

# A solution fit for Pharma

## Pharmaceuticals | Case Study

### The Client

Our client is a contract manufacturer that specialises in handling volatile pharmaceuticals.



### Key Benefits

- Pharmaceutical-specific solution with the ORION® S system for European Pharmacopoeia grade water
- Water savings, thanks to the ORION®S built-in recovery RO and recirculation
- Increased water purity and flow rate to meet a daily demand of 40 m<sup>3</sup>
- Independent hot water sanitisable systems for efficient scheduling and compliance with MHRA

### The Client's Needs

The original system that supplied water to the manufacturing area had a semi-sanitary design, designed for periodic chemical sanitisation, and it was getting old, placing it under scrutiny from the Medicines and Healthcare products Regulatory Agency (MHRA). The client wanted to modernise and upgrade to a state-of-the-art system to meet a number of requirements in line with current good manufacturing practice (cGMP) and the European Pharmacopoeia, including a hot water sanitisable design to meet MHRA expectations and minimise bacterial growth.

The new solution needed to integrate with the existing stainless steel ring main, while adding two extra points of use. The facility also required an increased purified water flow rate and storage volume, and our client wanted to introduce water saving measures where possible. Finally, installation needed to be achieved with a minimum of disruption to on-site production.

### The Solution

Veolia's team of expert engineers developed a solution comprising three connected sub-systems with a minimum of dead legs: a raw water pre-treatment system, a purified water generation system, and a storage and distribution system. The pre-treatment system consists of a break tank and pump arrangement, providing the required flow and pressure to the purified water generation system. An ORION® S system is central to the second treatment stage, softening the water prior to reverse osmosis and continuous electrodeionisation, all within a skid-mounted, self-contained platform.

This brings the raw water feed up to the correct water quality to meet European Pharmacopoeia guidelines, for feeding into the storage and distribution system. The final step comprises individual equipment to store and continuously recirculate the purified water to the distribution loop, as well as UV control to inhibit bacterial growth. The total installation is hot water sanitisable from the purified water generation onwards. Both the ORION®S and distribution system have independently controlled sanitisation functions, allowing optimised scheduling of daily or one-off sanitisation cycles at a time convenient to the external process, such as when water consumption is at a minimum. A bespoke system control panel was also installed, fitted with a paperless chart recorder for electronic data trending and remote monitoring to aid the batch manufacturing process.

## Results

The entire installation was managed by Veolia's experienced project manager, who worked closely on site with the client. The system was initially commissioned, validated and run for 30 days in isolation from the ring main to check the consistency of purified water quality and production. Following successful compliance, the solution was sanitised and connected over the weekend, ensuring that the client did not suffer any production downtime. The new water treatment solution is more than sufficient to meet the daily demand of 40 m<sup>3</sup> of purified water and the water purity exceeds European Pharmacopoeia requirements. A conductivity of  $\leq 0.5 \mu\text{S}/\text{cm}$  at 20 °C or less is well below the necessary  $\leq 4.3 \mu\text{S}/\text{cm}$ , and the bacteria total viable count of  $\leq 010 \text{ cfu}/\text{ml}$  offers a 10-fold improvement on the specified requirement. Choosing the ORION® S model gave the client a system with a built-in RO unit, reducing water consumption, and a recirculation mode that reuses most of the water that previously would have gone to drain, both significantly contributing to reduced waste water costs.

## Design Technical Specifications

- All materials are ASTM 316L or equivalent
- Air breaks (nominally 50 mm)
- Hygienic stainless steel diaphragm valves (butt weld ends or tri-clamp connections)
- Both the ORION® S and main control panels are 21 CFR Part 11 compliant

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