MARKTHOMPSON
LIFESCIENCES

Pharmaceutical Engineering & GEP Trends

Overview

This course delivers an update on pharmaceutical engineering for engineers, validation professionals & QA.

Annex 15 updates and recent regulatory trends have significantly impacted upon the approach to project engineering, qualification and requalification.

As an example Annex 15 asks for OQ tests to be developed from the knowledge of the process also that upper and lower operating limits are confirmed. But what does this mean in practice.

This course is structured to deliver an overview of current project engineering and qualification approaches with worked examples throughput as to how companies are addressing these regulatory requirements. There is an opportunity in this to improve the project process and also make the qualification phase more efficient by focusing on the critical.

Key technologies employed in the pharmaceutical industry are discussed with examples of current industry approaches, risk based approaches and regulatory feedback in each areas. This approach to the course provides an overview of key technologies and identifies current issues and trends with each.

The course will also deliver proposed documentation structures to enable compliance as efficiently as possible and ensure that documentation integrates throughout the project. The course uses an example of a new sterile product filling line as a worked example throughout the project, this is where the 'real world' examples come from several current and recent projects.

Target audience

This course will be of great value to anyone currently involved or responsible for project engineering, process improvement, commissioning, qualification and validation activities.

About the Lecturers

All courses are led by Mark Thompson who delivers most of the 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.

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Course Programme

DAY 1:

- Engineering GMP's and the regulatory structure (EU and US)
- Quality Critical Requirements and Process Impact Assessments
- Process Lifecycles from Concept to Decommissioning of Equipment
- Process Risk Assessment (PRA) Throughout the project, maintaining a live PRA that adds value.
- Project Definition and Initial Risk Assessment (URS and Initial PRA)
- Project Lifecycle and the Documentation structure to support
- Supplier Auditing and Control

DAY 2:

- The Use of Requirements Traceability Matrix (RTM) as the hub of the project
- Integration of URS and PRA into the RTM
- Establishing the design window and understanding the maximum and minimum limits for all critical parameters.
- The use of FAT, Commissioning, Development work to establish the limits for qualification.
- How to document process development and commissioning
- Worked examples for development and Qualification of:-
  - Glassware washing processes
  - Depyrogenation ovens and Tunnels
  - Filling Processes
  - RABS and Isolator Technologies
  - VHP Sanitisation
  - Equipment Sterilisation and SIP systems
  - Clean Rooms and HVAC
  - HEPA Filtration
  - Critical Utilities

(NOTE : Each of these sections will include current regulatory and industry trends as well as examples from various projects as to the qualification approach to take).

DAY 3:

- Project Change Control from URS to Production
- Leveraging data throughout the project
- Use of 'Wrap around' protocols to leverage data.
- Calibration Requirements and Traceability
- Defining the ongoing Maintenance, Calibration and Requalification requirements and frequency.
- Link to site VMP and direct impact systems assessments.
- Maintaining compliance, self inspection and annual review.
- Preparation for regulatory inspection
- Engineering Involvement in inspections and data presentation / discussions
- Regulatory feedback

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

Recent Comments

"This approach to Project Control and Qualification is going to add so much value to our Projects and Qualification we should have had this 2 years ago before we started"

"The Practical 'real world' examples throughout the course has brought the subject to life and I can really see where we need to go from here – Thank you"