

Environmental Data Tracking **GOES WIRELESS**

KV Pharmaceutical is turning to wireless mesh networking technology as a way to save money, while reliably meeting regulatory requirements for temperature and humidity monitoring.
By Wes Iversen, Managing Editor

As a manufacturer of generic and branded drugs using proprietary drug delivery systems such as time-release and site-release processes, St. Louis-based KV Pharmaceutical Co. is subject to plenty of federal regulation.

"Being in a regulated industry, we're required to do environmental monitoring for temperature, relative humidity and that kind of thing. We're required to monitor those things and record them, so that we can present those data to the FDA (Food and Drug Administration) if requested," notes Chip Bennett, validation specialist at the company.

For KV Pharmaceutical, this once meant the need for hundreds of permanent chart recorders wired to sensors throughout the company's multiple St. Louis area facilities. And when the time came for periodic revalidation based on data from so-called "temperature maps" of a warehouse, stability chamber or other facility, for example, KV Pharmaceutical personnel would string temporary wires with attached thermocouples throughout the facility to gather the necessary temperature data.

Today, though, that is rapidly changing, as the company converts to mesh network-based wireless systems—both for revalidation and for permanent environmental monitoring. The wireless systems, supplied by GE Sensing, a Billerica, Mass.-based division of General Electric Co., rely on wireless mesh technology from Dust Networks Inc., based in Hayward, Calif. And according to Bennett,

the technology is not only easier to install and maintain, with vastly superior scalability, but it is also much more cost-effective than previous approaches. Return on investment (ROI) is "considerably less than a year," he says, for the wireless permanent monitoring systems installed by KV Pharmaceutical to date.

LABOR INTENSIVE

The traditional monitoring method based on chart recorders has various drawbacks, says Bennett. One of the largest is that maintenance is labor intensive. "You have personnel constantly going around to maintain the chart recorders and replace recorder papers weekly," he notes, "and when you've got hundreds of monitoring locations spread over several locations that may be miles apart, as we have here, that only compounds the problem."

To avoid these issues, KV Pharmaceutical began replacing its chart recorders with GE Sensing's Kaye LabWatch systems, which use sensors with integrated input/output hardware that are networked for alarming, data acquisition and storage, viewing and reporting from a central location. These initial systems relied on wires to connect the sensors. But around mid-year 2005, KV Pharmaceutical began making the switch to the wireless version of the LabWatch system, says Bennett.

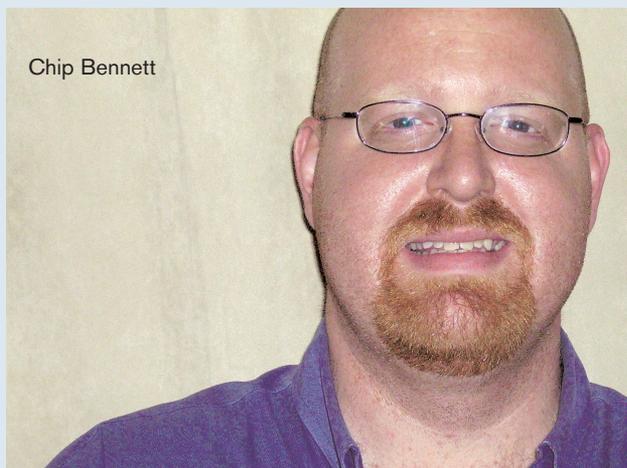
With the 2.4 Gigahertz wireless LabWatch system, which uses self-organizing mesh network technology based on the Institute of

Electrical and Electronics Engineers' IEEE 802.15.4 standard, "it's much easier to locate sensors wherever you need them," Bennett observes. "It's much easier to maintain because you don't have to worry about a wiring system, and it's a whole lot more scalable."

The wireless LabWatch systems work primarily with temperature and/or relative humidity sensors at KV Pharmaceutical, depending on the application. Current sensor locations include processing areas, manufacturing rooms, packaging areas, drying ovens, stability chambers, incubators and cold storage areas.

