VAISALA

Customer Case

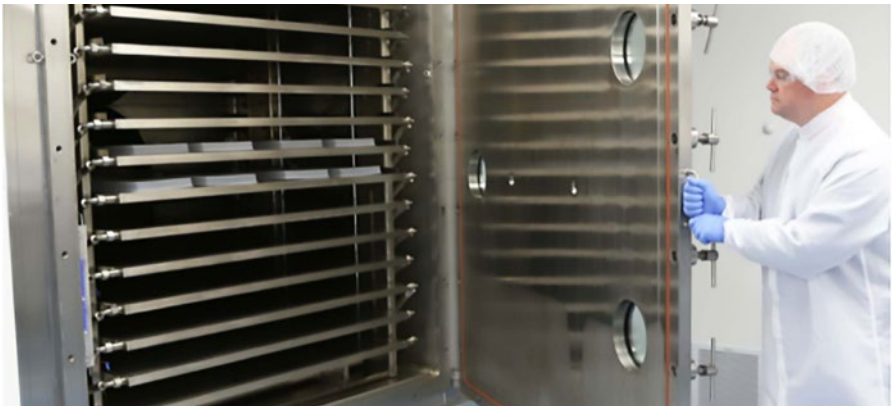
www.vaisala.com

LSNE (a PCI Pharma Company) leverages digitization to ensure quality, compliance, and data integrity

Lyophilization Services of New England, Inc. (LSNE, now part of PCI Pharma Services) is a contract development and manufacturing organization (CDMO) that serves global pharmaceutical, biotechnology, and medical device companies. Among an array of contract manufacturing services, LSNE specializes in cGMP aseptic fill-finish and scaling lyophilization applications.

LSNE comprises five FDA-inspected facilities in the U.S. and Europe, with a sixth facility opening in 2022. In support of commercially approved medical devices and drug products to over 30 countries across North America, South America, Europe, Africa, Middle East, and Asia, LSNE's services fall into three categories: development, manufacturing, and analytical. With the PCI acquisition, the combined companies now offer global end-to-end integrated CDMO services for clients, including development and manufacturing, clinical trial services, and commercial packaging.

While LSNE provides multiple services, such as formulation processes for emulsions, suspensions, liposomes, and polymer or lipid nanoparticles (LNPs), the company is an industry leader in lyophilization (freeze drying), which stabilizes biologic substances through freezing and the sublimation of frozen water under high vacuum. Products that degrade in solutions, which is most drug or biological products, benefit from lyophilization to ensure product efficacy and extend shelf-life. Using heat to remove moisture would degrade many products. Instead, lyophilization uses freezing conditions under vacuum. With over 30 lyophilizers across the world, LSNE is currently one of the largest service providers in the industry.



Photos Source: Lyophilization Services of New England, Inc.

Daniel Gabrault has been a plant engineer with LSNE for over three years. Currently he provides overall support for facilities, systems, utilities, and equipment. When he started with the company, there were multiple different monitoring systems distributed across facilities. In 2018, LSNE decided to standardize several facilities' environmental monitoring with the Vaisala viewLinc continuous monitoring system.

Monitoring multiple parameters

“Initially, we had Vaisala do the installation and validation for system deployment,” recalls Gabrault. “Now after many years of using viewLinc, we find it’s easy to expand the system on our own.”

Vaisala offers Installation Qualification and Operational Qualification protocols to simplify validation. Gabrault was able to further streamline the documents for simplicity. “I took the data in the IQ and OQ from Vaisala and customized it for our needs. I simply capture the location, serial numbers, alarms, and function, and it’s a straightforward validation.”

Once the viewLinc system was installed and validated, LSNE was able to monitor multiple environments, including walk-in or reach-in freezers and refrigerators, and cleanrooms. For most applications, they use VaiNet wireless data loggers – the RFL100.

“I like the wireless RFL100 data loggers because they are easy to place and easy to configure,” says Gabrault. “The RFL100s also have a digital display, so we can quickly check conditions and see whether the device is working properly.”

The viewLinc system is also easy to standardize across applications.

“It was important to us to have as much environmental data as possible in one system,” says Gabrault. “So, we use other devices in viewLinc to monitor parameters the RFL100 loggers don’t currently include. We also use Vaisala’s CAB100 in our clean suites to monitor ambient temperature, relative humidity, and differential pressure.”

