

competences

Life Sciences: attain operational excellence

The pulse of life sciences





Your challenges are our mission

First serve, then earn. This principle was coined by our founder George Endress and has shaped our company to this day. Customer focus is our mantra. This means that we are committed to develop products, solutions and services that fit our customers' specific challenges. Some of the challenges include, faster time to market, increasing productivity and managing risk.

Society, with its changing demographics, increasingly relies on the development of new medications. At the moment, more than 7000 medications are being developed worldwide. However, this process is long and arduous. Starting with initial idea to approval, on average the process lasts 13.5 years and costs roughly 2.6 billion US dollars. In biopharmaceutical manufacturing, transferring a technology from small scale to commercial manufacturing is a challenge. Due to the higher level of integration and automation, scale-up adds a lot of complexity. This is why early standardization is essential when it comes to reducing complexity so ultimately your product gets to market faster.

The life sciences industry is one of the world's most heavily regulated industries with regulatory pressure continuously growing. Therefore, compliancy and quality are main drivers. At the same time, the industry is facing growing pressure from public health care systems to reduce pricing. As a result, process optimization and innovation also play major roles. To increase productivity while managing risk, acquiring better process understanding and implementing real-time monitoring of quality parameters are where it all begins. In this context, highly automated processes are becoming more and more important in pharmaceutical plants.



13.5 years on average from initial idea to approval of new medication



8% productivity growth due to less plant downtime thanks to integrated calibration concepts



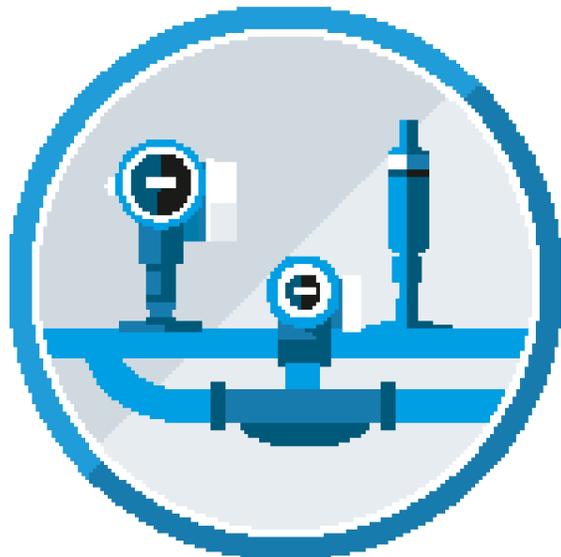
30% loss of CAPEX and time in your process automation project using the traditional approach according to project experts

The pulse of life sciences

Attain operational excellence with an experienced and reliable partner at your side

In biopharmaceutical manufacturing, we are a reliable partner, who helps support your projects from pilot plant to a fully automated commercial scale. This helps reduce risk and optimize your operational performance simultaneously. We support you with solid processes that help you meet stringent project schedules. It is a daily requirement to comply with GMP regulations and productivity goals throughout a product's lifecycle.

You can count on our world-class instruments, designed to ASME-BPE standards and rely on our experienced engineering and support services. We partner with you to help you reach your goals of process optimization, increased plant availability and continuous improvement.



Customers around the world gain a wealth of information from their processes by using our products, solutions and services



Relying on our industry knowledge and skills, we work together with our customers to find the best solution for every application



As a family-owned company since 1953, we are a reliable partner in every aspect – for our customers, employees and shareholders



Get to market faster

Reduce time-to-market by standardizing with the largest offering of instruments designed according to industry standards and rely on our engineering support to streamline your project.

- entire offering designed according to ASME BPE standard
- embedded resources for efficient engineering support and project management
- worldwide available commissioning, qualification and calibration expertise services



