

zenon used for automated fill-finish platform

Regulation-ready software at 3P Innovation

Pharmaceutical compliance is no easy feat. To support 3P Innovation in its development of production equipment for life sciences, COPA-DATA provided flexible, regulation-proof software for the creation of an ultra-compact fill-finish platform.



3P is a life sciences engineering and custom automation company. The organization works collaboratively with pharmaceutical and medical device businesses to develop new products through the design, manufacture and support of production equipment.

Based in a brand-new purpose-built facility in Warwick, UK, 3P services a multi-national customer base with machines installed right across the world.

3P's offering includes aseptic processing machines, powder and liquid filling technologies, custom device manufacture, as well as assembly and testing. For this project, 3P used zenon to develop an automated, ultra-compact and highly flexible fill-finish platform.

FILL-FINISH PLATFORM

As a life sciences organization, regulatory compliance is high on 3P's agenda, and a project to create a new fill-finish platform was no exception.

The project's desired outcome was the creation of an improved fill-finish platform — fill-finish platforms are used to manage the process of filling vials, syringes, cartridges, and bottles with a vaccine, medicine or ingredient. Naturally, these platforms must be aseptic, precise and in an ideal world, fully automated.

The goal was an automated fill-finish process that could be used in either single or multi-container formats. The technology



*3P Innovation's Multi-Container
Liquid Filling and Stoppering*

would help 3P's customers to manufacture pre-clinical and GMP clinical batches quickly and cost effectively and crucially, would reduce end user's engineering time.

As a product for the life sciences sector, this technology also needed to comply with FDA 21 CFR Part 11 and EudraLex Annex 11 — regulations covering the pharmaceutical industries in both the United States and Europe.

MEETING INDUSTRY STANDARDS

In the pharmaceutical sector, regulatory compliance is largely reliant on accurate record keeping and audit trails. However, as many pharmaceutical and life sciences organizations move away from paper-based records, compliance against FDA 21 CFR Part 11 also has specific requirements for electronic record keeping.

The regulation requires organizations to provide evidence that electronic documents and signatures are authentic. FDA 21 CFR Part 11 compatible software is the most effective way to ensure compliance and COPA-DATA's pharmaceutical automation software, zenon, provides this reassurance.

zenon is an industrial software platform with specific advantages to the life sciences sector. While it can be used at the application level for operating projects, it can also be used in the engineering environment to create projects. Most importantly, for 3P, zenon is developed specifically to meet the FDA 21 CFR Part 11 criteria and carries compliance against the regulation throughout all its modules.



3P Innovation's Vial Filling with stoppering

For 3P, choosing zenon as a software platform could ensure compliance for the fill-finish process through built-in recipe management, accurate audit trails and user administration functionality.

DEVELOPING NEW TECH

The objective of 3P's new fill-finish technology was to minimize the risk involved in filling and finishing processes. The new platform needed to be flexible, scalable and allow end users to integrate a wide variety of different pump brands and technologies.

Notably, 3P needed the platform to be compatible with both rotary piston and peristaltic pumps to ensure it was suitable for different types of end users.

"At 3P, many of our machines are uniquely configured for a client application or are even a completely bespoke machine," explained Chris Webber, Control Systems Manager at 3P Innovation. "This requires us to generate new HMI screens for each project and all of those must enable operators to intuitively operate a complex piece of automation. COPA-DATA's zenon software allows us to quickly evolve our HMI designs during the development phase, synchronizing our in-house design styles with the new functionality needed on each machine and incorporating feedback from operators."

By choosing to develop an ultra-compact platform, 3P's technology also needed to fit easily into existing isolators, bio-safety cabinets and other containment equipment. The design of the platform also included multiple tools on the same machine; liquid fill, nitrogen flush, check-weigh, stopper and cap.



3P Innovation's brand-new purpose-built facility

Developing such a multifaceted platform required software that facilitated this level of diversity. zenon was ideal for this.

As a truly independent software platform, zenon does not limit users to specific equipment manufacturers or communication protocols. In fact, zenon allows for communication with a wide variety of manufacturers and technologies, making it truly flexible and scalable. For customers like 3P, this ensures the platform is versatile and future proof.

Regulatory compliance is key for the life sciences industry, as well as the machinery deployed in pharmaceutical plants. Thankfully though, it needn't cause a headache. New technology is providing easier, faster, and more effective ways to adhere to the industries regulatory hurdles.

HIGHLIGHTS:

- ▶ FDA 21 CFR Part 11 compatibility
- ▶ Seamless communication with other technologies
- ▶ Built-in recipe management
- ▶ Scalable technology
- ▶ Flexible user administration