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Vaisala's Humidity Measurement in the Pharmaceutical Industry

# Validated Data even in the Most Demanding Environments

Orion Pharma, the leading Finnish pharmaceutical company, has awarded a contract to Vaisala to support their operations. Vaisala's HMP233 and HMP243 Humidity and Temperature Transmitters are used 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 Pharma is a research and development oriented pharmaceutical division of the Orion Group, the leading Finnish company specializing in healthcare products. Pharmaceutical R&D at Orion Pharma focuses on four therapy areas: Central Nervous System (CNS) disorders, Cardiology and Critical Care, Hormonal therapies, and Respiratory disorders. New innovative pharmaceutical products are discovered, developed, manufactured and marketed both for human and animal health.

In Scandinavia, which is Orion Pharma's home territory, company operations include a broad selection of human and veterinary preparations, as well as active pharmaceutical ingredients. In Finland, Orion Pharma is the leading supplier of pharmaceuticals with a 13% market share.

The research and development and production units of Orion Pharma are situated in several locations in Finland. Orion Pharma also has a research and development center in Nottingham, United Kingdom, which focuses on cardiovascular and CNS drug development. Moreover, subsidiaries in Denmark, Germany, the UK, France and Sweden have medical departments. In the US, ➤

*Mr. Pasi Kollanus (right) and Mr. Jyrki Salminen from Orion Pharma's maintenance department in Turku.*

Orion Pharma collaborates in clinical research projects with partners.

## Validated system for production control

Orion Pharma's Turku premises have used Vaisala products for a decade to measure relative humidity and temperature, both indoors and outdoors. They are now building 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 Mr. Salminen from Orion Pharma's maintenance department. Orion Pharma's validated measurement system fulfils GMP regulations. The objective of the system is to provide proven information about the environment in Orion Pharma 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 Mr. Kollanus, Maintenance Manager of Orion Pharma, Turku.

## HMP243 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's HMP243 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 manufacturing of drugs and other pharmaceutical products is strictly controlled by GMP guidelines.*

# Vaisala HMP233 Humidity and Temperature Transmitter for tight places

The HMP233 is a versatile and easy-to-use transmitter for demanding industrial and air conditioning applications. The transmitter measures relative humidity and temperature, and also outputs dewpoint and wet bulb temperature as calculated variables, mixing ratio and absolute humidity. The HMP233 Transmitter can be configured to the customer's requirements on the production line; configuration and parameters can also be set by the user. Both analog and serial outputs are available as well as several other options: different cable lengths, power supply modules, serial interface modules and a local display.

The sensor head in the HMP233 Transmitter is small and fits into tight spaces. It can be fitted with two different cables: one is for lower temperatures of up to +80 °C and the other is for temperatures of up to +120 °C. ●

*The HMP233 is suitable for duct installations, tight spaces and outdoor installations.*

# Vaisala HMP243 Humidity and Temperature Transmitter - designed for use in high humidity

The Vaisala HMP243 Humidity and Temperature Transmitter is specially designed for reliable and fast dewpoint measurement at high humidities and/or rapidly changing temperatures, where condensing water vapor has been a problem. The HMP243 incorporates Vaisala's advanced HUMICAP® technology and a warmed probe head to guarantee accurate and reliable dewpoint measurement even in condensing environments.

The HMP243 works well both at lower humidities and in saturating conditions. In addition to industrial applications it is suitable for use in outdoor/meteorological applications where sudden temperature changes and windy conditions can occur. The HMP243 Transmitter is fully configurable and outputs dewpoint, relative humidity, ppmv and temperature.

## Excellent Performance under High Humidity

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. As the probe is warmed, the humidity level inside the head stays below the ambient. With accurate temperature measurement the dewpoint of the ambient environment can be precisely calculated. ●

*The HMP243 can be equipped with an optional temperature sensor for ambient temperature and relative humidity measurement.*