

Variety of Connections, Unlimited Licensing Aid Cancer Therapy

New SCADA Delivers Compliance, Mobility, Lower Costs, and More

Autolus Therapeutics is working hard to deliver life-changing benefits to cancer patients. Autolus is a biopharmaceutical company based in London developing next-generation T cell therapies. T cells are part of the immune system and can be changed in a lab so they can fight cancer better in the body. Autolus is creating therapies designed to better recognize cancer cells, break down their defenses, and eliminate them. Autolus has grown rapidly since its founding in 2014, raising hundreds of millions of dollars along the way.

Autolus manufactures its product candidates at a facility in Stevenage, near London. A modernization project for that facility and a new facility under construction is built on Ignition by Inductive Automation®, an industrial application platform with tools for building solutions in human-machine interface (HMI), supervisory control and data acquisition (SCADA), and the Industrial Internet of Things (IIoT). Autolus is using Ignition for data acquisition, visualization, alarming, reporting, and regulatory compliance. Ignition will also be used in the new 72,000-square-foot manufacturing facility that's under construction in Stevenage.

Modernization and More

Ignition's ability to handle multiple communication protocols — including Modbus, MQTT, OPC UA, and Web API — was very important to the project. "This was a key factor, because we use so many different types of equipment," said Miranda Neville, VP of global engineering, logistics and procurement for Autolus. "The industry is fairly new, and many companies are still developing their processes, and these processes are established in hospitals and universities across the globe. Where you begin this journey will determine what process equipment you end up using in your commercial



Autolus Therapeutics is expanding on its ambitious work with next-generation T cell therapies.

manufacturing facility. Ignition was selected, in part, because of its 'multilingual' capabilities."

Ignition was implemented at Autolus by Barry-Wehmiller Design Group. Design Group is a St. Louis-based engineering and system integration firm with multidisciplinary, subject matter expertise across multiple industries including life sciences, food & beverage, and semiconductor. Design Group is helping Autolus take a big jump forward in its automation. "This was a first real software-integration project and application for Autolus," said Steve Chapman, partner, control system integration at Design Group. "Prior to this, there were small ad hoc data collection tools. This project and application were a leap into modernization. I commend Autolus on their technology-progressive vision as they prepare for product commercialization."

Chapman also said this type of project is part of a growing trend. "This industry of personalized medicine will continue to face challenges as lab equipment is brought into commercial manufacturing," he said. "There will need to be an evolution to bring this equipment up to par with other traditional automation hardware

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Autolus Therapeutics

platforms. Ignition has proven to be a valuable tool with its flexibility, mobility — and above all, device integration — that will serve this industry well.”

Strong Compliance

To prepare for the commercial launch of a new therapy, Autolus built a new cell-processing suite at its current facility. Ignition Perspective was implemented to 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. The process also needs to satisfy the similar European Union requirements, known as EudraLex Annex 11.

Ignition helps Autolus comply with the regulations, making contributions in document storage, record retention, record rendering, system access, authority checks, and audit trails. Tsuyoshi Kuroki, manager of information solutions at Design Group, noted a couple of key areas. “Ignition allows for easy integration of a sitewide Active Directory, which helps ensure secure user access for Autolus,” said Kuroki. “Also, Ignition provides a robust audit trail feature which is very important for compliance.”

Ignition is the foundation for the process control system (PCS), which includes process data, alarms, and audit trail from T cell transduction systems, cell harvesting, cell counters, controlled rate freezers, and vaporized hydrogen peroxide (VHP) sterilization generators. The environmental monitoring system (EMS) includes monitoring and

alarming of incubators, isolators, refrigerators, freezers, and non-viable particle counters.

Lower Licensing Costs

Another benefit for Autolus is improved mobility. “Ignition allows people to use portable devices like tablets, laptops, and embedded wall-mounted monitors with web browsers,” said Kuroki. “These allow users to visualize and interact with the application in clean rooms where traditional HMIs are not ideal because they’re difficult to clean and rather large. And licensing costs were also a major consideration in choosing Ignition.”

Ignition comes with unlimited licensing, meaning there are no extra costs for adding clients, screens, tags, devices, or connections. “The unlimited licensing was a key consideration to help reduce our cost,” said Neville. “Cell and gene therapy companies are developing lifesaving therapies and always looking for ways to reduce our cost and time to deliver. Companies developing these therapies often start out operating without making a profit, and therefore must be cost-conscious.”

“The current implementation at Autolus is just the beginning,” said Kuroki. “We’re working on integrating the new facility, and we’re using what we’ve learned to push integration to new heights.” Chapman said Autolus has been “fantastic” to work with. “They’ve provided the opportunity to work directly with OEMs on first-time equipment integration efforts, which also further enhanced the OEM offerings to the industry,” said Chapman.

“I’ve always been a big believer in automation,” said Neville. “There is a time and cost element to designing and deploying automation systems, but at the end of the day, you take comfort in knowing that you have the data that you need at your fingertips, and that you are maintaining compliance.”

Barry-Wehmiller Design Group is one of the largest system integrators in the United States and is an Ignition Premier integrator with the Enterprise designation. The company pairs deep industry experience with multidisciplinary, subject matter expertise across more than 45 offices to deliver fully customized solutions to its clients. For more information, visit bwdesigngroup.com.