High Purity Water Systems Generation, Storage & Distribution

Every pharmaceutical process relies on one or more of the following water qualities either for cleaning or as a raw material; Purified Water (PW), Water for Injection (WFI) and Pure Steam. 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!

about the course

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. It is relevant for Engineers, Validation professionals & QA.

Purified Water (PW), Water for Injection (WFI) and Pure Steam. Annex 1 updates/drafts which are in the pipeline have considerable additional requirements and focus on critical utilities and biofilm control. This is a significant regulatory interest area currently. These regulatory trends and actual examples are discussed throughout the course.

who should attend

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 gxp training

GXP Training was set up in 2016 to harness the expertise within The Compliance Group, EUPS and its wider network to develop and deliver a suite of training courses in the GxP environment.

As well as providing professional and focus scheduled courses that will provide cost effective ways to meet training needs within the industry all courses will be available for in-house training should this be the customers preferred route.

course content

day one	day two
• Introduction to High Purity Water and Regulatory Standards / Guidelines • Pharmacopeia defined water qualities and specifications • Specifications from Raw Water to WFI • Water Chemistry and Microbiology • Developing a URS for a water system • System Design, User requirements and POU schedules • Pre-Treatment Systems	• RO and EDI Technology and Design • Overall Design of PW Generation System • Overall Design of WFI Generation System • Design of Pure Steam Generation System • Storage and Distribution system design principles • Defining User Requirements • Loop Design options • Point of Use controls for Temp, Press, Flow.

what else should I know

Course Fee: €2,000 for 3 days. The course fee includes all course material, lunches and refreshments. Please note that this course may also be organised in an in-house basis. Please contact us for further information. High Purity Water Systems Training delivered on your site is generally tailored to the specific loads, sterilisation processes, autoclaves, tunnels and any current issues.

how to apply

Applications can be made online at **www.gxp.ie** or by emailing **training@gxp.ie**

location and date

For details on the next available course please see **www.gxp.ie**

about the presenters

Mark Thompson - Mark Thompson Life Sciences

Mark is a Chartered Engineer with over 25 years' experience in the Life Sciences industry. Mark has been delivering Training and Consultancy all over the world to a significant number of organisations within the industry for the past 18 years.

Lee Eyres

Lee 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.

Stan O'Neill – The Compliance Group

After qualifying as a Pharmacist, Stan spent over five years working in the pharmaceutical industry before joining the Irish Medicines Board (now the HPRA) for a period of ten years. In his capacity as a Senior Inspector, he performed GMP inspections throughout the world, represented Ireland at European level for the negotiation of standards of inspection for medicinal products (including Annex 1) and trained Inspectors at Irish, European and International levels.

course content

day three	
• Biofilm in Water systems • Control of Biofilm in Water systems • Hygienic Engineering Design • Troubleshooting Water and Steam Systems • Qualification and Routine Monitoring of Water and Steam Systems, • New Technology and regulatory developments	• Generation Plant Efficiency, opportunities for reducing consumption • Maintenance Requirements for High Purity Water • QC Data interpretation and ongoing review • Regulatory Trends and inspection / audit findings.

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