

## Continuous monitoring system brings peace of mind

### PCI selects Vaisala monitoring equipment to ensure quality

Headquartered in Philadelphia, USA, Packaging Coordinators Inc. (PCI) is a global leader in pharmaceutical packaging solutions.

Partnering with global pharmaceutical manufacturers, PCI offers packaging services from early phase clinical studies through to commercial launch, and on-going supply.

Due to the unique requirements of a new project, PCI's UK facility in Hay on Wye had a need to upgrade its environmental monitoring system for one of their warehouses. The redefined system needed to provide real-time temperature information and reliable alarm and reporting capabilities, whilst also eliminating manual processes for reviewing and archiving data.



#### System upgrade required

PCI prides itself on reliable and flexible operations, working with customers to ensure their needs are met. "The new project prescribed that drug product was monitored at temperatures as low as  $-80^{\circ}\text{C}$ ," explains Lee Tatton, Facilities and Utilities Supervisor at PCI.

"We needed a system that could monitor conditions remotely when the site was not manned and we also wanted to ensure that the data was safe and segregated. The current system was not able to manage all the customers' requirements, and as such we considered it the right time to invest in an upgraded system

which could eliminate manual processes, have reliable alarm and reporting capabilities, and provide easy and accessible real-time temperature monitoring in critical areas. We also wanted to ensure the chosen system would meet any future needs, for example regarding electronic signatures."

#### Challenge

- To remotely monitor a warehouse and its freezers
- To ensure that products are always stored, processed, and handled according to product specifications
- To generate accurate alarms on temperature excursions
- To generate reports that prove adherence to regulatory requirements

#### Solution

- Vaisala Continuous Monitoring System with redundant recording: data logger histories are stored on PCI's server, on user PCs, and in each data logger's memory at the point of measurement
- Flexible, user-selectable notification options that allow alarms to be sent via email to PCs and mobile phones

#### Benefits

- Reduction in man-hours through remote and automatic reporting and monitoring
- Triple redundant recording provides total data protection
- Quick, easy reporting allows PCI to prove compliance to multiple governmental and regulatory agencies
- Personnel have more awareness of changing and baseline conditions with real-time trends and user-configured alarms

*“Losing the stock would be just the tip of the iceberg. It would mean a loss of R&D investment, lost client commitments, and missed business opportunities. Most importantly the new system gives peace of mind.”*

**Lee Tatton**  
Facilities and Utilities Supervisor  
Packaging Coordinators Inc. (PCI)

## New system to ensure fail-safe operation

PCI reviewed a variety of monitoring systems that could address their challenges. After evaluating the options available it was agreed that the Vaisala Continuous Monitoring System could meet all of the company's needs and the contract was awarded.

“Regulatory compliance is critical in the pharmaceutical market” states Mr. Tatton. “However, it is not just about compliance and providing necessary data, it is also about how accessible that data is. Browser-based access allows users to create custom reports on demand, whilst frequently run reports can be automatically generated and delivered by email on a set schedule. Reports can also be generated quickly and easily for the regulatory auditors, who visit PCI frequently throughout the year.”

One of the key requirements from PCI was the use of wireless monitoring. As the reliability of wireless systems is often questioned the company needed to be sure that their data was safe at all times. One of the key reasons PCI chose to use Vaisala was the reliability of their wireless data loggers with on-board memory, and which operate independently regardless of network connectivity. As the data is logged locally, it is safe even during power outages. Data is



Lee Tatton (middle) with Stefan Danyliw (left) and Katri Heikkilä from Vaisala.

then automatically backfilled to the server and client PCs, ensuring gap-free data.

The Vaisala monitoring system supports PCI's business model and is intuitive to use. “The system will become even more valuable as our teams become more familiar with the system and the data it provides,” says Mr. Tatton. “Thanks to the system's remote monitoring capabilities, personnel no longer have to collect data manually, reducing workload and ensuring resource efficiencies.”

The Vaisala system supports laboratory, storage and distribution, and production personnel in their day-to-day work, readily identifying issues, supporting customer requests, and ensuring compliance with regulatory requirements.

## Partnering for success

PCI's timeline for the project was challenging, and a lot of background installation, including the continuous monitoring system, had to be carried out before the freezers could be installed into the warehouse. Vaisala worked with PCI to draft a comprehensive installation plan for

the rollout of the project and also carried out a series of staff training courses. PCI executed the system validation themselves, adopting the validation process and protocol from Vaisala. “It was a very large protocol but thanks to help from Vaisala and step-by-step instructions, it was easy to follow and complete in a reasonable amount of time,” says Tim Davies, Validation Specialist.

“In a highly regulated industry it is important to utilise the most reliable and innovative products available to meet the need of your project” points out Mr. Tatton, “Knowing that your chosen partner understands these needs and works with you to deliver the right solution is paramount and delivers peace of mind.”

During negotiations the scope of the project changed and as such the solution has been expanded to a site wide system covering cold rooms, laboratories, stability chambers, and the manufacturing area. Moving forward Mr. Tatton is sure this system will continue to give PCI the innovation and scope to meet its future needs and the needs of its customers.

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