STATE-OF-THE-ART AUTOMATION UNLOCKS NEW POSSIBILITIES FOR E DEVELOPMENT. VACC OTECAN.

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The vaccine development process has transformed dramatically in recent years, driven by the urgent need for effective immunization against emerging contagious diseases. Traditional pipelines for the creation of novel vaccines relied on more than 10 years of research, preclinical investigations and clinical trials, but advanced laboratory technologies have led the way to rapid vaccine development, production and upscaling. Automation has enabled vaccine research to go beyond the bounds of what was previously possible in terms of reliability and throughput, leading to faster progress and new ways of designing experiments. The Vaccines Global Bioprocess Development Platform at Sanofi has recently automated its miniaturized chromatography workflows to speed up downstream processing, achieving even greater productivity and efficiency for the company's workflows.

The evolution of vaccines has come a long way since Louis Pasteur first discovered the connection between microorganisms and infection. In the past 150 years, many types of vaccine technologies have been developed to train our immune systems to combat infectious diseases, from inactivated or live attenuated vaccines to immunizations based on recombinant proteins, virus-like particles (VLPs) and nucleic acids. Research and development scientists at Sanofi contribute to this field by developing a wide range of vaccine antigens molecules that help trigger the body's immune response against pathogens - as well as exploring the potential uses of vaccines to prevent chronic diseases on a global scale.

Multiple production steps and quality control procedures are required to develop a vaccine. The process begins by producing the antigen in a prokaryotic or eukaryotic expression system under strict culture conditions. Any process- and product-related impurities are then removed during a purification step to ensure the safety and efficiency of the final product. An inactivation step is also sometimes needed for inactivated vaccines, eliminating their ability to cause disease while retaining their ability to elicit a precautionary immune response. Once downstream processing is complete, the final vaccines can be formulated, tested, packaged and shipped. It is therefore essential that labs have efficient, high throughput inactivation and purification methodologies in place.

Chromatography is а popular method for large-scale purification of vaccines, and the Vaccines Global **Bioprocess Development Platform at** Sanofi has miniaturized this process to meet requirements for very small sample volumes and minimal reagent consumption. In addition, Sanofi recently introduced a new Fluent® Automation Workstation to its chromatography workflow to provide fully automated parallel column chromatography using Repligen's OPUS[®] RoboColumn[®] system. Eric Forma, Principal Scientist in Global Bioprocess Development at Sanofi, described the benefits of this technology: "Introducing automation to our purification workflows means that all protocols are now performed at the same time, with the same product and under the same conditions, ensuring consistent and comparable results. We can now avoid sources of manual variation within our experiments, which is essential in the world of preventative healthcare, where quality standards are extremely high."

Automation has also helped to increase the rate of novel process development within the group. Eric continued: "Since implementing the Fluent 780 workstation. we have noticed a major improvement in our lab's productivity. We are able to perform a very high number of tests, in a very short time. We previously performed our chromatography workflows manually, which limited our throughput to approximately five experiments per day, but we can now perform up to 30 tests daily! In addition, the system is flexible, and we can now conduct experiments under 50 to 100 different conditions in just one week. We are proud of this adaptability."

Some scientists may find the introduction of new, automated lab systems daunting, but combining Tecan's user-friendly instruments with an easy-to-use programming software ensured an easy transition from manual to automated protocols. Eric explained: "To complement the Fluent workstation, we have also introduced a digital experiment platform from Synthace into our workflows. This cloud-based software simplifies the programming of the new equipment and protocols, ensuring that the instruments can be used by anyone

sanofi

"Since implementing the Fluent 780 workstation, we have noticed a major improvement in our lab's productivity. We are able to perform a very high number of tests, in a very short time." in the lab, without extensive training or coding knowledge. It transforms basic manual inputs into scripts that can be read by Tecan instruments, so we can program an experimental set-up virtually - ensuring that we encounter no issues - then run it quickly and easily in our lab."

"Looking to the future. the combination of our Fluent instruments and Synthace software will allow us to adapt and expand our processes to address future challenges. If we want to add new components to our workflows, such as increasing the spectra of our chromatography solutions, these versatile technologies will enable us to do this. This means that we can experience ongoing growth and development as a company, and continue to improve the scope and quality of vaccines that we produce," Eric concluded.





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