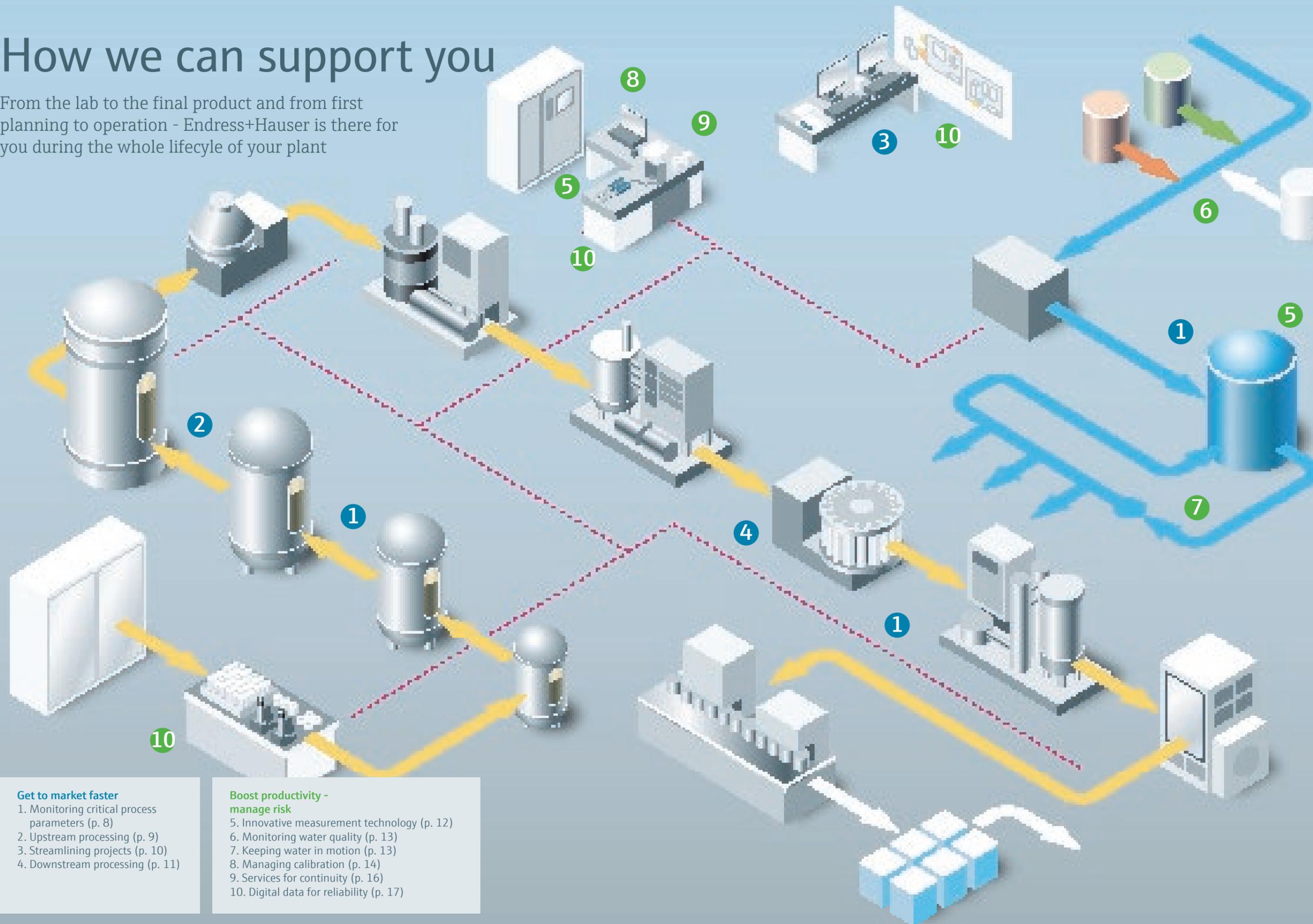
Boost productivity – manage risk

With our innovative measurement instrument portfolio and maintenance services you can increase productivity without compromising supply quality.

- innovative instrumentation and data technology
- scalability from small to large scale for data integrity
- standardization in engineering and operation
- continuous maintenance and calibration optimization

How we can support you

From the lab to the final product and from first planning to operation - Endress+Hauser is there for you during the whole lifecycle of your plant



Get to market faster

- 1. Monitoring critical process parameters (p. 8)
- 2. Upstream processing (p. 9)
- 3. Streamlining projects (p. 10)
- 4. Downstream processing (p. 11)

Boost productivity - manage risk

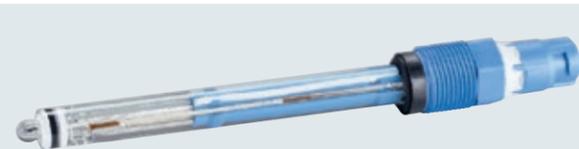
- 5. Innovative measurement technology (p. 12)
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Get to market faster

Reduce time-to-market by standardizing with the largest offering of instruments designed according to industry standards and rely on our engineering support to streamline your project

Monitoring critical process parameters

Monitoring Critical Quality Attributes in biopharmaceutical manufacturing is of the utmost importance when it comes to ensure consistent batch-to-batch quality. Measurement devices are used to control the Critical Process Parameters, making sure that the cells are growing and the desired protein is produced. To be fully GMP compliant, both critical and key process parameters need to be monitored and controlled in real-time. Our entire offering for physical and analytical measurement solutions also complies with all relevant industry regulations and standards. We work with you to find the best ways to keep your process under control.



i Memosens - the solution for critical measuring points

The Memosens technology, for liquid analysis, is based on smart-digital sensors with integrated data chips. The digitalization of the raw data in the sensor's head makes it possible to achieve stable measurement and reliable data transfer, regardless of external factors, such as moisture and dirt, that may be an influence. The data chip in the sensor head stores all relevant, sensor-specific information such as calibration data and history. Therefore, sensor calibration can be done under optimal conditions in the laboratory. This simplifies calibration and lengthens the sensor's service life.