"We currently have LabWatch systems installed in five facilities," says Bennett; this encompasses a total of about 200 wireless monitoring points. A sixth location is currently being added, and Bennett plans to request funding next year to add wireless LabWatch systems at the company's two remaining primary manufacturing facilities.

The LabWatch systems monitor environmental conditions continuously. In most cases, only one sensor is mounted within a room or area, in a spot that is deemed to be the "worst-case" location for variability of the parameter being monitored, Bennett says. Determining that "worst-case" location is done during periodic required revalidation tests through temperature mapping, which is done using another system provided by GE Sensing.



Chip Bennett

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“Generating temperature map data is a requirement for validation [and revalidation] of a facility, a process or a stability chamber—demonstrating the temperature change across the entire volume,” Bennett notes. The traditional way of doing this, he says, is to string up typically 15 or 27 wired thermocouples in a given area, where they are used to gather temperatures for a designated time period—in some cases, up to 30 days. The thermocouples are arranged in a three-plane grid with either five or nine monitoring points to create the “temperature map,” Bennett explains. Each sensor wire—up to 30 feet in length—is linked back to a central data collection unit such as GE Sensing’s Kaye Validator 2000.

When the study is complete, the temperature map data can be used to prove that air handling systems are maintaining temperatures in line with regulatory requirements. The data can also be used to determine the “worst-case” location for monitoring, says Bennett, which can then be the point where a LabWatch sensor is installed to perform permanent, constant monitoring until the next required revalidation. Facilities must typically be revalidated every two years.

The approach using the wire-based Validator 2000 system has lots of limitations, however. In warehouses and other areas where people must work, the thermocouple wires can get in the way, and are frequently damaged,

Bennett notes. And if a facility is very large, it becomes impossible to string the temporary wires for long enough distances, forcing a fall-back to use of chart recorders, he adds.

Further, when wired thermocouple systems are practical for use, they are time- and labor-intensive to put up. “You’re up and down a lot of ladders,” says Bennett. “It takes easily a couple of hours to set up, and it’s the same thing removing it once the study is completed.”

WIRELESS VALIDATION

KV Pharmaceutical’s validation group expects to overcome many of these problems, however, by converting to a wireless system for temperature map validation studies. The company is currently testing a portable, wireless mesh network-based validation system, also from GE Sensing, known as the RF Valprobe. And the early results look promising.

The integrated RF Valprobe sensor units are about the same 5-by-3-by-1-inch form factor as the sensors used in the wireless LabWatch system, notes Bennett. Because each unit has a range of several hundred feet, and communicates with the RF Valprobe base station via a self-forming mesh network, practical restrictions on the size of an area to be mapped are eliminated.

Further, set-up is significantly simplified. “It’s a whole lot easier to install a sensor and have it start recording data, compared to trying to string thermocouple wires everywhere.

And of course, there’s much less chance of something happening to the sensor,” Bennett adds. “Basically, all you do is plug in the base station, and then place the wireless sensors wherever you need them,” he notes. “When you’re done, you download the data to your computer, turn it off, and take it somewhere else to do another study.” Bennett expects ROI on the RF Valprobe system to be in the neighborhood of one year, based largely on labor and maintenance savings.

In general, Bennett says, he is well pleased with the wireless technology. He has replaced several wireless sensors used with LabWatch systems due to water damage that occurred during washdowns, he notes. But that situation should improve, Bennett says, with “a little bit of training to let people know what they are and the proper care for them.”

Reliability and security of the wireless technology is strong, Bennett believes. And so far, regulators seem to agree. “It’s very easy to defend data integrity with these systems,” he says. “You can show inspectors a report from a Validator 2000 and they pretty much won’t even question it. And I think the same thing generally holds true with the LabWatch and Valprobe data,” he adds, “because the same rigor has gone into ensuring data integrity.”

For more information, search keywords “**mesh network**” at www.automationworld.com.



KV Pharmaceutical relies on permanently installed LabWatch wireless sensors (left) for continuous monitoring of temperature and humidity. During validation, the wireless sensors used with the RF Valprobe system (right) can easily be placed temporarily wherever they are needed.

