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NEW TECHNOLOGY FOR THE PHARMACEUTICAL INDUSTRY

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Monitoring Systems You Can Have It All

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Pharmaceutical and biotechnology companies know that maintaining stable conditions in their chambers, incubators, research labs and storage facilities is critical. Significant variations in such vital parameters as temperature and relative humidity could adversely affect the quality and usability of the company's final product, or result in its failure to receive the necessary regulatory approvals.

That is why continuous, reliable monitoring and data collection of these environmental conditions is so important.

Historical records of the conditions under which pharmaceutical products have undergone stability testing or have been manufactured and stored are subject to stringent controls by regulatory bodies. Missing information could prompt a regulator to question what may have gone wrong.

Significant variations in such vital parameters as temperature and relative humidity could adversely affect the quality and usability of a company's final product.

If there is a breakdown in a lab or storage system – if the power goes out and a freezer starts to warm up, for instance – your monitoring system *must* alert you immediately so you can address the problem quickly to minimize potential damage. Companies that fail to rectify a problem rapidly could lose tens of thousands of dollars in wasted products, along with potentially higher costs due to recalls or legal issues. The ultimate cost is the blow to an organization's reputation

if a problem is not fixed quickly. With the increased cost of raw materials, now, more than ever, companies are motivated to do everything they can to prevent waste that could arise from inconsistent or inaccurate data collection. That means reliable monitoring systems are a must.

Currently, two technologies are on the market to continually monitor the conditions in chambers and storage units such as freezers, labs, warehouses and the like: decentralized and centralized systems. Each has its pros and cons.

However, a third type of monitoring system, the hybrid system, has become available to provide companies with the best characteristics of both decentralized *and* centralized systems. In short, when it comes to monitoring, the hybrid system lets your organization have it all.

Let's look at the decentralized and centralized methods:

Decentralized Monitoring System – the Chart Recorder

The chart recorder is currently the most common monitoring system on the market. This system, typically analog, has served as the industry standard for monitoring temperature and relative humidity conditions for more than 70 years.

Individual chart recorders, which use simple paper and ink to monitor conditions, are installed wherever they are needed in a facility; hence their “decentralized” label. This is one of their biggest advantages, since if one chart recorder fails, the other units will continue to operate.

However, in a large facility, there is no way for operators to keep track of all chart recorders simultaneously. Furthermore, there is often no alarming of Out of

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Tolerance (OOT) conditions, or in the event of a power outage or equipment failure. In addition, because chart recorders are mechanical devices with plenty of moving parts, the potential for breakdowns or problems with those parts is high. The ink supply may dry up. Or, moisture that may be present in the facility could be absorbed by the chart recorder's paper, affecting the accuracy of the readings. These may sound like minor inconveniences but could lead to tremendous product waste because of the impact on readings and the time required to fix them.

Another downside to the chart recorders is that once the data is recorded on the chart, it is difficult to use. Those who analyze multiple charts must manually transfer multiple points before they begin their analysis.

Furthermore, chart recorders cannot be viewed remotely. An individual must be on site to see whether the data is being consistently recorded, and to ensure the equipment is working. As well, it is difficult to back up data from chart recorders because the information collected is not electronic. Again, this could affect the reliability of data collection, along with the ability to retrieve it.

In our digital age, it might seem that the chart recorder should be facing the same fate as the vinyl record and rotary-dial telephone. Yet because chart recorders have been around for so long and meet regulatory standards, they are considered "legacy" systems that offer familiarity and comfort. For that reason, there is sometimes resistance to replacing this system for another more modern variety.

The Centralized Monitoring System

The centralized monitoring system brings data recording into the digital age. It is the second most common monitoring technology in use after the chart recorder.

This system consists of a network of remote sensors that are wired to centralized input panels, or multiplexers.

Central monitoring systems offer features such as remote data display, alarming and reporting. Unlike chart recorders, there is no need for manual data collection, resulting in significant savings of time compared with the manual system.

Data enters a centralized computer system, allowing it to be easily viewed in one place. Centralized monitoring systems offer full multi-stage alarming capability. It is easy to view the long-term trend data on your computer, making information collected easier to analyze than the chart recorder.

There are weaknesses, though. The initial capital costs of installing the centralized monitoring system can be high, while the addition of extra points later on could be expensive if outside installers are required, or if the central hardware, such as the multiplexers, must be expanded. And special wiring is needed to add incremental points, which can be costly.

A big concern is that if anything along the path goes wrong, the whole system is compromised. In other words, because all the sensor signals are processed centrally, through the same piece of hardware, one problem along the line could distort all the data collected, in much the same way as those old-fashioned strings of Christmas lights where one faulty bulb would send the whole string into darkness.

Centralized systems are also vulnerable to computer crashes, network or power failures or other incidents that can lead to missing data and unreliable reporting. And with some systems, data can only be viewed or retrieved at a central, versus a series of local locations.

The Hybrid Solution

Hybrid systems represent the best of both centralized and decentralized monitoring technology. Because each monitoring point is a data logger, not just a sensor, the system provides the redundancy and simplicity of a chart recorder. Meanwhile, because each data logger is networked together, the system offers the superior functionality of a centralized system.

The networked autonomous recorder, true to its name, consists of a network of independent loggers that run on internal lithium batteries. Each logger is an autonomous data-collection device that is connected to a facility's existing computer network. No expensive centralized system needs to be purchased and installed. Each device features integrated temperature or temperature and humidity sensors, memory and clock, along with real-time alarming.

All historical data is downloaded onto a computer server at time intervals set by the customer. For example, a company could program the system to archive the data every week or every month, eliminating the need to constantly download or physically collect the data.

Unlike chart recorders, the hybrid systems are solid state and require less maintenance because they have no moving parts.

Another plus is that with this digital system, there is no degradation or distortion of sensor data. It's easy to read and can be imported into spreadsheet, database or graphing programs for easy and precise analysis.

As for the all-important consideration of cost, hybrid systems don't represent a large investment. The individual data loggers are relatively inexpensive and can be added on incrementally. What many chart-recorder clients may not appreciate is that, over time, chart recorders are actually expensive to run because they are manual, requiring the frequent need to change charts and pens. They also require regular servicing.

Choosing the right data-monitoring system can be a complicated process, with much review of a particular system's upsides and downsides. Until recently, companies had the choice of only two data-monitoring systems. With the hybrid system, things have become easier. This third option offers companies the best of both worlds, offering easy installation and maintenance, accuracy, and reliability – all at a very reasonable cost. ■

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