



The manufacturing of drugs and other pharmaceutical products is strictly controlled by the GMP guidelines.

Validated Data even in the Most Demanding Environments

Vaisala's Humidity Measurement in the Pharmaceutical Industry

Orion Corporation, the Finnish pharmaceutical company, uses Vaisala's humidity and temperature transmitters as part of a validated system that provides measurement data in all manufacturing and storage facilities at Orion's premises in Turku. The system follows strict Good Manufacturing Practice (GMP) guidelines.

Orion is a research and development oriented pharmaceuticals company, the leading enterprise in its field in Finland. With an investment of approximately

15 percent of the consolidated annual net sales, Orion is strongly devoted to exploring new medicinal treatments. Pharmaceutical R&D at Orion focuses on three therapy areas: Central Nervous System (CNS) disorders and Urological and Critical Care therapies. New innovative pharmaceutical products are discovered, developed, manufactured and marketed both for human and animal health.

Orion's operations include a broad selection of human and veterinary preparations, as well as active pharmaceutical ingredients, with established marketing and sales operations in most European markets. The research and development and production units of Orion are situated in Finland, in several locations. Orion also has a clinical research center in the UK.

Validated system for production control

Orion's Turku premises have used Vaisala products more than ten years to measure relative humidity and temperature, both indoors and outdoors. They have a separate, validated system to measure conditions in laboratories, production, packaging and storage rooms. In addition to humidity and temperature, other variables are also measured. Measured conditions vary from normal room conditions to more demanding environments.

GMP – Good Manufacturing Practice

The pharmaceutical industry follows Good Manufacturing Practice (GMP) regulations on safety and quality in manufacturing pharmaceutical preparations. According to the World Health Organization (WHO), Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. GMP covers all aspects of production from raw materials, premises and equipment, to the training and personal hygiene of staff. Detailed, written procedures are essential for

everything that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step of the manufacturing process, every time a product is made.

"Compared to ISO9000 quality systems, GMP is much stricter," says Jyrki Salminen from Orion's maintenance department. Orion's validated measurement system fulfils the GMP regulations. The objective of the system is to provide proven information about the environment in Orion at all stages of production.

Superior accuracy and easy calibration

Vaisala was the clear winner when the supplier for new installations was decided upon, due to the superior performance of their instruments. "With Vaisala instruments we can always be sure the readings are true – if the signal is zero, it really means zero! This is a simple thing as such, but it was not so obvious with the other instruments we tested," points out Mr. Salminen.

Easy calibration was also found to be a clear advantage for Vaisala. "Each measurement instrument is calibrated

and adjusted both in the sensor and as part of the measurement system. Because of the validated system, the measurement instruments cannot be dismantled for calibration. Vaisala could offer us the solution – the HMK15 Salt Bath Calibrator and the HMI41 Indicator with HMP45 Humidity and Temperature Probe - for on-site calibration and adjustment. We are extremely happy with it," says Pasi Kollanus, Safety Manager of Orion's Turku site.

Vaisala humidity transmitter for wash-down areas

Moreover, Vaisala's technology provided a solution for humidity measurements in spaces that are often washed. "Our production facilities are high pressure cleaned with water once or even twice a day. Traditional humidity transmitters show overscale for hours after washing due to water in the sensor. Vaisala HUMICAP® Humidity and Temperature Transmitter with warmed probe recovers much faster from such humidities and we have therefore used them to equip our wash-down areas," says Mr. Salminen.

The pictures of the manufacturing site and Mr. Kollanus and Mr. Salminen.



Pasi Kollanus ja Jyrki Salminen from Orion's maintenance department.

Vaisala HUMICAP® Humidity and Temperature Transmitter HMT330



Even Further Improved Performance and Better Connectivity

Unique Warmed Probe

Vaisala's unique warmed probe provides fast and reliable dewpoint measurements in environments where humidity almost reaches saturation. The sensor also recovers very fast from condensation in extreme conditions.

Data Logging Option

The data logging module has an enhanced memory that can store data of three measured parameters. When logging is fixed at 10 second intervals, data can be stored for more than 4 years. A real-time clock with a battery backup ensures accurate date and time stamps even when no power is supplied to the transmitter. The stored data can be viewed graphically

on the display throughout the logging period, and the user can zoom in and out as necessary. Any period of measured results can be downloaded via a serial interface to a computer.

LAN and WLAN options

HMT330 transmitter has been upgraded with LAN and WLAN communication options and a display alarm. With the new Ethernet communication options you can connect the transmitter into a computer network and easily add a new humidity transmitter to an existing Ethernet network. Also, applications that do not allow holes through walls and ceilings, or the installation of new cables, benefit from this solution.

Display Alarm

A new display alarm function is now a standard feature in Vaisala humidity transmitters equipped with a built-in display. With this function the user can set alarm trigger limits for two distinct measured quantities. When the trigger limits are exceeded, a real-time alarm appears on the display.

www.vaisala.com/humidity

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