

High Purity Water Systems Generation, Storage & Distribution

Overview

This course delivers a detailed understanding of high purity water systems from raw water to point of use. From user requirements and system design considerations to the routine operation, maintenance and monitoring of these systems. Purified water (PW), water for Injection (WFI) and pure steam.

Every pharmaceutical process relies on one or more of the above water qualities either for cleaning or as a raw material. Water of controlled consistent quality needs to be available at each user point at the temperature, pressure and flow required by the process/product. This is a lot harder to get right than anticipated and getting it wrong can cost €millions!

Annex 1 updates / drafts which are in the pipeline have considerable additional requirements and focus on critical utilities and bio film control. This is a significant regulatory interest area currently. These regulatory trends and actual examples are discussed throughout the course.

Target audience

This course has been delivered all over the world to designers, maintenance engineering functions, operations and QC personnel who wish to develop a 'subject matter expertise'.

Successful ownership and operation of a high purity water system requires a multi-disciplined team approach involving engineering, QC, chemistry and micro, operations and validation. This course begins from first principles and finishes with the latest regulatory trends, interest areas and industry feedback.

About the Lecturers

Mark Thompson has over 27 years of pharmaceutical industry experience and has been delivering training and consultancy to the industry for the past 19 years.

Lee Eyres is a Chemist who has previously worked for water generation/purification companies and his expertise is in the water quality, purification technologies as well as high purity water systems as a whole.

These lecturers have delivered this training all over the world, throughout EU, China and Brazil as well as being involved in project delivery in the same regions.

| Consultancy & training in sterile product manufacture |

Course Programme

DAY 1: Introduction to High Purity Water, Chemistry, Microbiology and Controls

- Introduction to High Purity Water
- Pharmacopeia defined water qualities and specifications
- Specifications from Raw Water to WFI
- Water Chemistry and Microbiology
- Biofilm in Water systems
- Control of Biofilm in Water systems
- Understanding surface properties and materials of construction
- Mechanisms for Water Purification Chemistry, Microbiology and Control
- URS for a High Purity Water System

DAY 2: High Purity Water Systems Generation

- Pre Treatment Systems
- RO Technology and Design
- EDI Technology and Design
- Design of PW Generation System
- Design of WFI Generation System
- Design of Pure Steam Generation System
- Qualification and Routine Monitoring of a Generation system
- Troubleshooting Generation Systems
- New Technology and regulatory developments
- Generation Plant Efficiency, opportunities for reducing waste water.

DAY 3: Storage and Distribution and Overall Compliant control

- Storage and Distribution system design principles
- Defining User Requirements
- Loop Design options
- Point of Use controls for Temp, Press, Flow.
- Point of use hygienic management
- Qualification of the Storage and Distribution System
- Troubleshooting Storage and Distribution Systems.
- Maintenance Requirements for High Purity Water Systems
- QC Data interpretation and ongoing review
- Water Quality Team and continuous compliance
- Regulatory Trends and inspection / audit findings.

NOTE : Above example programme can be tailored to site specific needs, technologies and regulatory requirements.

Recent Comments

"Lee's explanation of water purification system design has allowed me to understand inside the Purification skid for the first time. Our site issues are so easily solvable with the help and guidance given"

"Mark's Engineering background in system design has delivered real clarity to our distribution system specification and qualification. Previous Issues with Biofilm are now in control."



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