collaboration

Life Sciences Edition

Endress+Hauser
People for Process Automation

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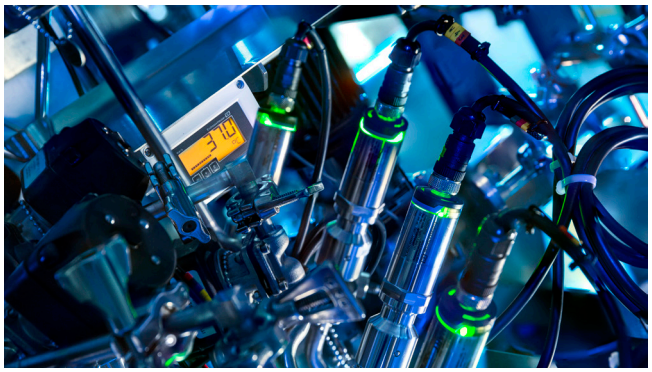

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Increase Bioprocess Productivity with Innovative Technology

Dear Reader,

Welcome to collaboration – Life Sciences edition

The Life Science Industry is driven heavily by developments such as aging societies, growing populations and expanded access to health care services in emerging and developing countries. These developments are providing steady, above average growth in the US. The industry has undergone major changes and has now shifted its focus to research and development, strengthening the portfolio and pipelines and Endress+Hauser is here to help overcome the industry's challenges.

A wealth of new medications is being developed for the treatment of rare illnesses and targeted therapies. Success has been achieved with the innovative mechanisms of biotechnology-based pharmaceuticals. Because production takes place in bioreactors using living cells, biotechnology is more expensive and complex than chemical synthesis. The stability, effectiveness and safety of the medication depends on hundreds of factors, from the air quality and the nutrients' solution, to the design of the system. It's a process that requires around-the-clock ideal conditions, especially in the bioreactors, so that the cells will produce the desired active substances in sufficient amounts and at high quality.

Life Sciences is one of the world's most heavily regulated industries – and regulatory requirements have increased over the past few years and this trend is expected to continue. The primary guidelines of regulatory requirements assure the quality of production processes and production environment. The aim is to ensure that medications are manufactured with consistent quality. Endress+Hauser understands the industry's challenges and adapts its technology, solutions and services to help meet specific needs.

Process optimization plays a significant role in the Life Science Industry. Innovative biotechnology processes, a process analysis initiative originated by the US Food and Drug Association (FDA), plus a drive towards operational excellence, have combined forcing the Life Science Industry to think outside the box and utilize state-of-the-art technology and processes. Among other things, this involves acquiring a better understanding of the manufacturing processes and implementing real-time monitoring and control of quality parameters. At the end of the day, the goal is to manufacture products more efficiently with the same quality. In this context, continuous, highly-automated processes are becoming more established in new plants, in contrast to traditional batch manufacturing.

Endress+Hauser strives to understand and attain the goals of each industry it serves, making your goals a priority. In this edition, you will find white papers with detailed information on technologies and services that help run manufacturing facilities effectively. We want to be your trusted, dedicated and reliable partner who puts quality and compliance at the heart of Life Sciences. Thank you and enjoy!

Sincerely,

Ravi Shankar
Life Science Industry Marketing Manager, Endress+Hauser, Sales Center US

Instrument Technology Moves Into Process Development Laboratories

The same instruments can be used in process development laboratories, clinical trials, pilot plants and large scale manufacturing – thus simplifying product development, scale-up and regulatory record-keeping.

Regulatory authorities require drug manufacturers to continuously review and improve instrument calibration and verification procedures. Compliance is checked at regular intervals by external inspectors to ensure the quality of the process and subsequently patient safety.

Compliance is required at all stages of drug development including process development (PD) laboratories, clinical trials, pilot plants and large-scale manufacturing. If a drug company uses different instruments–for example, pH sensors–at each stage, it has to keep records on each one, and then integrate new sensors into the next stage of the process. Today, modern instruments have built-in technology to simplify compliance and verification, making it possible to use the same pH sensor at all stages of drug development.

Labs versus Plant calibrations

Typically, the development of a drug and its manufacturing begins in a PD lab, where the manufacturing process is tested in small quantities, such as 0.5 to 5 liter batch sizes (Figure 1). Then, the process moves to a small pilot plant for testing the process with larger batch sizes of 10 to 50 liters. When pilot plant testing is completed, the process is scaled up to a full manufacturing plant.

At each stage in the development, various instruments–such as pH and conductivity sensors–are employed to analyze and control the process, and these must be calibrated and verified on a regular basis. Legal requirements for regular checks on analytical sensors are commonly fulfilled with wet calibration; that is, a pH or conductivity sensor is immersed in a reference solution and checked for accuracy.

