MARKTHOMPSON
LIFESCIENCES

Introduction to Pharmaceutical Engineering

Overview

This course provides an overview of the unique challenges of Engineering in the highly regulated environment of Pharmaceutical and Medical Device manufacture. Engineers are often employed from food, beverage, electronics industry backgrounds and these engineers need to understand the unique aspects of engineering in this area.

As can be seen from the typical two¬ day course content the key aspects of: viable and non-viable control; regulatory framework; the clean room and all aspects of documentation traceability are covered.

Target audience

Although specifically targeted at engineers new to the pharmaceutical industry, this course will also benefit engineers and technicians requiring an update on current trends and regulatory expectations as well as anyone moving to a different area of responsibility such as a higher grade clean room, aseptic manufacture etc.

Many sites use this course as a core engineering module and then build further training beyond this core GEP module.

About the Lecturers

All 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.

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Course Programme

DAY 1:

- Engineering GMP's and Regulatory Guidance
- Understanding the manufacturing Process
- Quality Critical Requirements
- Introduction to Micro biology
- Viable and Non-viable controls, monitoring and improvements
- Engineering Systems in a GMP Environment
- Project Engineering, Validation Lifecycle, Annex 15 and ASTM2500
- Project and Engineering Documentation systems. Deviations, Impact assessments and traceability
- Control Systems. Control and Maintenance of Software, GAMP 5

DAY 2:

- Engineering in a clean room environment, Clean area controls, Tools, Equipment and Black areas
- Change Control and Process Improvement
- Impact Assessment and scoping qualification
- Maintenance and Calibration, setting and defining the scope
- Calibration Traceability
- Control of Contractors and Technical agreements
- Self-Inspection, Internal Audits and Regulatory Inspections
- Course Assessment

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

Recent Comments

"Excellent course, the latest industry trends and regulatory trends sections are exactly what we need"

"Micro data has made sense to me for the first time, Mark's ability to make the subjects interesting and understandable has kept the whole group engaged for the 2 days"