Advanced Digital Sensors Improve Lifecycle Management

Digital sensors make it possible for the same sensor, lifecycle management software and SOPs to work in both lab and production environments.

By Steven Smith, Endress+Hauser

FIGURE 1. Digital sensors, such as these pH and conductivity probes in a fermenter production process, make it possible to use the same sensor in a process development lab, pilot plant and production process, thus simplifying scale-up.

The number of biopharmaceuticals in life sciences facilities is increasing, and these more complex drugs require more sophisticated sensor technologies. Pharma companies are responding by putting more reliance on digital sensors—such as pH, conductivity, dissolved oxygen and other probes (Figure 1) in labs, R&D, pilot plants and production. These advanced sensors require equally advanced lifecycle management procedures to meet various regulations, remain accurate, and receive maintenance when needed.

While the pharmaceutical industry has historically been more lab-centric than other process industries, Process Analytical Technology (PAT) approaches are being implemented and require a greater need for proper sensor lifecycle management in production environments as well as in the lab. With digital sensor technology, the best practices for sensor lifecycle management in lab environments also apply to sensors in pilot plants and production environments.

Sensors and PAT

Process analytical technology is driven by the United States Food and Drug Administration (FDA) to design, analyze and control pharmaceutical manufacturing processes through the measurement of the Critical Process Parameters (CPPs) affecting Critical Quality Attributes (CQAs). PAT aims to understand the processes by defining their CPPs, and by monitoring these processes in real time.

The goal of PAT is to develop processes that consistently generate higher quality products and improve efficiency through increased automation, reduction in cycle times, and uninterrupted batch and continuous processing. Such processes minimize rejection of products, thus improving efficiency. Uninterrupted processing also improves energy consumption, material usage and capacity. The move to PAT generates significant benefits by improving coordination of sensor management among lab, R&D and production environments.

PAT is FDA driven and is being implemented across the pharmaceutical industry with a heavy reliance placed on sensors used to monitor variables deemed critical to product quality in the production process. This need for advanced sensors in production environments does not take away from the need for lab-based sensors (Figure 2), but instead drives the need for a common best-practices approach for both lab and production sensors.

With digital sensor technology and lab-based sensor lifecycle-management tools, the same sensors in the lab and in production can be managed using the same approach.

pH Measurement with Digital Sensors

Historically, pH measurement systems—and their associated sensors—have been applied specifically for use in each unique environment. pH measurement systems used in the lab have always been managed in the lab, while pH systems used in pilot plants and on production lines have always been managed separately.

For example, an analog-based pH measurement system must be managed at its point of use with the sensor, cable and transmitter calibrated together (Figure 3).

FIGURE 2. The same pH sensor used for a fermentation process can also be used in R&D and the process plant's lab.

An analog pH probe generates a small mV signal that is measured by the transmitter and converted to pH by a calibration routine residing in the transmitter. Any physical variation in the sensor, or between the sensor and the transmitter, will result in deviation of the measured value.

Calibration is easier to accomplish and maintain in the lab because the sensor, cable and transmitter are all within close proximity of each other. The lab system is typically validated and calibrated under controlled conditions. This is not always true of a production system, so the same pH sensor and calibration procedure used in a lab may not work in a production plant.

To calibrate an analog sensor in the process, a technician would need to bring all the necessary cleaning and calibration materials to the measurement location. The sensor would need to be extracted from the process and the measurement would be lost for the entire cleaning and calibration process. The sensor would be cleaned and a two-step calibration would be performed.

Unlike traditional analog sensors, digital pH sensors make an analog mV measurement and convert it to a pH value using a calibration routine embedded in the sensor head. Digital sensors also record and store a number of other pieces of performance data, facilitating individual sensor lifecycle management. With digital sensors, the same sensors can be used in the lab, pilot plant and production—with all sensors managed with a common tool.

FIGURE 3. Analog pH sensor calibration system.

The pH value, raw mV value, temperature and even glass impedance are all digitally transmitted to the transmitter from the digital pH sensor as discrete values. In addition, information about the sensor—such as its model number, serial number, hours of operation, calibration factors, number of calibrations, date of last calibration, calibration buffer values, change in zero and slope, and operation time at extreme conditions—are all stored in the sensor. This information becomes a valuable tool for proper lifecycle management of a sensor, whether it is used in the lab or production.

When a digital sensor needs calibration, a technician can simply swap sensors; that is, replace the current sensor with a calibrated one. Lifecycle management software accesses all the necessary data contained in the sensor, so it does not need to be commissioned. Process downtime is reduced to the time needed to simply remove and replace the sensor, and the current sensor can be calibrated in the lab under very controlled conditions.

