

AstraZeneca Increases Efficiency with Continuous Monitoring System in Leading Manufacturing Facility



improve their monitoring capabilities, for example, in regards to automating the checking of measurement points.

Project Manager Mats Andersson was responsible for the selection and installation project of the system for AstraZeneca: “We made a careful evaluation of various systems. Vaisala was one of the candidates as we had long experience with their monitoring instruments. We were quite sure their system would fit our needs, and our thorough evaluation proved it was so.”

AstraZeneca is a global, science-led biopharmaceutical business. They are one of a handful of companies to span the entire life cycle of a medicine – from research and development to manufacturing and supply – as well as the global commercialization of primary care and specialty care medicines. Operating in more than 100 countries, AstraZeneca employs around 57,500 people worldwide. The company has manufacturing operations in 17 countries, and their innovative medicines are used by millions of patients worldwide.

To ensure the products are protected during manufacturing, packaging, and storage, AstraZeneca maintains strict controls over environmental parameters. The company adheres to cGMP (Current Good Manufacturing Practices) and strives to meet or exceed all requirements that ensure purity, safety, and efficacy, from manufacture to final distribution.

AstraZeneca’s leading high-technology facility is located in Södertälje, Sweden and is one of the biggest tablet manufacturing facilities in the world. In 2015 it employed around 3,200 people.

In 2013, AstraZeneca Sweden Operations decided to acquire a new monitoring system for the Södertälje plant. They wanted to further

“Vaisala Continuous Monitoring System is easily scalable without extra costs, increases our efficiency with its remote reading abilities and ease of use, and the measurements are very accurate. Having used Vaisala’s measurement instruments for several years in the AstraZeneca facilities in Sweden, we trusted their quality. We look forward to continuing the good cooperation with them.”

Challenge

- **Historical Reporting**
To ensure compliance, all pharmaceutical companies must have reporting capabilities that prove adherence to the strict regulations within the industry and satisfy auditors.
- **Guaranteed Product Quality**
AstraZeneca adheres to cGMP (Current Good Manufacturing Practices) and has its own strict quality standards. The production area consists of several environments, which are kept in precise, regulated conditions.
- **Internal Efficiency**
AstraZeneca wanted to have a modern and reliable system with automated readings that would enable a more efficient way of working.

AstraZeneca's key considerations for the new monitoring system were the reliability of the measurements, the monitoring options, and the possibility to extend the system according to their needs.

"With no need to check the monitoring points manually, we can further increase the efficiency of our operation," says Mikael Ruda, Associate Director for Maintenance at the Södertälje plant.

The phased project was kicked off quickly and efficiently in 2014. In the first phase, Vaisala installed and validated their part of the project within one week. After that, AstraZeneca continued with their own validation and other preparations. In the next phases of the installation project, AstraZeneca added a lot of instruments to the system themselves: "In a vast facility such as Södertälje, it's a

Solution

- **High Performing System**
Vaisala Continuous Monitoring System can use a wide array of high-performance sensors to measure temperature, humidity, differential pressure, and more. Flexible, user-selectable notification options allow alarms to be sent via email or text to PCs and mobile phones.
- **Meet Quality Standards**
When monitoring the environment in real-time, AstraZeneca can ensure that they meet their own high quality standards and the strict regulations of the industry.

An extensive humidity and temperature mapping carried out by Vaisala in a large part of AstraZeneca's production environment in Södertälje gives AstraZeneca detailed information to further improve their operations.
- **Increased Internal Efficiency**
The Vaisala Continuous Monitoring System provides secure, permission-based access from any PC on AstraZeneca's existing network. The license allows for an unlimited increase in the number of both data loggers and users to the system. The real-time, remotely readable data increases internal efficiency, as manual readings of the data loggers are no longer necessary.



Benefits

- **Scalable Solution**
The ViewLinc software is fully scalable without extra cost, so AstraZeneca can add new data loggers to the system, and extend it to as many users as they consider necessary.
- **Efficiency**
Reduction in man-hours through remote and automatic reporting and monitoring.
- **Regulatory Compliance**
Quick, easy reporting allows AstraZeneca to prove compliance to multiple governmental and regulatory agencies. Reports are compliant with FDA 21 CFR Part 11, including an audit trail and several graphing and reporting options.

big benefit that we can add, and especially validate, new instruments by ourselves and expand the system with new and even existing instruments. We have done many extensions since the start of the project," Andersson says.

After the initial installation for a group of super users at the end of 2014, AstraZeneca extended access to the system to other factory personnel who use it in their daily work.

With Vaisala Continuous Monitoring System, AstraZeneca collects information about temperature, humidity, and differential pressure in the production facility. This information is being used to safeguard product quality. Since Vaisala Continuous Monitoring System also fulfills regulatory requirements, AstraZeneca can easily demonstrate their compliance to regulators.

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