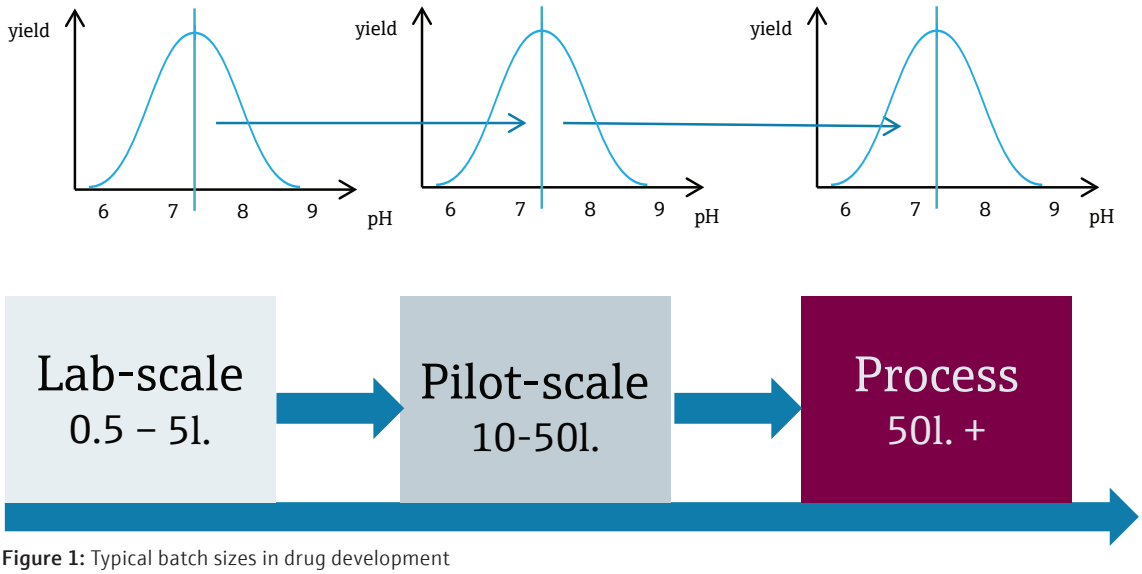

Figure 1: Typical batch sizes in drug development

Figure 2: Calibrations are easily done in a laboratory because all the necessary equipment is readily available, and the environment is controlled

Wet calibrations are easily done in a laboratory environment (Figure 2). The environment is controlled, the sensor is easy to access, and the necessary equipment is at hand. For example, an analog-based pH measurement system must be managed at its point of use with the sensor, cable and transmitter calibrated together. An analog pH probe generates a small mV signal 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.

A 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.

The downside of wet calibrations in a manufacturing plant is that the instruments typically have to be removed from the process (Figure 3) and sent to a laboratory. After the calibration the instrument is then installed again. Damages during transport or handling can sometimes stay undetected and lead to a situation where a recently calibrated instrument is not performing according to specifications.

Alternatively, a mobile calibration cart can be used to perform an on-site calibration. This method typically eliminates the need for dismounting the sensor being tested, but still requires the primary process loop to be opened, increasing the risk for contamination.

When sensor maintenance and calibration checks are done at the measuring point, it is hard to decide if the sensor is still adequate enough to stay in the process or if it should be replaced. Results between in-line and lab measurements often differ, and it is difficult for maintenance technicians to know which value is correct.

Figure 3: Calibrating sensors in a manufacturing plant often requires removal of the instrument for calibration in a lab

Figure 4: The Endress+Hauser CPS171D pH sensor has a glass membrane and reference gel that withstands SIP and CIP procedures

Sensor calibration and adjustment in the field consumes labor hours and can be challenging. It can be difficult because of process or weather conditions, and all calibration equipment needs to be present in the field. Paperwork is required for each calibration, which is time consuming and creates the possibility of data entry errors.

Nevertheless, the performance of analytical sensors is critical to the process and must be checked periodically. Media and buffer solutions used in bioprocesses need to be controlled as they have direct influence on the yield. To maximize the yield in a fermentation process, control of the optimum pH in a narrow range must be accomplished. In many plants, sensors are carefully evaluated, and identical sensors are used in the process and in the lab whenever possible.

In an ideal drug development world, the same sensor could be used at all stages of product development and the sensor would check its own calibration, thus simplifying calibration procedures, audit paperwork and scale-up from lab to manufacturing. Such sensors exist today.