80% fewer temperature measurement types through standardization

i Memobase

Memobase Plus is the perfect software to improve your process safety and reliability. It documents the complete lifetime of Memosens sensors offering full traceability with a minimum of paperwork. Memobase Plus turns your computer into a high-performance, space-saving measuring device for up to four parallel sensors. You can save and export measurement data and use identical sensors in the laboratory as in the process to achieve truly comparable measurements. Memobase Plus gives you 100% measuring consistency between lab and process measurements and a smooth scale up.



Upstream processing

The efficiency of your biological process highly depends on obtaining the right conditions so that the cells can thrive in a stable and predictable manner. Aseptic conditions must be ensured strictly over the whole biopharmaceutical manufacturing process. pH is thus one of the critical parameters in a bioreactor. Each cell line has its own optimum pH range for efficient cell growth and protein expression. From laboratory to large scale manufacturing, consistent and reliable data is required. Using the same digital technology over all scales for the pH loops, provides maximum safety and allows for a sophisticated calibration concept in the laboratory. All our pH probes are specifically designed and optimized to endure process conditions as well as a maximum number of sterilization cycles.



Streamlining projects

Instrumentation can be complex especially if there are multiple suppliers involved in a project. A great number of measurement instruments are engineered, installed and qualified during project execution. Once put in operation, instruments must be maintained, verified and calibrated regularly. Early standardization and the right experts can help simplify these steps, shorten time-to-market and optimize your complex biotech projects. Endress+Hauser offers you certified project management skills to ensure planning runs smoothly. Depending on the size of the biotech project and the degree of process integration, an embedded engineer from Endress+Hauser can help you reduce complexity.



3 weeks faster time-to-market thanks to perfectly engineered instrumentation packages

i Planning tools that will make your life easier

We offer digital tools that simplify your daily engineering work. Starting with Applicator, a convenient tool for selection and sizing the appropriate measuring instrument. Simply enter your known parameters and Applicator will determine a reliable selection of suitable devices. You can access Applicator freely via our website or install the tool locally. Our web-based W@M Portal allows data monitoring of your process, permitting proactive maintenance of your devices. You get fast access to critical information, such as spare parts, product availability and reports. With quick access to the proper information, processes such as instrument repair or replacement become faster. The pre-filled data available allows reliable planning of your maintenance events.



i Our services for safe and efficient processes

Our dedication towards improving your processes does not end with the delivery or commissioning of a new sensor. Our worldwide service offering supports you during the whole lifecycle of your plant. Apart from quick technical support we also offer calibration and maintenance services so that you can always rely on your measurement instrumentation. Our experts can recommend maintenance routines and with innovative tools such as our lifecycle management software (W@M) or our Installed Base Analysis application can enhance maintenance service.



Downstream processing

Chromatography is used to separate the target protein from the complex mixture of the fermentation broth by different interactions with the immobile phase. pH and conductivity define the conditions of the separation process. Precise flow control allows for in-line delusion to achieve a highly linear gradient. A UV sensor detects the target protein and assures maximum yield. All our process measuring instruments support continuous manufacturing so you can get the most out of your chromatography skid. In cell separation and concentration increase different steps of filtration are used. Endress+Hauser can cover all critical process parameters during filtration, such as temperature, pH, cell concentration, flow and pressure at the inlets and outlets.

