

Critical Utilities

Overview

A very topical subject with the regulators and likely to be a key part of Annex 1 update.

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.

Ownership of critical utilities on site can sometimes be unclear and this course is often delivered as part of SME development to improve ownership and control of critical utilities.

The two day programme shown is typical two-day content for critical utilities. In some cases, the course is expanded to four days to include much more detail in key areas (generally water systems and HVAC/filtration). The course content can be tailored to suit, based upon site discussions.

Target audience

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

The best courses often have representation from each of these groups which helps the understanding of the cross functional requirements.

Application of Knowledge

Information is only a click away on any subject. Internet content, webinars, on line 'training' etc. In many cases there is information overload, and contradiction. Intelligent Application of this readily available information is where Mark Thompson Lifesciences can help.

About the Lecturers

DALL courses are led by Mark Thompson who delivers the majority of lectures. Mark has over 27 years of pharmaceutical industry experience and has been delivering training and consultancy to the industry for the past 19 years.

Dependent upon the agreed course scope, additional lecturers in the areas of chemistry, microbiology and other technical disciplines may be involved.

| Consultancy & training in sterile product manufacture |

Course Programme

DAY 1:

- 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
- Storage and Distribution
- Rouge Management
- Other wet systems and Drains

DAY 2:

- Pure Steam Systems: Generation
- Pure Steam Systems: Distribution and use
- Steam Quality Testing and Fault Finding
- 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
- Course Assessment

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

Recent Comments

"We booked this course as part of our SME process improvement program and have got so much out of the course! Highly recommended!"

"The Practical examples and case studies were so relevant to our site and our current issues"

"Mark is such an engaging lecturer with a lifetimes experience of solving these problems, the case studies used throughout kept the course alive."