

Production and distribution of purified water



In June 2002, a major pharmaceutical laboratory launched an invitation to tender for constructing a new purified water production and distribution unit.

The projects included the following lots:

- > Production of purified water
- > Distribution of purified water
- > Control system.

The purified water, (produced from cold raw municipal water) must comply with the most stringent pharmacopeia requirements :

- USP 25
- EP 4^o edition
- JP

The quality of the water when coming out of production and at supply points must at least comply with the following characteristics :

- Conductivity < 1,1 $\mu\text{S}/\text{cm}$ at 20°C
- TOC < 500PPB
- Bacteriological quality < 5 UFC/ml
- Endotoxins < 0.25 UI/ml

Overall requirement for running in three shifts, 5 days a week

- Consumption of purified water \Rightarrow 60 to 126 m³ per day
- Production capacity \Rightarrow 6.3 m³ per hour
- Purified water temperature \Rightarrow 15° C
- Purified water storage capacity \Rightarrow 16 m³

Pharmaceutical constraints:

- cGMP
- CFR21 part11 (electrical records)
- GAMP 4 (méthodology)



DESCRIPTION OF THE INSTALLATION: PRODUCTION SECTION



- Piping : PVC and STAINLESS after the 1 μ filtration output.
- Processing line:
 - 2000 liters disconnection tank
 - Booster pump
 - Chlorination
 - 300 μ filtration
 - Softening
 - 10 μ filtration
 - Injection of caustic soda
 - Injection of bisulfite
 - 1 μ filtration
 - Osmosis (single stage)
 - EDI
 - 0.2 μ final filtration

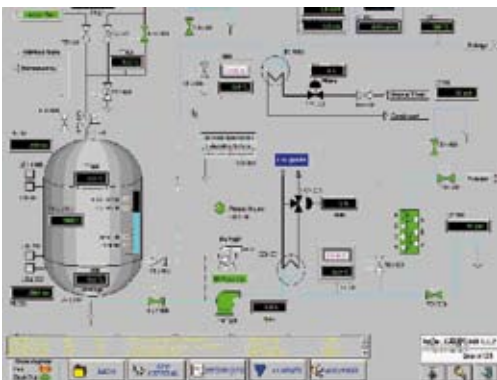


- Production flow on exit from EDI : > 6300 l/h
- Quality: > 10 M Ohms
- Quality of stainless pipe-work on permeate outlet after osmosis: Ra < 0.6 electro-polished
- NOTE: Automation of 3 chemical disinfecting cycles on the pre-processing circuit.

DESCRIPTION OF THE INSTALLATION: DISTRIBUTION SECTION



- Piping: for sections in contact with purified water STAINLESS Ra 0,6 μ electro-polished Dockweiler type.
- Processing line :
 - Purified water storage tank 16 000 litres (Ra < 0.6 electro-polished)
 - Single-stage booster pump 40 m³ per hour, 9.5 B
 - Cold exchanger
 - Ozonisation circuit
 - Ozone measurement before UV
 - UV
 - Ozone measurement after UV
 - Circuit outlet
 - Circuit return
 - Flow measurement (mass flow-meter)
 - Steam exchanger (sterilisation at 121°C)



- Loop Flowrate, draw off excluded: 16 000 l/h
- Flow at maximum draw off: 40 000 l/h
- Quality: > 10 M Ohms
- Quality of stainless piping: Ra < 0.6 imperial type
- Number of draw-off points: 45 automatic

NOTE :

- Two disinfecting cycles on the circuit and the purified water tank : ozonisation, thermal sterilisation at 121 °C
- The tank is continuously inerted and ozonised except during the 121°C sterilisation cycle.

DISTRIBUTION LOOP



- Design and construction of the purified water distribution loop :

Approximately 1000 metres of DOCKWEILER piping, diameter 76 Ra 0.6 microns electro-polished with 45 draw-off points.

- The service consists of :
 - Taking account of the customer's requirements and necessities,
 - Defining the route followed by the loop,
 - Doing the isometrics,
 - Having all the plans validated by the customer,
 - Deal with supplies for loop elements,
 - Build and weld the loop,
 - Draw up the welding inspection file as per official procedures
 - Check welds by endoscopy,
 - Carry out pressure tests,
 - Passivate the loop by circulation,
 - Adjust flow rates at every draw-off point



SYSTEM FUNCTIONALITIES



- The control system must enable the whole purified water installation to be operated.
- This application has been handled and constructed in compliance with pharmaceutical industry requirements:
 - cGMP
 - CFR 21 part 11
 - GAMP 4

- The service consisted of :
 - Design work
 - Drawing up a functional analysis
 - Developing the application
 - Qualification

- Main technological aspects :

- Windows 2000
- Intouch V8 control
- Siemens S7 PLCs
- Approvals and reports: Development under Delphi

