

critical utilities

Critical utilities that have a direct impact on product quality can include water, steam, compressed air and other process gases. These services often move throughout the whole plant and link 'uncontrolled' plant room environments with the highest grades of the manufacturing process and product contact. While important for all dosage forms, they are of particular interest to Regulators for sterile products as reflected in the updated Annex 1"

Ownership of critical utilities on site can sometimes be unclear and this course supports SME development to improve ownership and control of critical utilities.

about the course

This course delivers a detailed understanding of Critical Utilities from black services to maintenance interventions, from storage and distribution to filtration, steam quality testing and fault finding. 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. This is a significant regulatory interest area currently. These regulatory trends and actual examples are discussed throughout the course.

course content

day one

- Introduction to Quality Critical Utilities
- Quality Impact of Black Services
- User Schedules and Controls
- Maintenance Interventions and Controls
- High Purity Water Systems and Water Quality Spectrum Tap Water to WFI
- PW and WFI Generation Systems

day two

- Storage and Distribution
- Rouge Management
- Other Wet Systems and Drains
- Pure Steam Systems: Generation
- Pure Steam Systems: Distribution and Use
- Steam Quality Testing and Fault Finding

day three

- Compressed Air and Process Gases
- User Point Schedules and Criticality Assessments
- Filtration in Critical Utilities
- HVAC Systems Monitoring and Maintenance
- Annex 1 Developments for Critical Utilities
- Bio film in Critical Utilities Systems
- Regulatory Landscape
- Managing GMP Inspections of Critical Utilities

who should attend

Control of critical utilities requires a multi-disciplinary approach, involving Engineering, QC Chemistry and Micro, Operations and Validation, as it cuts across engineering (site and production), QC testing, QA and operations. All of these disciplines would benefit from attending.

what else should I know

Course fee: €2,000

The course fee includes all course material, and where applicable, all refreshments and lunches. Please note that this course can be tailored to your specific needs. Please contact us for further information.

how to apply

Bookings can be made online at www.gxp.ie

location and date

Dublin, Ireland or Live online

For upcoming course dates see www.gxp.ie

about the presenters



past 18 years.

Mark Thompson 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

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.



Stan O'Neill 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.

about gxp training

GXP Training was set up to harness the expertise within The Compliance Group, Compliance Management and its wider network to develop and deliver a suite of Training Courses in the GxP environment. As well as providing professional and focus schedule courses that will provide cost effective ways to meet training needs within the industry, all courses will be available for in-house trainings, should this be the customers preferred route. We also do live-online training.

www.compliancegroup.eu

www.gxp.ie

www.compliancemanagement.eu