. “Ignition accelerated a big part of this timeline. In general, developing any drug would take years to be manufacturing-ready. In this case, Ignition helped us shrink the timeline from years to a few months.”

Ford agreed that speed is an important factor. “Ignition helps us rapidly build robust and compliant software,” said Ford. “In these projects, where we’re rapidly transitioning from lab-scale experiments into manufacturing, we wanted to make sure we could meet the very tight timelines required to support clinical trials. We were very impressed with how quickly the software could come together to support those goals.”

Ease of use is another reason Snapdragon likes the software. “Ignition gave us an intuitive graphic interface between the operator and a very sophisticated machine,” said Fang. “And it’s very easy to use. It’s easy for the operator to understand, and to operate without any mistakes.”

“I personally love Ignition because of its ease of use and flexibility,” said NeoMatrix’s Haskell. “It truly is a flexible platform not just for automation, but for a lot of operation-type IT business processes.” NeoMatrix has used the software in a variety of industries.

It certainly works for Snapdragon. “Ignition gives us the flexibility to build one control system that we can use across a range of projects and also in a range of manufacturing facilities,” said Ford.

NeoMatrix is a software and hardware services firm based in Portsmouth, New Hampshire. The company works in a variety of industries, offering a wide range of programming and integration services. For more information, visit neomatrixinc.com.

Watch the video online at:

bit.ly/ia-Snapdragon