Ensuring a high-purity water system for pharma applications

Advanced, hygienic instrumentation designed for critical water with continuous, compliant measurement technologies

Benefits at a glance

- Assured compliance for regulated water systems
- Continuous quality protection across PW, WFI and clean steam
- Faster detection of organic contamination
- Confidence in ionic purity
- Stable, hygienic pressure control with built-in verification
- Temperature accuracy without calibration gaps
- Hygienic, accurate flow with simple validation support
- Centralized data, traceability and audit readiness
- Proven impact on release timelines and reliability

Summary Pharmaceutical and biotechnology manufacturers rely on a high-performance water system for pharma applications to support safe, compliant and efficient manufacturing. Purified Water (PW), Water for Injection (WFI) and clean steam serve as essential raw materials, cleaning agents and integral components of finished products. Because these systems operate as critical utilities, any deviation in quality, whether conductivity drift, TOC spikes or temperature inaccuracies, can challenge manufacturing integrity. A single excursion can force batch quarantine, contamination investigations or regulatory delays.

To avoid these risks, facilities can consider instrumentation engineered specifically for hygienic environments, regulatory compliance and continuous

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monitoring. Endress+Hauser provides a complete portfolio of digitally enabled technologies designed to strengthen reliability and control across every water for pharma processes.

Challenge Life Sciences water systems must operate within precisely defined global regulatory frameworks. Requirements such as USP <643> for TOC define strict limits for key parameters, while ASME BPE establishes expectations for hygienic design and materials of construction.

Additionally, data handling should have complete traceability and integrity of electronic records. Maintaining these dimensions can be challenging, especially when facilities rely on periodic, manual or reactive testing methods.

Without continuous, validated and reliable instrumentation, manufacturers may face undetected contamination, unexpected excursion events during sanitization cycles or incomplete traceability during audits. Traditional monitoring approaches can be slow to identify process issues and calibration uncertainties can introduce risk into critical quality assessments.

Solution Endress+Hauser equips water system operators with real-time, compliant and digitally supported measurement technologies engineered specifically for regulated Life Sciences environments. This includes the three most critical parameters in pharma water systems: conductivity, TOC, and pressure, along with other compliant and digitally supported measurement technologies engineered specifically for regulated Life Sciences environments.

Figure 3: Endress+Hauser's Cerabar PMP43

- **Conductivity:** The Memosens CLS16E (figure 1) sensor delivers highly accurate, moisture-proof conductivity measurement with onboard calibration and comprehensive health diagnostics.
- **TOC:** The CA79 (figure 2) analyzer provides truly continuous TOC monitoring with a rapid ~50-second response time, enabling immediate detection of organic contamination and full alignment with USP <643>.
- **Pressure:** The Cerabar PMP43 (figure 3) ensures stable pressure control and hygienic performance, while its verification capabilities help confirm that the system is functioning with no fouling, blockage or leaks.

Figure 1: Endress+Hauser's Memosens CLS16E

Figure 2: Endress+Hauser's low-range TOC analyzer CA79

- **Flow:** Proline Promass P 100/300 Coriolis flowmeters offer hygienic drainability, high accuracy and advanced digital connectivity for seamless integration and validation support.
- **Temperature:** The iTHERM TrustSens TM372 performs automatic self-calibration during every sterilization cycle, eliminating calibration gaps and ensuring temperature accuracy for critical water processes.
- **Digital integration:** Netilion cloud software and Liquiline CM44x transmitters (when paired with an Edge Device) centralize diagnostics, calibration data and predictive maintenance insights. This architecture strengthens data integrity and simplifies audit readiness across an entire facility.

Results Hypothetically speaking, suppose a biologics manufacturer is experiencing intermittent total organic carbon (TOC) spikes in its water-for-injection (WFI) loop, particularly during cooldown after sanitization-in-place (SIP). To better understand the behavior of the system, the facility implements a full suite of Endress+Hauser instrumentation across the loop.

With the CA79 TOC analyzer, operators gain continuous visibility into organic loading throughout the cooldown cycle. The analyzer detects a recurring pattern of brief TOC excursions coinciding with specific temperature transitions, a trend that may previously have been challenging to pinpoint.

In parallel, Memosens CLS16E conductivity sensors verify that conductivity always remains stable, helping engineers rule out ionic contamination as a root cause.

Temperature accuracy is confirmed using the iTHERM TrustSens TM372, which performs automatic self-verification during SIP and cooldown, ensuring thermal readings, especially during the suspected excursion window, are trustworthy.

The Cerabar PMP43 pressure transmitter, equipped with in-process verification, confirms that pressure fluctuations are not contributing to TOC instability. At the same time, Proline Promass P Coriolis flowmeters validate that flow and recirculation rates remain consistent and hygienic throughout the loop.

Using Netilion and Liquiline CM44x for centralized data visualization and trend analysis, engineers correlate TOC, temperature, pressure, flow and conductivity signals. This multi-parameter view reveals the true root cause: an organics desorption event triggered by a specific cooldown ramp rate.

With this insight, the team adjusts the thermal profile, refines alarm thresholds and strengthens documentation practices. As a result, the manufacturer experiences:

- Fewer TOC excursions
- Shortened batch release timelines
- Improved reliability and compliance of the WFI system

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