

Intelligent sub loops can optimise hygiene for ultra-pure water applications

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Maintaining hygienic flow conditions in purified water (PW) and water for injection (WFI) sub-loops, a critical challenge is minimising the biofilm risk. Traditional approaches like monitored T-valve systems fail to guarantee consistent conditions, while the geometry of Coriolis flow meters aren't typically optimised for hygiene. Instead, by integrating an intelligent, fully automated sub loop with hygienically optimised flow measurement and valve technology, it is possible to achieve controlled circulation, precise dosing, and prevention of biofilm formation.

Bürkert's Business Development Manager for Pharma & Biotech, Damien Moran, explains.

In a pharmaceutical manufacturing facility, a purified water or water for injection point-of-use (POU) system delivers ultra-pure water exactly where it's needed, with the main loop continuously flowing to maintain hygiene. From this main distribution circuit, sub loops are typically required to supply specific production areas or skids. However, a core challenge is managing the flow conditions within them.

If flow in a sub loop is demand-driven, or dependent on main loop conditions, there's a risk of low or zero flow velocity, or even flow reversal, all of which can impact PW or WFI quality. Even with an ultra-pure water main loop, trace bacteria can enter the system through microscopic leaks or cracks, or contamination from maintenance,

so when trace bacteria enter the sub loop, below optimal flow conditions can lead to biofilm growth. As a result, accurate flow management in the sub loop is critical.

Manual control challenges

In an attempt to manage flow, manual control of the sub loop is an option, and it's an approach more commonly used for PW applications rather than the greater precision demanded for WFI applications. However, a manual approach ultimately results in undefined quantities through operator-dependent volumes, particularly if there's no direct flow measurement at each POU. This can lead to media waste, but conversely it can also heighten hygiene risk in the event of under flushing. Either way, the demand for accuracy when controlling sub loop flow with manual methods requires training and experience to achieve.

Integrating a manual T-valve system with a simple branch to the POU, rather than integrating a sub-loop with its demand for continual and accurate flow management, can reduce the potential of biofilm growth. However, this approach can't eliminate the hygiene risk as flow in the dosing path, which still depends on user demand and manual control, will remain undefined, inconsistent, and intermittent. Even a flow-monitored T-valve system presents a contamination risk in the dosing line, because while this approach improves visibility, it can't remove the potential for dead legs and stagnation.

Surface Acoustic Waves

Instead, to achieve a POU batch dosing system that can effectively prevent biofilm build up, the alternative is to integrate an intelligent sub loop that can ensure constant and optimal flow. The flow meter is crucial to this system, and ideally it should measure velocity and volumetric flow, as opposed to only monitoring mass, as these criteria directly relate to the conditions that prevent biofilm build-up. Crucial for hygienic design, the geometry of the flow meter should also include a straight

tube, which not only minimises the potential of dead legs but also enables easier and more effective cleaning.

An effective way to achieve flow measurement while optimising hygiene is with Surface Acoustic Wave technology. This method calculates the time differences of acoustic waves that travel along the surface of the tube, proportional to the flow of the PW or WFI media. With this approach, the indicators of biofilm development, including real time volumetric flow, cumulative volume, velocity, and temperature, can all be accurately measured. As Surface Acoustic Wave sensors are positioned on the surface of the tube rather than in the flow path, this minimises the potential of biofilm development.

Bürkert's FLOWave flowmeter integrates Surface Acoustic Wave technology to achieve dosing accuracy down to 0.4% of the measurement, repeatable to 0.2% deviation. This ensures that sufficient turbulence can be maintained within the subloop for WFI and PW applications, as well as providing precision in dosing. Constructed from 316L stainless steel, the internal surface of Bürkert's Type 8098 FLOWave flow meter has an average roughness (Ra) rating of <0.4 µm, meaning there are no microscopic imperfections where biofilm can grow. The flowmeter is also CIP/SIP compatible.

2-weir valve technology

In combination with accurate flow metering optimised for hygienic applications, the accompanying valve system is crucial. For a POU sub loop, two valves would typically be required – one to continually channel flow through the sub loop, the other to allow dosing at the POU. However, by integrating a multi-way diaphragm valve, this can manage both flow operations within the footprint of a single valve.

Bürkert's pneumatically controlled Type 2036 Robolux multi-way diaphragm valve is based on 2-weir technology that incorporates two independently switchable valve

actuators in one housing. Rapid switching enables the valve to redirect flow almost instantly, optimising dosing accuracy and ensuring uninterrupted flow.

Designed for hygienic applications including PW and WFI applications, the Type 2036 valve features flow-optimised geometries that remove dead legs and enhance self-draining. Like the FLOWave flowmeter, the valve is also constructed from 316L stainless steel, and can be used within CIP/SIP cleaning processes.

Intelligent control

Bürkert's POU system is fully automated, and a key advantage is precision and repeatability in control. This is crucial both to ensure accuracy in dosing, as well as to optimise flow in the sub loop and prevent conditions that can cause biofilm. This level of control intelligence assures quality and compliance, crucial across WFI applications, and also provides full data in support.

The automated system optimises efficient use of PW or WFI, removing costly wastage. This approach also means the system is much easier to operate, which not only saves time in use, but minimises the training requirement and dependence on skilled operators. The system can integrate with a PLC or operate stand-alone via a display and can host flexible automation units and communication protocols to achieve a fully automated control loop.

In PW and WFI distribution systems, while sub loops place greater demands on design to optimise hygiene and remove the biofilm risk, the latest systems increasingly focus on combining hygienic geometry with controlled, measurable flow to ensure consistent performance at point of use. While this approach can enhance efficiency for PW applications, it's a next-generation upgrade for WFI loops that demand optimal hygienic quality, achieving optimal circulation with accurate, repeatable extraction.

Images & Captions:

Image 1: Bürkert's point-of-use system combines precision flow measurement with rapid valve switching for very accurate delivery and repeatability.

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Bürkert Fluid Control Systems is one of the leading manufacturers of control and measuring systems for fluids and gases. The products have a wide variety of applications and are used within food & beverage, pharmaceutical and water industries as well as in medical engineering and space technology. The company employs over 3,700 people and has a comprehensive network of branches in 36 countries world-wide.

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