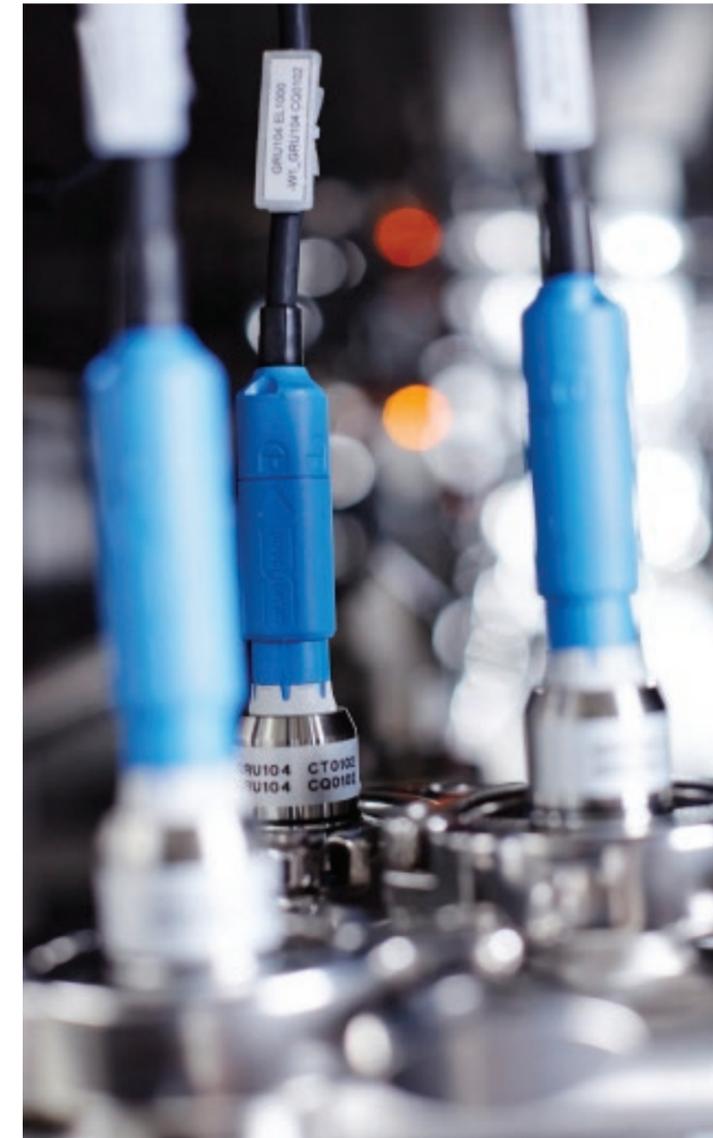
Boost productivity – manage risk

With our innovative measurement instrument portfolio and maintenance services you can increase productivity without compromising supply and quality



Innovative measurement technology

Innovation is a key factor for productivity growth and operational excellence. Digital technology allows for the generation of additional data which can be used to increase reliability and optimize manufacturing operations. Temperature is one of the main critical measurement points in a bioprocess with a strong impact on both, cell kinetics and solubility of dissolved gases. To ensure optimum output and quality, temperature devices should be calibrated regularly. Endress+Hauser has developed the world's first self-calibrating temperature sensor to help you boost your productivity without compromising quality. Using our innovative measurement technology can thus reduce your calibration effort and costs significantly.



850,000 euros is the amount that can be saved with TrustSens over a period of five years if 10'000 temperature sensors have to be recalibrated twice a year.

Monitoring water quality

Measurement instrumentation provides the critical information required by the regulatory agencies to prove that water quality is achieved and maintained. Conductivity, for example, is one of the main characteristics for purified water and water for injection. The limits, as defined in the pharmacopeias, must always be met. For these critical applications, Endress+Hauser provides highly accurate conductivity cells, transmitters and temperature sensors.

Keeping water in motion

To prevent bio-burden, water must be kept in motion. This makes reliable flow measurement very important. Heartbeat Technology provides reliable self-monitoring and verification and helps to optimize calibration procedures, especially in continuous processes. This directly results in higher plant availability and productivity. Of course, all our process measuring instruments are delivered with material certificates for the wetted parts, calibration certificate and roughness.



i **Self-calibrating temperature sensor**
The iTHERM TrustSens hygienic thermometer is for users who want seamless compliance to GMP rules. iTHERM TrustSens eliminates the risk of undetected non-conformities and is differentiated by automated inline self-calibrations before each batch during the SIP resulting in maximized product safety and process efficiency. This outstanding sensor technology offers you 100% compliance at 0% effort.



90% reduction of non-conformities per year thanks to optimized calibration management

Managing calibration

Managing calibration is often challenging. Outsourcing calibration to a service partner transfers the complexity of managing different calibration providers and measuring technologies to one partner, a single point of contact for the plant. All hidden calibration costs become visible to enable significant cost improvements. In addition, dynamically determined calibration intervals based on statistical methods may lead to extended intervals, while instrument failures can be predicted and reliability increased.



