

Pharma Company Meets Standards for 21 CFR 11 with Ignition

Success Inspires Plans for Expansion

When Bachem Americas needed a system for human-machine interface (HMI) and supervisory control and data acquisition (SCADA), it required one that could not only improve its processes, but also satisfy requirements from the United States Food & Drug Administration (FDA). The FDA's Title 21 of the Code of Federal Regulations Part 11 — also known as 21 CFR 11 — establishes rules for the use of electronic records and signatures, covering authentication, confidentiality, integrity, availability, and more.

Bachem is a leading biochemical company based in Switzerland, with facilities in Europe, Asia, and the United States. The company provides services to the pharma and biotech industries, specializing in development and manufacturing of peptides and complex organic molecules as active pharmaceutical ingredients, as well as innovative biochemical products for research purposes.

Bachem Americas has two sites in California, in Torrance and Vista. The Vista facility needed a control system for a specific step in the manufacturing of a peptide. The new HMI/SCADA system is for the cleavage operation, which involves separation from a resin support, precipitation, filtering, and drying of the peptide. For this project, Bachem selected the Ignition software platform. Ignition by Inductive Automation® is an industrial application platform with numerous tools for building solutions in HMI, SCADA, and the Industrial Internet of Things (IIoT).

Bachem worked with system integrator Wunderlich-Malec Engineering (WME). WME, based in Eden Prairie, Minn., is an employee-owned firm specializing in electrical and control systems engineering and integration services. The company has 350 employees.



Bachem Americas improves its processes and meets FDA standards with Ignition.

For Bachem, WME built a custom application in Ignition that satisfies the FDA requirements. The new system also saves money with its unlimited licensing, and improves troubleshooting, which can be done from a laptop. Bachem's Ignition system includes a data historian, trending, alarming, audit trails, and more.

Low-Cost Expansion

"Bachem picked Ignition because it's easy to expand," said Fred Zaboli, senior control systems engineer at WME. "It includes all the features Bachem wanted in a single software package. If you pick any other software, they all have something missing. For example, some of them are missing alarm notification, and you'd have to go with a third party. But Ignition has all the features that you want for pharmaceutical projects, and for meeting the FDA standards."

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— Tim Tran
Site Manager, Bachem Americas

Tim Tran, site manager for Bachem in Vista, said Ignition was the clear choice. “We picked Ignition because it can be described in one word: simplicity,” he said. “It eliminated a lot of the complexity that we saw in other systems that we reviewed.”

“We were looking for a software package that’s easy to operate, and also easy to roll out to the whole site in the future and be compatible with all the existing systems,” said Rudi Kuehnel, process engineer for Bachem. “With Ignition, we are able to have that. And we especially like the compliance to CFR Part 11.”

With Ignition’s unique licensing model — no extra fees for more tags, clients, users, or projects — Bachem can achieve its goals for less money than it would have to pay with other vendors. “Compared to other software packages, Ignition was very cost-efficient for this project,” said Zaboli.

There are also numerous benefits in functionality. “As a project manager, I was very impressed with the capability of Ignition in terms of validation and startup and factory acceptance testing,” said Kuehnel. “We were pretty much able to run a simulation on the first day that the programming was done. The simulation helped us to eliminate errors before starting it up in the manufacturing unit.”

Bright Future

Bachem also needed easy access to an audit trail, both for internal use and outside auditors. “Audit trails are very important in the pharmaceutical industry,” said Zaboli. “With Ignition, it’s easy to activate. On other platforms, you have to do a lot of engineering and programming ahead of time.”

Bachem has also seen benefits from improved reporting. “The reports and data from Ignition are very simple to retrieve and comprehend,” said Tran. “Overall, the experience with Ignition has been great.”

Easy integration with Microsoft Active Directory was another plus. “The Ignition system uses Active Directory for its authentication, which is part of 21 CFR 11,” said Anthony Chong, senior systems engineer for Bachem. “With other software, they use generic accounts and passwords, which is not part of 21 CFR 11.”

Bachem has been very pleased with Ignition’s performance, and is planning to expand its use. “We plan to roll this out to the rest of the Vista site, which will be a ten-times expansion,” said Tran. The company plans to use it for new projects and to upgrade existing projects. Ignition will also be implemented in Bachem’s facility in Torrance.

“We are looking forward to expanding the system, and we already have some projects in mind,” said Kuehnel. “For example, using some utility functions and integrating them into our process, to give operators more control over what’s happening outside of their process room.”

While WME uses Ignition in other industries and settings, Zaboli is excited with how well it works for Bachem and 21 CFR 11. “We see a lot of opportunity at Bachem with Ignition,” he said. “It’s a platform that makes it possible to do almost anything.”

Wunderlich-Malec Engineering is one of the largest and most well-established engineering companies in the U.S. It’s been providing engineering, system integration, and fabrication solutions for more than 30 years. For more information, visit wmeng.com.

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