Multipurpose Sensors

Two of the most common devices used in the bioprocessing industry are pH and conductivity sensors. A pH or conductivity sensor is subjected to steam-in-place (SIP) and clean-in-place (CIP) procedures in autoclaves, glass fermenters and batch reactor vessels. It's challenging to protect sensor connections during these processes, and even a small amount of humidity can create unstable values. For these reasons, it's important for a pH sensor to be protected against temperature extremes, and to undergo regular calibration checks to ensure the pH electrodes are functioning properly.

A pH sensor, such as the Endress+Hauser CPS171D (Figure 4), is designed to withstand SIP temperatures of >249.8°F (121°C) for 20 minutes, and CIP procedures with NaOH at 185°F (85°C).

These types of sensors accompany the active agent during all phases, from development in the lab to large scale production.

Typical applications include:
- Phase separations
- Chromatography
- Fermentations
- CIP monitoring in small pipes
- Ultrafiltration

Industrial pH and conductivity sensors have several features that differ from dedicated lab-only sensors. For example, the Endress+Hauser CLS82D conductivity sensor has hygienic process connections for installation in pipes or flow vessels, IP68 protection, and is easy to clean thanks to

its electropolished surfaces. The sensor can be sterilized up to 284°F (140°C), and its stainless steel construction (AISI 316L) meets all demands of the pharmaceutical industry.

The entire sensor is EHEDG- and 3-A-certified, has FDA conformity, and is available with a certificate of conformity for pharmaceutical requirements and an inspection certificate for EN 10204-3.1. In short, such a sensor can be used for every step in a drug development process, eliminating the need for a company to keep changing sensors.

It's all in the Transmitter

As always, a pH or conductivity instrument includes a sensor that measures the value and a transmitter that converts the sensor's output to a digital value and sends it to a control system via 4-20mA HART®, EtherNet/IP™, WirelessHART®, fieldbus or any of several other methods. The major difference with modern analytical instruments—compared to traditional devices—is that they perform many other functions.

For example, the transmitter for a CLS82D conductivity sensor stores measuring system data, such as:

- Manufacturer data, including serial number, order code and date of manufacture
- Calibration data, including calibration date, cell constant, delta cell constant, number of calibrations, and serial number of the transmitter used to perform the last calibration
- Operating data, including temperature application range, conductivity application range, date of initial commissioning, maximum temperature value, and hours of operation at high temperatures

Each instrument supplier provides a similar capability. Sensors with Endress+Hauser Memosens® technology have an integrated electronics unit that stores calibration data and other information. Once the sensor has been connected, the sensor data is transferred automatically to the transmitter and used to calculate the current measured value. The sensor can be calibrated and adjusted independently of the measuring point because calibration data is stored internally.

The result is easy calibration in the measuring lab under optimum external conditions, increasing the quality of the calibration. Pre-calibrated sensors can be replaced quickly and easily, resulting in a dramatic increase in the availability of the measuring point. If a sensor has to be removed for calibration, a calibrated sensor can be installed in its place. The new sensor communicates with the transmitter, and can be used immediately.

Maintenance intervals can be defined based on stored sensor load and calibration data, making predictive maintenance possible. The transmitter also continuously monitors the sensor, checking for problems and alerting maintenance when the sensor needs cleaning or calibration.

Paperwork for Audits

In addition to the continuous monitoring functionality running in the background, a traceable verification report about the health status of the sensor and instrument can be generated on demand. This report is produced, without the need of external devices, directly within the instrument.

For audit-safe documentation purposes, the report can be accessed and downloaded through any asset management system or, if enabled, even wirelessly via a built-in web server.

Again, instruments from various manufacturers have auditing capabilities built in. For example, Endress+Hauser's Memobase® Plus with pharma conformity meets FDA21 CFR Part 11 requirements for an audit trail and password protection, provides traceability for actions and setting changes, and protects sensor and measurement entries as each action is password protected.

Memobase Plus supports the "As found/As left" requirements in an intelligent and traceable way, stores all values in a database, and provides the audit trail needed for traceability purposes by keeping a chronological account in a table of all the actions and events that have occurred.

All changes and actions in Memobase Plus are documented in the audit report with the user's electronic signature and time stamps, thus fulfilling all the record-keeping requirements of the FDA and EMA automatically.

Summary

Today's analytical instruments have built-in capabilities to diagnose problems, perform calibration checks and generate audit trail reports. Reducing maintenance expenditures by performing fewer calibrations leads to a better overall equipment effectiveness as it increases the availability of the plant. Less downtime for maintenance and fewer unexpected shutdowns improve operations efficiency and operational excellence. Reliable data and certified proof that the measured process value is correct reduces the risk of product quality issues, and therefore supports the goal of maintaining the highest possible level of patient safety.


