The Primary Importance of Efficient WFI Distribution Loop Design

Session Description

Water for Injection (WFI) is the lifeblood of the pharmaceutical manufacturing industry. Keeping WFI media free from contaminants is paramount to patient safety and operational efficiency.

Generation of this critical media through Multi-Effect Distillation (MED) Vapor Compression (VC) or Membrane-Based Ambient WFI (AWFI) offer a range of advantages and disadvantages. This presents what often looks like a rigid binary choice. Thermal Generation (MED or VC) can provide optimal sterility but raises safety and sustainability challenges. Ambient (AWFI) Generation offers improved sustainability and safety but raises sterility challenges and limitations when heated WFI is required. All carry high Opex implications according to their respective limitations, a hidden and difficult metric when it comes to measuring true sustainability.

Designing a Distribution and Dispense Loop for WFI is challenging and much of the focus at the conceptual design phase goes into establishing which WFI Generation philosophy to adopt, even though dispense of WFI at point-of-use is where the combined challenges to Optimal Safety, Sterility and Sustainability are at their peak.

It is this gap in the conceptual design process for WFI systems that we believe needs to be closed if we want to achieve a true step-change in what has often been the Cinderella of WFI system designs, Distribution and Dispense.

Regardless of the generation method chosen, thermal WFI is recognized as the Gold Standard for Sterility in WFI distribution and dispense but presents potential dangers to staff. In recent years the focus on sustainability has grown significantly, with many companies searching for methods to strike a balance between reducing their carbon footprint, while maintaining a sufficiently robust WFI system to meet their regulatory and manufacturing goals at the same time.

There is however a Third Way in which these goals can be achieved when designing WFI systems, a way in which corporate carbon mitigation commitments can be achieved without compromising the productivity and regulatory requirements of Pharmaceutical Manufacturers.

This Third Way is to place *Sensibly Sustainable* Thermal WFI Distribution and Dispense system design as *the central and guiding principle* for all other equipment selection both upstream and downstream; Generation, Storage, Loop Design, Process Equipment. These all can be part of a fully optimized WFI philosophy, designed to deliver maximum efficiency in safe and sterile production, with full return on investment, and ongoing reduction in energy usage.

Exergy's experience on WFI Projects over many years has shown that, when deeper consideration is paid to the distribution and dispense philosophy of a new WFI System, major improvements can be made in manufacturing flexibility, reduced downtime,

reduced contamination events, increased safety and greater overall productivity with a smaller manufacturing footprint. This method can help facilities achieve that elusive goal of optimal safety and sterility with lasting and sensible sustainability.

We call it Sensible Sustainability – *by Design*.

Learning Format + engagement details
PowerPoint Presentation with Supporting Scientific Data covering.

Current WFI Loop Designs
Audience Engagement will take place through discussion on the various design options for WFI distribution loops and dispensing options, examining their respective strengths and weaknesses from the perspectives of safety, sterility and sustainability.

Clean Utility Capital Infrastructure planning.
Consideration will be given to how WFI capacity requirements are calculated based on the various process equipment and cleaning sink demands and the importance of placing WFI distribution loop and dispense design at the very front end of that process including.

> **Clean Utility Capital Equipment Specifications.**
> How the development of a fully optimized WFI System philosophy when executed in tandem with process equipment and user point specifications and demands, can reduce the scale of generation, storage, pipe diameters and facilitate better integration of communication and control architecture across all Capital Equipment Vendors.
>
> **Modular Offsite Production Facilities**
> Consideration will be given to the importance of good WFI Dispense Point design that can meet that challenge of integrating WFI user points into these Modular Solutions.
>
> **Safety, Sterility, and Sensible Sustainability in WFI Loop Design**
> Why prioritizing design of this critical infrastructure, which is the location for much of the hazards of burns, contamination and energy waste can greatly mitigate these occurrences without compromising efficient manufacturing.

Case Studies
Case studies to highlight both the benefits and importance of placing WFI Distribution and Dispense Loop Design as the central and guiding principle for all Clean Utility Capital Infrastructure planning.

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Target Audience

Biopharmaceutical Process Specialists	Manufacturing Technical Specialists	Process Automation Engineers
Automation & Instrumentation Engineers	Manufacturing Technology Engineers	Process C&Q Engineers
Biotech Utilities Engineers	Mechanical Projects Engineers	Process Design Consultants
Clean Utilities Engineers	Mechanical Design Engineers	Process Directors
Clean Utilities SME's	Mechanical Engineers	Process Engineering and Validation
Cleaning & Validation Engineers	Mechanical Engineers - Sterile Systems	Process Engineering Engineers
Construction Project Engineers	Mechanical Maintenance -Clean Utilities	Process Engineers
Controls Systems Engineers	Mechanical QA Engineers	Process Engineers - Clean Utilities
CQV & GMP Compliance SME's	Operations & Construction Engineers	Process Engineers - Clean Utilities
Design & Process Engineers	Operations Engineering Engineers	Process Engineers - Life Sciences
Electrical & Instrumentation Engineers	Pharmaceutical Process Engineers	Process Equipment Engineers
Energy/Utilities Engineers	Pharmaceutical Quality and Compliance	Process Equipment Project Engineers
Facilities & Building Projects Engineers	Pipe Design Engineers	Process Improvement Engineers
Facilities & Utilities Engineers	Piping & CAD Engineer	Process SME's
Facilities /Utilities Engineers	Plant & Facilities Engineers	Process Utility Engineers
Instrumentation & Controls Engineers	Plant and Equipment Engineers	Process/Biopharma Consultants
Lead Buyers CAPEX	Plant Design Heads	Procurement Specialists
Maintenance Engineers	Process & Project Engineers	Project Architects
Maintenance Leaders	Process & Technology Engineers	Project Coordinators
Manufacturing & Design Engineers	Process & Utilities Engineers	Project Engineering Engineers
Manufacturing & Projects Engineers	Process and Bio-Pharma Consultants	Safety & Environmental Officers
Manufacturing & Projects Engineers	Process and Clean Media Engineers	Safety Officers
Manufacturing Engineers	Process and CQV Engineers	Technical Procurement Engineers
Manufacturing Operations Engineers	Process and Piping Engineers	Test & Efficiency Engineers
Manufacturing Process Engineers	Process and Technology Engineers	Utilities Systems and Sustainability Engineers
Manufacturing Production Engineers	Process Automation Engineers	Validation Engineers
		WFI Systems Engineers

Each learning objective

1. **Designing for Capex Reduction and ROI.**
   How placing Thermal WFI Distribution and Dispense System design at the forefront of Clean Utility Capital Infrastructure planning can significantly reduce Capex expenditure

2. **Designing for Safe, Sterile, Sensibly Sustainable Outcomes.**
   How optimized Thermal WFI System Design removes safety hazards, reduces contamination events, drastically reduces WFI waste and operating costs, sensibly and sustainably.

3. **Designing for Modular Manufacturing.**
   The critical importance of designing pre-assembled Thermal WFI User Points for simplified installation, integration, and commissioning in Modular Process Facility builds.