

Alloga France has Selected the Vaisala Monitoring System to Ensure Security, Effectiveness, and GDP Conformity at its Locations

Alloga France (a member of the Walgreens Boots Alliance group) provides a range of commercial and marketing activities for health professionals. They handle drugs, health products, and medical devices after their production. An authorized pharmaceutical agent, Alloga France supplies drugs and other health products to distributors (wholesale distributors) who then deliver them to patients. The company is able to receive products from anywhere in the world and distribute them to the French market as well as to any country outside France.

The New Monitoring System Enables all Sites Within the Group to Stay Connected

Pharmaceutical management at Alloga France made the decision to replace the temperature-monitoring systems at each site with a new wireless probe system to adapt to each site's storage configuration, enable future development, create a documentation standard between all sites and, above all, to comply with quality standards.

Patrick Berger, Engineering Director at the Amiens site, oversaw the entire project at a national level for the five French sites: four storage sites and a server site. The Marseille server site is the Alloga France HQ and features a data center with array-based replication and Vaisala viewLinc software installed on a virtual computer. The four storage sites are warehouses that enable reception, storage, preparation, and shipping of pharmaceutical product orders.



There are temperature-controlled areas at each of these sites – Amiens (31,000 m²), Arras (25,000 m²), Lyon (28,000 m²), Angers (20,000 m²) – with a temperature of +15 °C ... +25 °C, and also different types of cold rooms with a temperature of +2 °C ... +8 °C. Specifications stipulated compliance with CFR21 part 11 and Good Distribution Practices (GDP); the software, in the form of a web application, had to handle MKT

(mean kinetic temperature). The Vaisala viewLinc solution met all these requirements.

Regarding the distribution and the number of data loggers, a mapping service was provided by Alloga. This delivered up-to-date knowledge of the premises, warehouses, and cold rooms, making it possible to know exactly where the data loggers should be positioned. Hot/cold points and



sources of variability were taken into account to ensure good distribution according to a logical procedure ready for presentation in the event of an inspection.

Importance of the Quality of Calibration

A total of 76 data loggers representing 84 humidity and temperature-measuring channels were installed across the four sites: Vaisala HMT143 loggers for temperature only, featuring Pt100 probes, and Vaisala HMT141 loggers for temperature and humidity measurement, featuring the patented Vaisala HUMICAP® capacitive polymer sensor.

In compliance with the specifications, each Vaisala data logger is delivered with a calibration certificate fully traceable to a reference standard (NIST, National Institute of Standards

and Technology). Calibration is performed at the plant by the Vaisala Measurement Standards Laboratory (MSL) calibration laboratory. Annual calibration of all temperature and humidity probes in compliance with GDP is also included.

Reliability of the Wireless Solution

One of the potential problems when rolling out a new wireless monitoring system lies in data communication. Thanks to the HMT140 utility module, the level and quality of the initial Wi-Fi signal can be verified for each data logger.

In addition, to ensure successful rollout and check communication quality, tests were run at the Amiens site for several weeks, where the positions of the two demonstration loggers were regularly changed.

Challenge

- Installation of a continuous temperature-monitoring system in compliance with CFR21 part 11 requirements and GDP and GMP guidelines
- Rollout at several sites, including administrator and operator training in different departments such as quality, IT, and maintenance
- User-friendly and upgradable system enabling future temperature monitoring of other equipment, including freezers and climatic test chambers
- System validation, IQ/OQ protocol, including compliance with CFR 21 part 11

Solutions

- Regulatory compliance, in particular with CFR 21 part 11
- Vaisala viewLinc software installed on a central server; all loggers configured in a few days, and existing Wi-Fi network utilized
- Probe installation solution that required no cabling in the pallet storage rooms
- Easy rollout on all sites and quick training for all those working with the system

Benefits

- **User-friendly interface:** browser-based access
- **Multi-site management:** initial creation of standard reports for all sites
- **Simple report customization via copy/paste functionality to create documents specific to certain areas.** These automated reports provide substantial time savings. Secure positions and events report history
- **Flexible alerts:** pop-up, email, and remote alarms via mobile device
- **Customized access rights** based on user responsibilities



"The Vaisala team provided a rapid, professional response to our requirement to replace the temperature-monitoring system at our sites. The technical proposal was confirmed by on-site tests at one of our sites with the material recommended by Vaisala. The wireless solution worked with all the configurations on the sites, including high rack storage," says Patrick Berger.

The final rollout of the solution took place over several weeks for all sites. The data loggers were sent directly to the Marseille IT department for internal configuration and identification, and then installed at the remote sites. After this step, general commissioning and validation (IQ/OQ protocol) were completed by Vaisala in only a few days. The IQ/OQ protocol from Vaisala is a turnkey solution that can be quickly and easily completed. All future developments are also taken into account in terms of validation. For example, the hardware addition protocol is designed to enable the addition of another site or data logger to viewLinc. User training on the viewLinc software and the system was delivered at all sites with support from Berger.

User-friendliness and Flexibility Were Decisive Factors

Five companies were initially asked to submit bids for the project. The user-friendliness and regulatory compliance of the Vaisala viewLinc solution as well as the responsiveness of the Vaisala team were key points in influencing the final choice.

The different functions of the Vaisala viewLinc web application, including the option to fully customize each report, generate standard reports for the entire group, limit user access to certain areas (each user seeing only their own site in the application, and access privileges for certain administrators to configuration

functions), and multi-site access were particularly decisive.

"Easy system installation, quick user training, and user-friendly interfaces make viewLinc the software that completely fulfills our clients' quality requirements," Berger says.

Thanks to our partners at Alloga, who are always willing to help during the course of a genuine long-term project partnership before, during, and after installation, the rollout of the Vaisala solution has been a success.

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