AGUA SUAVIZADA
SUMINISTRO

Advances in Temperature Calibration Procedures

Recent developments speed up the time it takes to do calibrations in the field

Critical processes in the pharmaceutical and biosciences industries often require frequent calibration of temperature instrumentation. Calibration typically requires shutting down a process every six months or so to remove and replace an instrument (Figure 1).

Recent developments in temperature sensor technology now make it possible for a sensor to determine if it actually needs calibration. When a sensor does need calibration, other new developments cut the time needed for a calibration in half.

In this article, we'll look at the need for frequent calibrations in the Life Science Industry, what's involved, and how sensor technology is making calibrations easier and less expensive.

Figure 1: In the Life Science Industry, just getting to a temperature sensor can be a problem because of the number of surrounding devices, and the need to maintain cleanliness

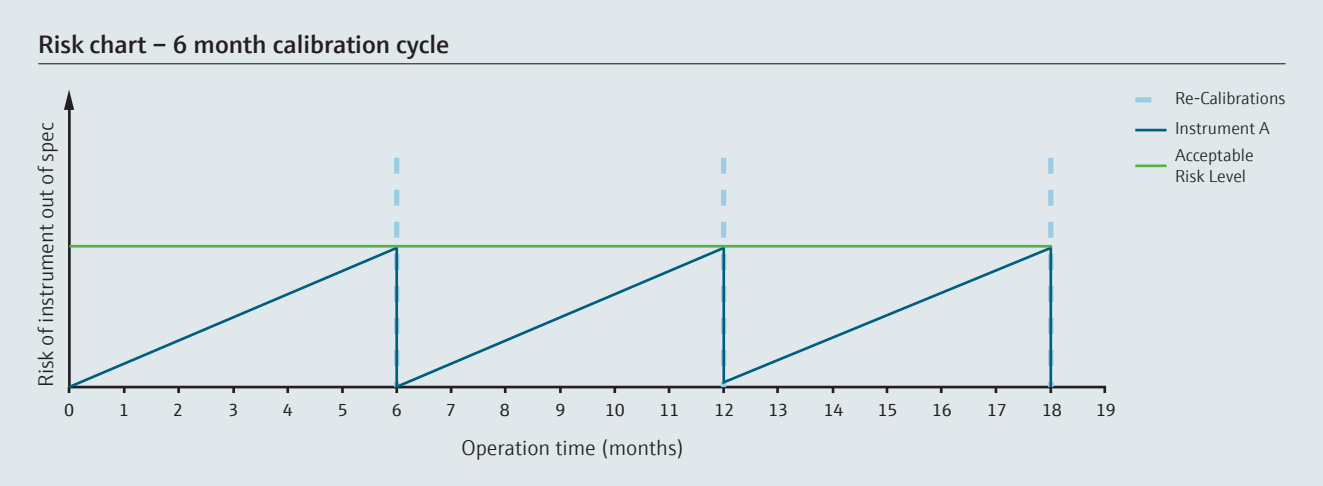

Figure 2: Six-month calibration cycle based on manufacturer's recommendation

Calibrate we must!

Recently, Quality Risk Management (QRM) has become a mandatory regulatory requirement for drug manufacturers. The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) publish guidelines and requirements which customers and vendors are expected to follow. Guidelines such as "Process Validation: General Principles and Practices" by the FDA and Annex 15 issued by the EMA offer input to help drug manufacturers design processes correctly.

Also, ISO9001:2008-7.6, GMP and WHO regulations and standards all require equipment and instrumentation to be calibrated or verified at specific intervals against measurement standards traceable to international or national standards. The main issue with scheduled calibration cycles is the performance of instruments between calibrations.

The blue line in Figure 2 shows how an instrument can deviate over time because of sensor drift, aging and other factors before being recalibrated back to initial specifications every six months. The deviation between calibrations must always remain below the acceptable level. However, the possibility for an undetected "out-of-spec" situation gradually increases over time, resulting in an increased risk of product quality issues.

If a temperature sensor goes "out of spec" before the next calibration, difficult questions will have to be addressed:

1. When did it go out of spec?
2. How many batches have been affected since then?
3. Do the products made from those batches have to be recalled?

Ideally, temperature sensors should be calibrated after each batch. Costs of doing unnecessary calibrations include labor and lost production, and a certain amount of risk is involved in handling and perhaps damaging the instrument. In most cases the calibration cycle is a statistical calculation based upon the risk of excessive drift of the sensor occurring versus the cost of conducting manual calibrations.

The batch nature of bioscience processes—where batches can run for days or weeks—don't really lend themselves to such an approach. Fermentation is a good example.

Fermenting processes

Fermentation is used to cultivate cell cultures. The cultures consume a nutrient solution, multiply, and create the desired product. Fermentation typically takes place in a series of bioreactors. Bioreactors are usually made of 316L stainless steel and are jacketed to either cool or heat as required by the reaction.

