

Vaisala's viewLinc Monitoring System Safeguards Vaccine Clinical Research at CTC North, Germany



Photo Source: Vaisala

Drug development is a time-intensive and costly process with a high risk of failure — especially in the early phases. The process is subject to the guidelines of Good Clinical Practice (GCP), which include laws and regulations that ensure the integrity of clinical data for product approvals.

CTC North, located on the premises of the University Hospital Hamburg Eppendorf (UKE), is an independent full-service contract research organization. Within a university environment, the professional conduct of clinical trials can be guaranteed in accordance with the AMG (Germany's Medicines Act) and MPG (Germany's Medical Devices Act).

The high quality standards feature ISO 9001:2008 certification, as

well as GCP-compliant monitoring. CTC North is entrusted with early-stage clinical trials, for example the development of an Ebola vaccine. The first human studies for the vaccine were conducted in Hamburg and in four other simultaneous Phase I trials in Europe, Africa, and the United States.

An advantage of CTC North is its longstanding experience in the organization and implementation of clinical trials and the availability of all relevant technical requisites, including environmental monitoring.

To ensure accurate and reliable sample monitoring, the existing refrigerator monitoring system at CTC North needed to be replaced. In addition to outdated software, the sensors and data storage in the

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existing refrigerator monitoring system were no longer up to-date. Furthermore, recorded values were not stored locally in data logger memory or redundantly. Additional problems included no technical support and unavailable spare parts. The replacement monitoring system would have to ensure the continuation of the required safety in terms of seamless monitoring.

In the end, CTC North selected the Vaisala viewLinc monitoring system. At the heart of the system lies the viewLinc software, which is complemented by other components such as data loggers with temperature and humidity sensors. Another important consideration in the selection of Vaisala's system was the accredited and traceable calibration that ensures the accuracy of measurements.

Data Integrity During Network & Power Outages

The Vaisala viewLinc monitoring system measures temperature, relative humidity, CO₂ content, differential pressure, fill level and door contacts. In some cases, the correct storage of hazardous material must always be demonstrable throughout the duration of a study by CTC North. As such, viewLinc's alarm function, which alerts staff in the event of deviations from specified values, was a crucial feature for the center — not least to ensure compliance with the medical and pharmaceutical GCP regulations.

At CTC North, Vaisala's viewLinc system monitors refrigerators, freezers, and ambient temperatures. The viewLinc system sends alerts via pop-up windows on a PC display, e-mails, SMS or through activated warning lights to responsible staff as soon as conditions exceed the



VaiNet Wireless Temperature Data Logger RFL100

specified range, or any sensor communication with the system is interrupted. If an interruption occurs, for example during network or power failure, Vaisala's battery-powered data loggers will continue to measure and save data. Once the connection is restored, missing data is automatically transferred to viewLinc.

"We opted for this system because it is validatable and also because it offers the best value for money in comparison to the competition," explains Ralf Freese, Medical Director and Director of Business & Corporate Development at CTC North. CTC North uses all alarm functions in the viewLinc system to ensure that no samples maybe destroyed due to improper storage conditions. Connecting viewLinc's alarm feature to CTC North's internal alarm system presented a technical challenge, as alarms had to be redirected automatically by telephone message. The problem was solved by a relay control directly from the viewLinc software.

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Reporting Complements Alarms

The viewLinc system's reporting capabilities play an important role at CTC North. Reports are customisable, easily exported to a table for analysis, and compliant

with 21 CFR Part 11 and Annex 11. All system interactions are recorded in viewLinc and stored in the audit trail in accordance with Good Manufacturing Practice (GMP) requirements.

"The simple Web-based operation, secure access for all users, as well as automated email delivery of reports were also important advantages for us," says Freese. "The system-supervising lab technicians no longer have to send manual reports, as they are now created and sent automatically, leaving more time for core scientific tasks." Another advantage of the system: The viewLinc software is browser-based and accessible from any network location.

The installation of the viewLinc system took only one day in Hamburg, with Vaisala employees on-site to troubleshoot any problems. Of supervising the installation, Vaisala's Matthias Lorenzen says, "It's nice to see our monitoring system supporting the important work of CTC North with data integrity and compliance that ensures patient safety."

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