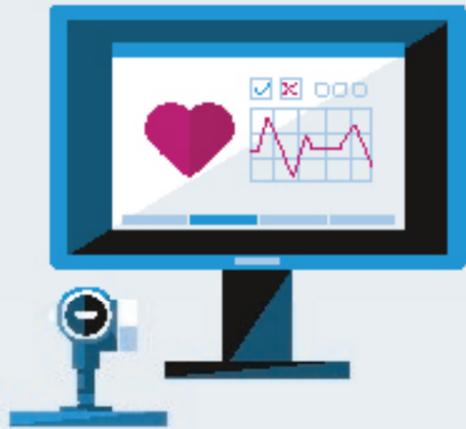
i **Comissioning and Maintenance services**
 When it comes to critical control points, operators have to make sure the instrumentation is properly installed so they can rely on the measurement. All of our service experts have the necessary expertise and experience to integrate the instruments into your processes safely, ensuring compliance to regulations and standards. Once the instruments are installed, they will have to be regularly maintained. Our service experts can support you with maintenance to ensure continuous performance of your instrumentation. By relying on us, your maintenance personnel can focus on your core processes.



More than **60** countries have access to local Endress+Hauser calibration service engineers



10% cost reduction thanks to preventive maintenance concepts



i Heartbeat Technology
Heartbeat Technology guarantees permanent diagnostics and verification without process interruptions. It ensures a cost-efficient and safe plant operation during the entire life cycle. Instruments with Heartbeat Technology extend proof test cycles significantly and deliver standardized diagnostic messages for economical maintenance. Verification occurs directly in the measuring point without process interruption in order to reduce verification efforts. Monitoring data facilitates predictive maintenance for further optimization of the process.



10% cost reduction thanks to preventive maintenance concepts



31 million Endress+Hauser devices are filed in the Endress+Hauser database to ensure full transparency for users



Services for continuity

Continuity is key for efficient pharmaceutical manufacturing. Unforeseen shutdowns may lead to drug shortages, which can have a significant impact on patient care and public health. Innovative services, continuous maintenance and calibration optimization help assure continuity in manufacturing, quality and availability. Services for efficiency and continuity in pharmaceutical manufacturing should include more than emergency support. For long-term support, global availability and knowledge on the stringent GMP regulations is essential – with Endress+Hauser you have a reliable and experienced partner at your side, no matter where you are located.



70% less calibration costs with Heartbeat Technology during 10 years of operation

Digital data for reliability

Undetected sensor failures can lead to non-conformities, quality issues and drug shortages. Endress+Hauser put great effort into increasing the reliability of its devices. Digital data provides real-time information about the relevant aspects of the measurement device. With our devices you are ready for IIoT and Pharma 4.0. Go a step further and reduce risk based on data provided digitally by Heartbeat Technology and Memosens. Continuously optimize your processes with real-time information, increase process reliability and extend calibration intervals.

References



Standardization facilitates plant engineering

Customer challenge:

The client, a local company in China aimed to manufacture Insulin for the local market. The project's goal was to build a fully automated and monitored facility. Completely reliable instruments play a critical role in achieving this objective and maximizing plant yield and availability. The instrumentation should ensure the best control, high accuracy as well as the lowest possible cost of maintenance and calibration.

Our solution

Endress+Hauser provided the majority of the measurement instruments: All-in-all, more than 350 pieces to measure flow, temperature, pressure, conductivity, chlorine and level. Endress+Hauser's Project team was involved to assure the best fit and quality for each application. We also provided a documentation service that complies with cGMP, EMEA and USFDA validation standards.

The results:

- Endress+Hauser's support enabled Biopharmax to build a world-leading plant which by far exceeded expectations
- The high-level GMP documentation and certificates assure compliance
- Standardization of instrumentation minimizes installation work and facilitates commissioning, staff training and spare part management

Efficient calibration services during summer shutdown

Customer challenge:

Schott's main goal is to deliver on the quality commitments made to the customer. They achieve this through regular calibration of critical measuring points. With systems being shut down for roughly two weeks in the summer, the maintenance manager needs to pack all scheduled and predictable inspection work into a tight program.

Our solution:

Schott has been able to rely on Endress+Hauser for support in performing these calibrations for eight years now. Today, the calibration contract covers 450 measuring points for temperature, conductivity, pH value and pressure. In addition, Schott uses the W@M portal. This browser-based application offers access to device information so that manuals, certificates and inspection reports are merely a mouse-click away.

The results:

- Tight deadlines can be met
- The maintenance team works to deadlines with peace of mind
- The maintenance manager makes better use of his resources during summer shutdown
- Endress+Hauser technicians contribute to process improvement

 ... and how can we help to improve your processes?
www.endress.com/life-sciences



www.addresses.endress.com

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