Pharmaceutical Engineering and GEP Trends

about the course

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 throughout 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 area. 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.

course content

day one

- GMPs 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 PRA)
- Project Lifecycle and the Documentation Structure to support Supplier Auditing and Control

day two

- 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 process
  - 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 three

- Project Change Control for 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 Re-qualification 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.)

who should attend

This course will benefit all involved in engineering and validation in the Pharmaceutical Sector. The course goes to SME level with ongoing consultancy support following the training as required.

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 in Sterilisation and Depyrogenation for the past 17 years. Throughout this period Mark has worked all over the world with hundreds of organisations, delivering training to thousands of people. This has included delivering training courses for regulatory inspectors from China, Saudi, UK, Ireland, Italy, Denmark and the Netherlands.

Stan O'Neill – The Compliance Group

After qualifying as a Pharmacist, Stan spent over five years working in the pharmaceutical industry in Regulatory Affairs, Marketing and Quality Assurance (QP) and then joined 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.

what else should I know?

Course Fee: €2,000 per person, and includes all course material, lunches and refreshments, where applicable. Please note that this course may also be organised on an in-house basis. Please contact us for further information. Good Engineering Practice Training delivered on your site is generally tailored to the specifics of your site and any current issues.

how to apply

Applications can be made online through our website, www.gxp.ie/training or by emailing training@gxp.ie.

location and date

Dublin, Ireland. See www.gxp.ie for dates.

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