The Vaisala Industrial Cabinet CAB100 integrates multiple sensors into a simple, pre-configured instrument panel. While typical parameters include differential pressure, ambient temperature, and relative humidity, the CAB100 can also take a variety of analog inputs, which can also be made intrinsically safe.

“In the case of the CAB100, based on my past experience of cleanroom monitoring systems, I estimate most systems would take up about four times the space as the Vaisala CAB100. The cabinets’ small footprint and the fact that it’s pre-configured make it very convenient.

“We also use DL4000 universal data loggers for parameters like pH in waste system monitoring. With those measurements in viewLinc, we ensure compliance with local requirements for environmental protection.”

Daniel Gabrault,
LSNE plant engineer

Monitoring for GMP compliance

To ensure the highest level of quality to client companies and patients, LSNE must undergo regulatory inspections from multiple agencies and host numerous client and Qualified Person audits. This regulatory scrutiny necessitates that the company’s Quality Systems are current, compliance focused, and continuously updated.

“Lately our focus has been on client-specific audits. Every time one of our clients receive a new drug approval, the FDA comes in for that client. Because our clients are seeking FDA approval, the FDA needs to survey everything involved with the product that has been submitted for approval.

“Our clients also audit our Quality Systems,” says Gabrault. “During these audits they appreciate viewLinc’s monitoring capabilities. The system provides data on all environments, for any time they request.”

In 2016, the FDA published a draft guidance on data integrity, which states: "In recent years, FDA has increasingly observed cGMP violations involving data integrity during cGMP inspections. This is troubling because ensuring data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health.[1]"

"Data integrity is extremely important to us. In viewLinc, the audit trail ensures you can't edit any data. Even if you were to delete the unit or the device, the data stays forever, which is ideal for GMP. Yes, it can be tricky at times – for example, every time you enter your password wrong, it's recorded; nothing can ever be erased. But we need that kind of data integrity and access control for GMP."

Monitoring with flexible, reliable alarming

The viewLinc system can send notifications several ways: email, SMS, voice calls, lights, sirens, and relays to external systems. This allows administrators and users to receive remote alarms for areas under their care.

"Currently most alarms are sent by email, but we've also set up important alarms to go directly to phone," says Gabrault. "Some users set their preferences to send to both email and text message. The system sends alerts on thresholds and communication failures immediately, without loss of data."

Gabrault also appreciates viewLinc's reporting capabilities. "The alarm reports are especially helpful. You can easily pull a report on only the data you need."

User-friendly software

"The viewLinc system has the best user experience of the monitoring systems I've worked with. In other systems, I would sometimes have to manually back up the data, but that's unnecessary in viewLinc. Also, if the system goes down and you don't receive a notification, it's very frustrating. I've worked with other systems where the devices are excessively large. That can mean extra effort to set them up."

The viewLinc software was designed to be easy to learn. The user interface is intuitive, with embedded prompts and functional "Tours" to guide users through common tasks, provide onscreen instructions, and embedded tooltips.

"Everyone seems to like using viewLinc. It's not hard to learn. We do an initial training and that one-time training has been sufficient. From that point on, users can make their own reports and see only the data that's relevant to them. As the viewLinc administrator, I segregate all the data, so staff only sees the applications they care about."

Vaisala also provides calibration options to ensure sensors maintain their accuracy, including: Vaisala service center calibration, probe replacement service, or software and equipment for in-house calibration.

"We have a calibration team as part of our engineering group, so we calibrate our sensors in-house," says Gabrault. "We use Vaisala's MI70s to calibrate the RFL100 probes. Being able to calibrate in-house definitely adds to the usability of the system."

Scalable, standardized, safe

The viewLinc monitoring system was designed to be easily scalable, a feature that LSNE has leveraged. "We have hundreds of devices over seven facilities, soon to be eight. I like that I can see what's happening in our facility out in Wisconsin from my location in New Hampshire.

"Before we installed viewLinc, we had several different monitoring methods," recalls Gabrault. "Some were using chart recorders, or other legacy systems. The viewLinc system gave us a single, centralized solution."

While Gabrault appreciates the usability and flexibility of viewLinc, the feature that is most important is viewLinc's remote alarming. Alarms ensure that products are safeguarded 24/7.

"In terms of alarming, viewLinc is relentless. It will not stop the alarm until it's been responded to."

[1] See: Data Integrity and Compliance with CGMP Guidance for Industry (fda.gov)

VAISALA

Please contact us at www.vaisala.com/contactus

www.vaisala.com

Scan the code for more information