The cell culture to be grown is placed in the bioreactor, which is filled with a nutrient solution. The nutrient solution varies based on the specific cell culture and desired product but typically consists of glucose, glutamine, hormones, and other growth factors. Agitator blades make sure that the solution and cell culture mix thoroughly to promote efficient growth within the vessel. The bioreactors are connected in series, with each successive vessel larger than the previous to contain the increasing cell mass.

The product that results from the reactions can be anything from antibiotics to vaccines and other cell-based products. Typical waste products of the reactions are CO2, ammonium and lactate. After the nutrient solution is consumed, the reaction is complete and the desired yield has been achieved, the solution moves to the harvesting process where the product is separated from the dead cells and other waste products.

Fermentation batches essentially are broken up into several

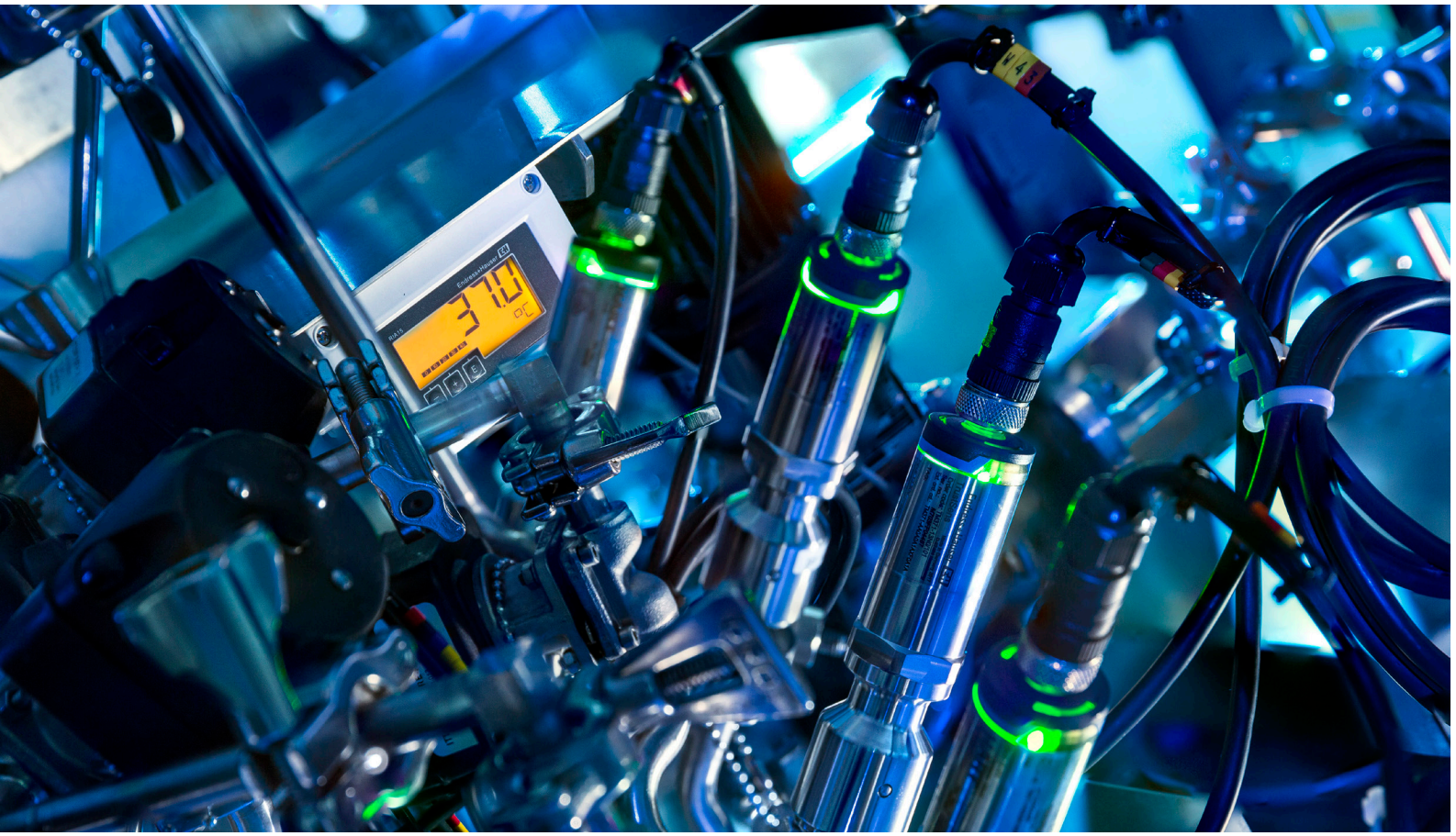

Figure 3: Multiple temperature sensors are used in a fermentation vessel

phases: sterile media preparation, fermentation, harvest, cleaning in place (CIP), final rinse and sterilization in place (SIP). There are three common types of fermentation batch processes: single batch, intermittent harvest/fed batch and continuous batch.

