Perspectives On: Instrumentation

Is Your RH System Safe?

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In the pharmaceutical industry, relative humidity (RH) must be carefully controlled to ensure suitable manufacturing and storage environments and to assure proper stability testing. If the RH rises or falls above pre-established parameters, it can jeopardize product quality, derail FDA submissions, increase liability and damage a company's reputation. And while many companies rely on RH regulating control systems to monitor and control humidity within their facilities, few realize just how sensitive and prone to distortion RH sensors can be.

Factors That Affect Sensor Functionality

RH sensors are "air breathers." Like tiny sponges, they "absorb" water vapor from the air. To function properly, RH sensors must maintain intimate contact with the environment. Unfortunately, this exposure leaves sensors vulnerable to airborne contaminants such as chemicals and cleaners, which can coat or permanently damage a sensor's surface, prevent it from properly absorbing water vapor and ultimately distort its signal.

Even simple condensation can affect an RH sensor's accuracy. If the door to a high humidity environment is opened, for example, condensation may form on the RH sensor inside. Long after the RH reading appears normal, the sensor can remain wet internally causing an offset in value and it may need to be removed and dried before it can once again provide accurate readings.

To ensure RH remains within a given range, many companies install RH system alarms. However, as I'll demonstrate below, these alarms provide a false sense of security. In reality, RH sensors can drift – and RH can stray well outside pre-established parameters – without any notification from the alarm system.

RH control systems work by measuring the current RH, comparing it against a desired setpoint and automatically increasing or decreasing humidity as necessary to achieve and maintain the setpoint. RH sensors convey information via electrical signals that are proportionate to the amount of RH detected. For every 10 percentage points that humidity varies, for example, the sensor might send a 1-volt signal. RH recorders, displays and system alarms work by monitoring these same electrical signals. The alarm system will alert users if they stray outside a pre-defined range (e.g. 35%-45%, or 3.5V-4.5V).

If an RH sensor has been damaged or contaminated, it might send a signal of 4V, indicating 40% humidity – and the system display would reflect this – when in reality the relative humidity might be just 38%. As this sensor drifts over time, it may continue sending a 4V signal, when RH is just 36%, then 34%, and so on until the RH is well outside the pre-defined range of 35%-45%. And yet, because the RH alarm system relies on the sensor signal, and the signal remains at 4V, the alarm system will not be activated and the system display and recorder will look normal.

What To Do To Protect Your Processes

How can your company protect itself from the challenges inherent in RH sensors? By incorporating redundancy and using two RH sensors – one to regulate the RH and a second, independent sensor to monitor the system. The second sensor will verify the results from the primary sensor and highlight any irregularities or discrepancies. And, while it's technically possible for both sensors to become distorted, the likelihood that both will drift at exactly the same rate, and exactly the same time, is miniscule. As long as there's variation between the two, you'll know a potential problem exists.

In addition to verifying the results of your primary RH sensor, a secondary sensor can provide continuous monitoring during primary system failures. The secondary sensor will supply a valuable record of RH levels throughout the system failure, enabling you to identify potential problems that may have occurred as a result.

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To maximize the benefit from your secondary sensor system, choose one with an extended battery life. If your primary system is knocked out due to power failure, your secondary system may need to function on battery power for an extended period of time. Some sensors have batteries that last 10 years while others are unlikely to last through a long weekend.

To minimize malfunctions and down time, choose a secondary RH system that's easy to use, with a minimum number of moving parts. Chart recorder's pens, for example, can run out of ink and recorder paper must be replaced regularly. A better option might be a data logger, which is self-contained, has no moving parts and can be installed in minutes.

For the most accurate results, place sensors as far apart as possible within the monitored environment. This way, if contamination or condensation occurs in one area of the space, the chance of both sensors being affected in the same way is greatly reduced. Also, because temperature variations can have a significant impact on RH, the RH in an environment is much less uniform than you might think. In a stability chamber operating at 40°C and 75% RH, for example, 1°C of nonuniformity will cause a 4% variation in RH. While the amount of water in the air may remain close to constant, the RH may not. Positioning sensors at multiple monitoring points gives you a much more accurate idea of what's happening throughout the environment.

While risk reduction through redundancy is common in many other process control applications, the pharmaceutical industry has been slow to adopt this practice. This may be due in part to price – it used to cost several thousand dollars to set up a second RH sensor system. Today, however, when a complete, self-contained secondary monitoring system can be purchased for around a third as much, there's simply no excuse for not protecting your company's operations, products, clients and reputation by building redundancy into RH regulating systems. ■