Digital sensors are also available with inductively coupled connections between the sensor and its cable (Figure 4). This type of connection removes the problems found with traditional metal-to-metal contacts found with other sensors. With no metal contacts, the sensor to cable connection is extremely reliable, and resistant to moisture and the effects of EMI or RFI interference.

FIGURE 5. PC-based life-cycle management software.

PC-Based Sensor Lifecycle Management Tools

PC-based sensor measurement and life-cycle management tools (Figure 5) are designed to be used with digital sensors. These tools functions as a lab-based measurement system, and as an advanced sensor calibration and maintenance tool with full documentation. With a PC-based system, all information including bench-top measurements, sensor calibrations and sensor data are stored in a common database.

With one common database and 21 CFR Part 11 Compliance, these systems track all activities associated with a sensor including data-logging of time, date and user. Calibrations associated with each individual sensor are stored in the data base for reporting at any time, even after the sensor has been disconnected from the system.

In case of an FDA review, such a system can provide sensor, calibration and measurement reports directly from its database that are approved and signed-off.

Reports required for validation are readily available from the database. In addition to tracking sensor information, these systems also store calibration standards information for full traceability. With automatic sensor recognition, the system tracks a sensor without any manual data entry, monitors performance over time, and reports on the health of the sensor.

When using a PC-based system, sample information is recorded and stored in the system database, eliminating the need for the manual data recording required with analog sensors. Standard one- and two-point calibrations can be performed along with multi-point sensor adjustments by selecting individual points for calibration, adjustment or removal.

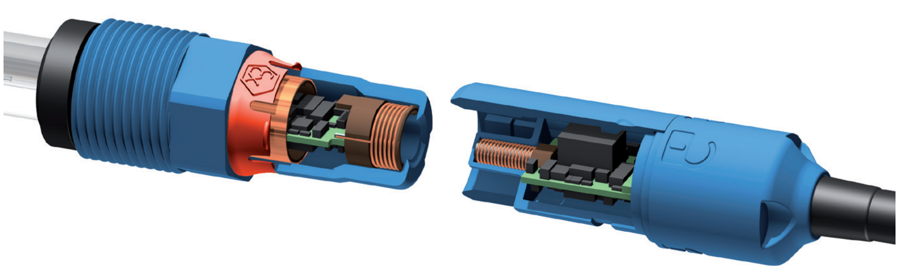

FIGURE 4. Inductively-coupled connection between a digital pH sensor and the cable connecting it the transmitter eliminates problems with moisture and interference.

Multipoint adjustment can provide higher measurement reliability and improved sensor evaluation.

For standard operating procedures (SOPs) specifying a multipoint calibration, this functionality allows for easy adaptation. As part of the calibration, “as-found/as-left” data can be selected with deviation monitoring, leading to a better understanding of the sensor’s performance profile.

A PC-based system also provides advanced diagnostics to detect measurement problems. Additional diagnostic functions allow for editable sensor limits, such as slope or zero offset. Pre-defined limits exist within the system or they can be defined by the user. When a calibration is performed, the system will evaluate the sensor based on these criteria to ensure the sensor is within limits. This approach allows for simplified sensor evaluation, improving safety and minimizing the risk that an out of spec sensor is returned to use.

Sensor Management Best Practices

Best practices in sensor management require the right tools and prescribed SOPs for sensor maintenance. With pH probes, sensor performance in the lab and process (pilot or production) is highly dependent on the condition and the cleanliness of the sensor. Calibrating a pH probe without cleaning the sensor first is a self-defeating process.

Proper sensor management begins with initial documentation of the sensor. This can be accomplished by connecting the sensor to a PC-based tool to extract and log the sensor information in a database. This initial record sets a baseline for the sensor in its life-cycle management, and once recorded the sensor can be used for lab-based or process measurements. From this point forward, users can define their own maintenance and calibration schedule using sensor data recorded in the PC-based system.

The sensor should be cleaned on a routine basis using a range of methods depending on the environment to which the sensor has been exposed. A calibration check should also be performed in buffer solutions. If verification readings are within tolerance for the process, sensor cleaning and verification may be all that is required, with no need for a calibration check.

If calibration is called for, a PC-based system walks the user through the process and documents not only the calibration, but the buffer solutions used in the calibration. There is no need for manual documentation because the system automatically stores the information, with report printouts available if required.

Summary

Digital sensor technology facilitates more efficient and effective sensor management. It also allows for the application of the same sensors in the lab, pilot and production environments by using a common platform for sensor lifecycle management. With a PC-based system, sensor management is controlled, validated and documented. Manual documentation is eliminated and sensor maintenance requirements are reduced, yielding lower costs and improved measurements.

When scaling up from R&D to a process development lab, then to a pilot plant, and finally to production, being able to use the same sensors and lifecycle-management tools helps simplify the entire project.

About the author

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