- A single batch fermentation process runs until there are no more nutrients left for culture to consume. A typical run is 7-14 days.
- Intermittent harvest batch runs are similar to a single batch except as nutrients are depleted and product is harvested, fresh nutrient solution is added to allow for longer batch cycles. A typical run is 2-3 weeks. Similarly, a fed batch process adds nutrients and additional feed solutions, but puts off harvest until the end of the batch cycle. Vaccine production is typically intermittent harvest, while protein production is typically fed batch.
- A continuous batch continually adds nutrients and harvests product and waste with a cell retention device, resulting in higher production concentration. This type of batch is especially used for labile processes such as stem cell production. Nutrients and new cell culture are continuously added and harvesting is done without shutting down the process. The process is only brought down for maintenance, cleaning/sterilization of vessel or calibration.

With batches lasting for several weeks—or even months—an undetected out-of-spec temperature sensor could ruin the entire batch, at a cost of several million dollars' worth of spoiled product.

That's because temperature is usually the most important measured parameter in fermentation processes. It's used to optimize growth and productivity and to monitor conditions in the vessel. Temperature is important in maintaining the solubility of the media as well as providing stable conditions for the produced protein. Fermenters usually have multiple sensors (Figure 3) monitoring temperature at various levels within the solution to maintain uniform temperature. Temperature sensors are also in the vessel jacketing to maintain adequate heating or cooling of the vessel.

Cleaning up

It's important that unwanted biological elements (e.g. foreign bacteria) do not grow in vessels. Contamination of tanks can result in lost batches or even complete tear down and rebuild of the vessels. To this end fermentation tanks are typically cleaned and sterilized between each batch with CIP and SIP procedures.

CIP is a cleaning process that consists of injecting hot water, introducing a base to neutralize acids, followed by another injection of hot water. Once done, the entire vessel is rinsed with water. SIP is a sterilization process that consists of injecting steam into the vessel and holding temperature around 249.8°F (121°C) for up to an hour.

CIP is commonly used for cleaning bioreactors, fermenters, mix vessels and other equipment used in biotech, pharmaceutical and food and beverage manufacturing. CIP is performed to remove or obliterate previous cell culture batch components. It removes in-process residues and control bioburden, and reduces endotoxin levels within processing equipment and systems. This is accomplished during CIP with a combination of heat, chemical action and turbulent flow to remove mineral precipitates and protein residues. Caustic solution (base) is the main cleaning solution, applied in single pass, recirculation through the Bioreactor followed by WFI (Water For Injection) or PW (Pure Water) rinse. Acid solution wash is used to remove mineral precipitates and protein residues.

Calibration

Three-wire, platinum-100 ohm Resistance Temperature Detectors (RTDs) are the most common sensor type used. High accuracy and fast response are very important for temperature measurement in fermenters, so sensors are regularly calibrated to maintain measurement accuracy. Sensors within a vessel are also compared to each other to monitor potential sensor drift.

Unlike CIP/SIP processes, calibration of sensors is not always performed between batch runs. One reason for this is that calibration is time-consuming and requires the entire process to be offline, resulting in less production. This results in tradeoffs in measurement accuracy and reliability that could cause unacceptable levels of uncertainty to creep into the process between calibrations. Care must be taken by plant reliability engineers to balance these tradeoffs when considering a calibration schedule.

Process reliability engineers must give careful thought and analysis when setting calibration frequencies. Calibrating too often results in unacceptable production reductions, while calibrating too seldom can result in out-of-spec product. Consideration should be given to products and sensors that have better long-term stability, lower drift and (if possible) self-monitoring to indicate if a sensor is out of tolerance in between calibration cycles.

Self-Monitoring Sensors

One of the most recent developments are self-calibrating temperature sensors (Figure 4) that have a high precision reference built into the temperature sensor itself. This is accomplished using a physical fixed point known as the Curie Point or Curie Temperature. The Curie Point is the temperature at which the ferromagnetic properties of a material abruptly change. This change in properties can be detected electronically which then enables the point at which the Curie Temperature is reached to be determined.

