Utilities. Focus on water for injection.

The quality is continuously monitored by measuring instruments

Water for Injection (WFI) is one of the very high purity water types used in the pharmaceutical and life science industries. Water types are defined based on the treatment process and on the physical, chemical and microbiological characteristics. The parameters have been defined by the European Pharmacopoeia (Ph.Eur.) and United States Pharmacopoeia (USP).

Endress+Hauser GMP trained technician during an inspection of a WFI loop.

Treatment process WFI could, according to the Ph. Eur., only be produced by a distillation treatment. This is not the case in other countries. Other water treatment systems can be used, such as reverse osmosis followed by ultrafiltration according to the Japanese Pharmacopoeia or any other water treatment giving the same or better results than distillation according to USP. Since April 2017, also non-distillation treatments are allowed by the Ph.Eur

The role of sensors WFI is a critical utility in which measuring instruments play an important role. Process control and compliance to the applicable regulations are the primary functions of the sensors. The WFI water treatment process, supply and distribution should be continuously monitored. WFI distribution must be continuously monitored. The physical and chemical quality of the water is established with inline instruments, such as conductivity, temperature, pressure and flow meters.

In the field, we find hot and cold WFI loops or subcooling installations. Because of the Ph.Eur. guidelines, there is a hot WFI loop on every site in Europe in which WFI is produced. In order to minimize microbial growth, water continuously circulates through the hot loop. Typical set values are a flow rate higher than 1.5m/s and a temperature between 80°C and 90°C.

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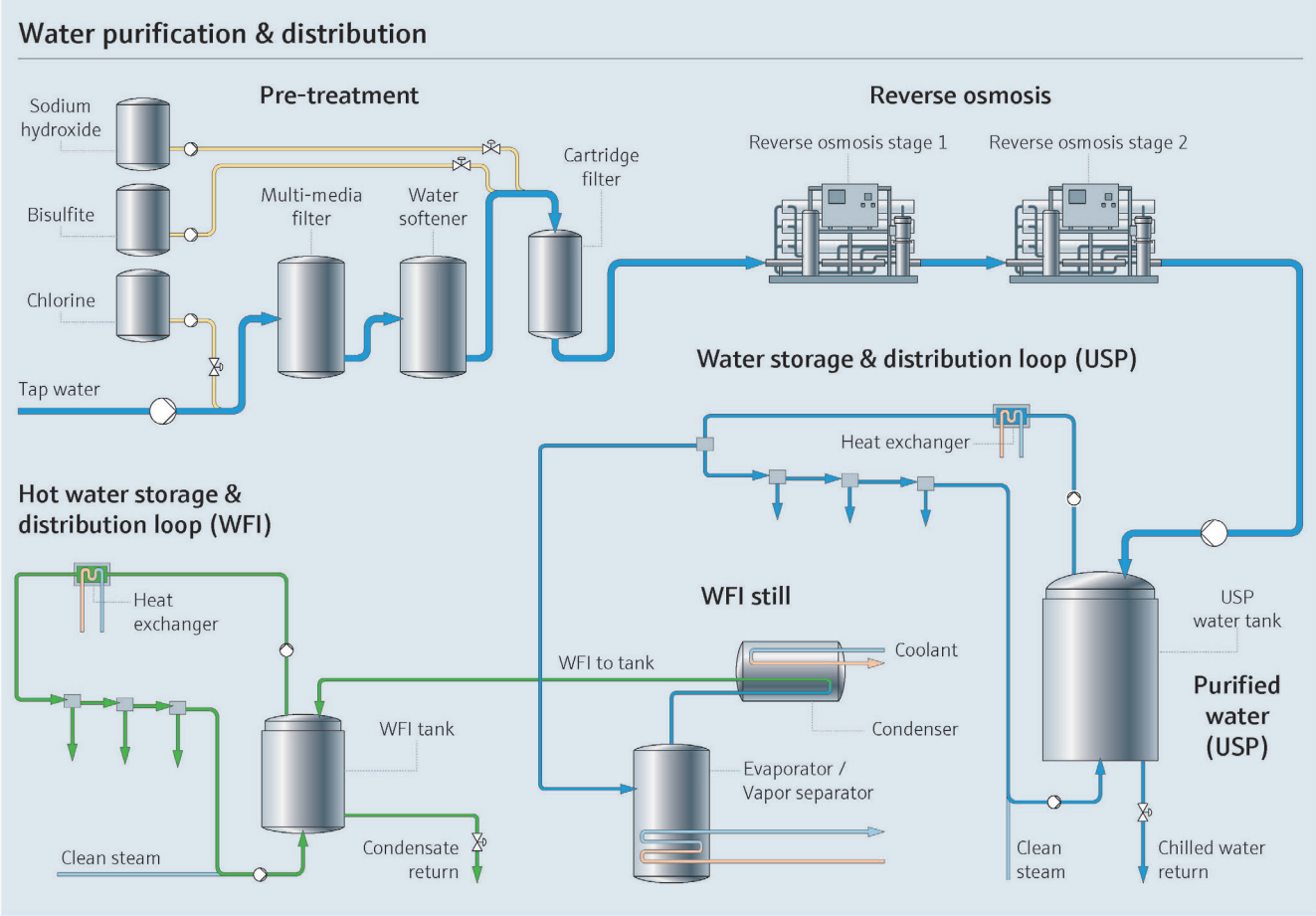

