

IPS Laboratory Monitoring Safeguards HIV/AIDS Vaccines

It was winter in the Brazilian state of Rio Grande do Sul when Dr. Leonardo Motta, a research pharmacist, received an email alarm notification while attending a conference in the USA. The alarm came from his lab at the University of Caxias do Sul. The temperature in a fridge storing HIV/AIDS medicines and vaccines had increased beyond storage specifications for the drugs. Motta acted immediately, contacting the lab technicians and letting them know which fridge to check. The technicians quickly found the issue: a frozen unit in the building's HVAC system. Thanks to the alarm, the lab technicians took corrective action and saved the drugs. The medicines and vaccines inside the fridge were not only valuable, but also critical for the people undergoing treatment at the lab, Instituto de Pesquisas em Saúde (IPS) at University of Caxias do Sul (UCS).



Main entrance of Instituto de Pesquisas em Saúde.

Continuous, Flexible and Easy to Use

Medicines, vaccines and active ingredients for drug manufacturing are sensitive to temperature; their chemical properties can change in different conditions, especially temperature and humidity. A drug or vaccine stored in conditions other than specified for that product must be destroyed. To ensure this does not occur, drugs and vaccines at IPS have been monitored by the Vaisala viewLinc Continuous Monitoring System for the last decade.

“We deployed viewLinc in October 2009,” says Motta. “Originally we installed the system in our ultra-low temperature freezers and a cryogenic freezer. After installing the loggers in freezers, we installed more data loggers in the pharmacy. Later we expanded the system to our refrigerators and to monitor ambient temperature and humidity.”

One feature of the viewLinc monitoring system that has been especially useful at IPS is the software's dashboard. Dashboards

allow a graphic overview of all environments monitored by viewLinc in the facility. Users upload an image file — photo or facility schematic — and add sensors to locations on the image to provide a visual representation of their monitored area. The dashboard interface includes features like color-based status (green, yellow and red) and the ability to click on a monitored location to get historical data and trends from that data logger.

Using viewLinc's secure historical data, lab technicians generated trend-line graphs that indicated a slow temperature increase in an ultra-low freezer. By analyzing the data over time, technicians predicted a possible compressor failure in the freezer. They proactively transferred the specimens to another, more stable ultra-low freezer. Within a week, the freezer that had shown a trend of impending malfunction failed and was decommissioned.



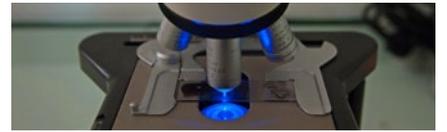
viewLinc's software interface showing customizable dashboards.

"Our original reasons for choosing viewLinc included remote alarm notification and a wide temperature measurement range. We needed to monitor temperatures in three ultra-low temperature (-70 °C) freezers and one cryogenic freezer (-150 °C). Since deploying the system, we've made use of many other useful features. In addition to graphs and historical data, viewLinc has a Rate of Change (ROC) function that allows us to receive alerts if temperatures vary at a specified rate, for example, 2°C per minute. We also benefit from viewLinc's automated reports that are delivered according to a schedule we set up. We've configured viewLinc's functions to optimize monitoring according to the needs of each application."

*Dr. Leonardo Motta
University of Caxias do Sul*



One of the freezers where reliable monitoring is crucial.



Automated & Compliant

Prior to installing the viewLinc monitoring system, laboratory temperatures were monitored using calibrated thermohygrometer equipment. Lab technicians performed daily temperature checks, manually recording the data. "This was inadequate for several reasons," says Motta.

"First, it left us without daily data checks and records during weekends and holidays. We would only become aware of any temperature deviation when we checked the monitoring equipment on the next business day.

"Second, the measurement range of the thermohygmeters (-50 °C to + 70 °C) did not permit freezer temperature monitoring to -70 °C. We also needed a system that could send notifications remotely if conditions ever went out-of-specification."

Another benefit to IPS has been viewLinc's GxP-compliant reporting. "An important part of clinical research is sample storage, which can extend over a long period," says Motta. "We always have to be able to demonstrate proper sample storage to research sponsors. The viewLinc system not only safeguards our research, but it's proved very useful during audits or inspections," says Motta.

In Brazil, the National Health Surveillance Agency (ANVISA) publishes Good Manufacturing Practices that provide guidance monitoring conditions in drug processing and storage. ANVISA regularly audits laboratories, warehouses, manufacturing and processing facilities.



Dr. Motta checking the status of a cryogenic freezer in a viewLinc pop-up alarm window.



The IPS research team during a Vaisala visit, from left to right: Dr. Leonardo Motta, Dr. Machline Paim Paganella, Lab Technician Aline de Gregori Adami, and Vaisala Sales Manager Fernanda Cunha.

Local Support, Friendly Interface

The viewLinc monitoring system has evolved over time to reflect the newest technology. The viewLinc software interface features on-screen prompts that guide users through common tasks, making the system easy to learn. Embedded help allows end users to install, configure and maintain their system. Additionally, IPS has ensured FDA and ANVISA compliance by validating their monitoring system with viewLinc's IQOQ documentation. IPS has their data loggers calibrated at Vaisala's Sao Paulo service center.

The ease of use, flexibility and reliability of the viewLinc system are crucial to ensuring IPS's core mission: "To develop clinical research and provide services in the area of translational medicine, through the generation of knowledge and the pursuit of

excellence in health technologies, contributing to the well-being of society." IPS carries out research through multiple partnerships with universities, governmental organizations, private institutions and national and international funding agencies. Since 2002, IPS has conducted over fifty clinical research projects involving more than 100,000 patients.



"Our goal is to ensure that patients have access to new therapeutic regimens, drugs and diagnostic methods without having to wait until they become available through public or private networks. Our laboratory is integrated with the health programs at the University of Caxias do Sul. Through our research into the diagnosis, prevention and treatment of HIV and associated pathologies, we provide life-saving benefits to the community. As our research has evolved, viewLinc has met our needs. We are extremely pleased with the viewLinc system and the services Vaisala provides."

*Dr. Leonardo Motta
University of Caxias do Sul*

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