The Curie point of a given material is a fixed constant that is specific to all materials of that given type. The sensor uses this value in the form of a reference sensor consisting of such a material. This provides a physical fixed point that can be used as a reference for comparison with the actual RTD temperature sensor. The Curie temperature of the material for batch processes is 244.4°F (118°C). Each time a cooling phase is initiated from a temperature greater than 244.4°F (118°C) (e.g., from 249.8°F (121°C) during the cooling phase of all SIP processes) the sensor is calibrated automatically.

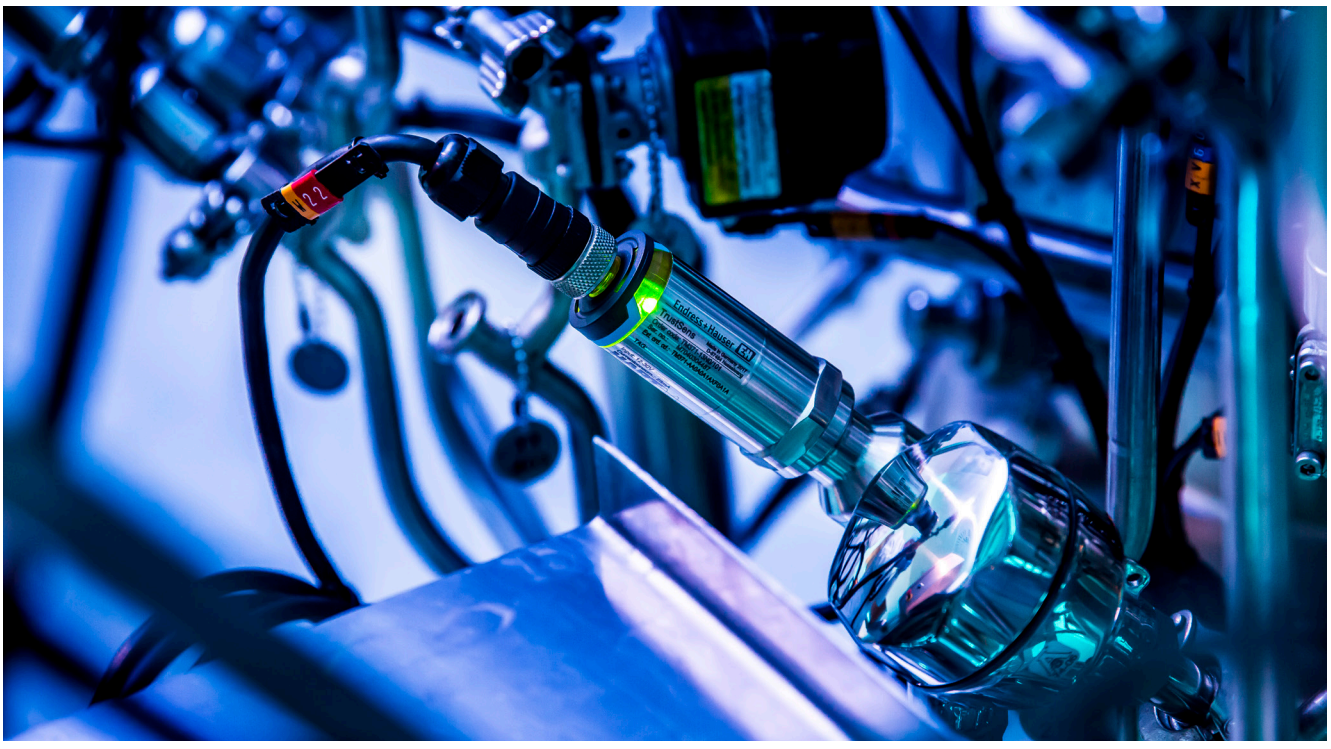

Figure 4: Multiple temperature sensors are used in a fermentation vessel

Figure 5: The Endress+Hauser TrustSens is a self-calibrating RTD sensors that self-calibrates during every SIP procedure

When the Curie Temperature of 244.4°F (118°C) is reached, the reference sensor transmits an electrical signal. At the same time, a measurement is made in parallel via the RTD's temperature sensor. Comparison between these two values effectively is a calibration that identifies errors in the temperature sensor. If the measured deviation is outside set limits, the device issues an alarm or error message that is also displayed via LED.

The calibration data acquired is sent electronically and can be read using asset management software such as FieldCare® from Endress+Hauser. This also enables an auditable certificate of calibration to be created automatically.

With such a sensor, calibration can now be carried out automatically each time the temperature passes through the Curie Point in SIP processes. This reduces the risk of drift-related process errors which could lead to costly lost production. In some cases, it could allow a facility to reduce the frequency of manual calibration intervals, allowing for greater production.