The water conductivity is measured with a sensor that does not need to be temperature compensated. The conductivity must be lower than 2.7µS/cm at 85°C. The pressure is constantly monitored in the outlet pipe before the WFI storage tank. The signals from the level and temperature sensor in the tank are required for the control of the system as well as for registration purposes. Endress+Hauser offers a measurement solution for all mentioned quality measurements. All sensors have approval certificates from the Food and Drug Administration (FDA) and United States Pharmacopoeia (USP).

The emphasis on technology To monitor the flow in WFI loops, the **Promass P** is ideally suited. The Promass P is a mass flow meter that does not suffer from the low conductivity of water and offers the best possible accuracy. The mass meter is designed and manufactured according to ASME BPE (American Society of Mechanical Engineers Bioprocessing Equipment) regulations.

The conductivity sensor **Memosens CLS16E** and **Liquiline CM transmitters family** perfectly meet the critical

Flow measurent in WFI loop with Promass P.

requirements in utilities. In addition to the accuracy of the sensor, the transmitter shows the internal standard table with continuous comparison of the measured value (tables according to USP <645> and Ph. Eur <0169>). If the upper limit is reached, an alarm is triggered by the transmitter.

Furthermore, there is no galvanic connection between the sensor and the transmitter (**Memosens** connector technology). This solves the problems of electromagnetic interference, moisture and faulty cables. The Memobase Plus CYZ71D software supports the complete life cycle of each sensor and complies with FDA CFR21 Part.11. This is a clear advantage in a GLP/GMP working environment.
The Cerabar PMP51 pressure transducer offers a wide range of typical process connections from Tri-Clamp ISO2852 to Neumo BioControl. The previously mentioned ASME BPE design requirements applies here as well. The PMP51 is the best solution to monitor the pressure in the discharge line. The **Levelflex FMP53** is a level meter that is not affected by temperature, moisture, density, gas and pressure. Designed for sanitary applications, this guided radar is the most reliable solution. The rod can be tailor made to fit in tanks where a vertical installation is not possible.

The Levelflex can continuously measure the contents of the tank up to 1 cm gap from the tank bottom surface. The Levelflex is not hindered by internal tank constructions, spray balls or rotating spray nozzles. The use of a nitrogen blanket plays no role.

The radar is designed according to ASME BPE.

Temperature is measured in the WFI loop, in the pipe before the point of use and in the WFI storage tank. The ideal temperature sensor should have a fast response time as this is beneficial for process control, especially in heating and cooling applications. In these applications, tight control within a defined measurement range, ensures correct use of energy sources (e.g. steam and refrigerant) and safeguards product quality. The **iTHERM® QuickSens** from Endress+Hauser help achieve these results. The sensor has the fastest Independent of classification GMP critical, GMP non-critical or GMP utility, the instruments must be calibrated more or less frequently.

The entire loop from the instrument to the control system is checked by the calibration process. In practice, this is a lengthy process with additional risks because the wiring of the measuring insert has to be disconnected. This is no longer necessary with iTHERM® QuickNeck, thanks to the new quick connection design. The sensor can be removed without the use of tools, which in turn saves time and money.

The thermowells are available with various sanitary connections. In order to reduce the contamination risk, there is the thermowell version with spherical weld-on adapter, e.g. for installation in the WFI tank bottom.

The recorder **Memograph RSG45** visualizes and stores data according to FDA 21CFR part 11.

Data storage is essential to demonstrate full compliance of the WFI production process. In addition, the Memograph is supplied with specific documentation for Installation Qualification (IQ) and Operational Qualification (OQ) and with back-up software. The display, suitable for use in a sanitary environment, is operated via a touch screen.
The recorder can share data via digital communication with other systems that do not have to be FDA compliant. The communication options are: Modbus TCP/RTU, Profibus DP, ProfiNet or EtherNet/IP.

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