Quicker Calibrations

All sensors have to be calibrated eventually. This involves removing the sensor from the process, which takes time and is subject to errors. The biggest problem is that most sensors require disconnecting the wires while removing the sensor and then reconnecting them after calibration. While the procedure is fairly simple, wiring errors can occur. Wiring terminations are problematic in any manufacturing environment. Such a procedure typically takes about 30 minutes.

If the transmitter is improperly rewired or the wiring is damaged, that could increase the total calibration time by 10 to 20 minutes. In some cases, if the damage to the sensor wires is severe enough, it could require replacement of the calibrated temperature sensor.

Another recent development involves RTD sensors with a feature that does not require disconnecting wires when removing the sensor (Figure 5). The technician simply twists the top of the sensor a quarter turn, and the sensor can be removed easily. Eliminating the need to disconnect and reconnect wiring cuts calibration time in half. A calibration can be performed in about 15 minutes.

Summary

Temperature is such a critical measurement in bioscience processes, the FDA and other agencies require regular calibration of temperature sensors. Most plants calibrate sensors every six months, but sensors can drift out of calibration during that time, potentially ruining expensive batches. New technology makes it possible for RTDs to calibrate themselves at the end of each batch. And, when calibration is needed, another development eliminates the need to disconnect wires, cutting calibration time in half.

A partner to help you stay compliant

ISO 17025 accredited lab and on-site calibration

Understanding your challenges

A reputable, reliable and accredited partner Calibration of your instruments according to current Good Manufacturing Practices (cGMP) is essential in staying compliant.

Certified and trained service engineers conforming to your site's SOP's When calibrating your instruments, a comprehensive database of Standard Operating procedures (SOP's) ensures that professional service is maintained and repeatable within your application framework.

Ensuring current Good Manufacturing Practice (cGMP) regulations and universal guidelines are followed Metrological traceability is vital to your operation. You need a partner that has traceable calibration reference equipment and can provide the comprehensive documents and records you need.

Minimizing quality fluctuations and associated costs The costs of an out-of-tolerance situation can be extremely high. To avoid this, it often times makes sense to calibrate your instruments more often. A vendor that understands the role uncertainty plays in calibration and the importance of staying in compliance is mandatory.

Keeping your tank in full working order Accurate and redundant level measurement preventing spills, maintaining batch integrity under changing process conditions, and conformance to bioprocess standards are crucial to your process. Therefore, you need calibration verification that can be accomplished as quickly as possible – while ensuring quality – and without breaking sterility.

Traceability throughout your instruments entire life cycle To ensure effectiveness of your critical measuring points and in case of inspection, you need traceability. Demonstrating to your auditors all requirements are being verified, accepted and implemented in accordance to the guidelines and by qualified personnel can be a daunting task.

Endress+Hauser can help

One partner for all your needs As an ISO 17025 accredited calibration provider, we can easily help you stay compliant. Through our continuous investment in our U.S. operations, we can perform fully accredited in-situ, on-site and laboratory calibration across a wide variety of measuring principles and even on third party instrumentation. Our accredited calibration offering:

- Flow
- Pressure
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- Voltage, current

Local, on-site support When you need fast turnaround to keep up and running, we offer on-site calibration of:

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- Pressure
- Temperature
- pH
- Conductivity
- Recorders
- Level (Volume)

Our mobile trailers with portable flow calibration rigs are stationed close to you, allowing your instruments to remain at your place of operation. Depending on plant topology, many measuring points can be quickly calibrated with minimal interruption to your process.

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100% Compliance – 0% Effort: Outstanding sensor technology with self-calibrating function

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- Automatized documentation, memory for 350 calibration points

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Digital pH sensor
Memosens CPS171D

Memosens glass electrode for bioreactors and fermenters in the biotech industry

- The sensor's exceptional accuracy, reproducibility and reliability helps you to keep the pH value in the optimum range for a maximized product yield
- A specialized glass membrane and reference system makes the sensor CIP/SIP and autoclaving resistant (up to 140°C/284°F) offering maximum long-term stability

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Memosens CLS82D

Memosens conductivity sensor for hygienic applications in Life Sciences, Pharma and Food

- Broad measurement range
- Hygienic design certified by EHEDG and 3-A
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- Intelligent design: One controller for all parameters including process photometers
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- Easy to operate and calibrate thanks to intuitive user interface and menu guidance

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- The sensor can be used in process applications as well as benchtop fermenters. Providing you with 100% measuring consistency from the first lab trials to the final scaled-up process and your process lab

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The integration of a complete shopping experience into our website underlines our goal to help streamline your procurement processes and to improve your buying experience - both online and offline. This is much more than just a website redesign. A great deal of focus was placed on maximizing functionality and usability to create a comprehensive information and procurement platform. The website now connects you directly to Endress+Hauser and our expansive network of sales representatives.

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