

Validation and Qualification in GDP/ GWP environment

Introduction

The regulatory environment continues to evolve with an increase focus on validation and qualification requirements. Validation and Qualification originated within the GMP environment, and while the principles remain the same, some adaption is required to effectively apply these principles in a GDP/ GWP environment to ensure compliance while managing cost. This training workshop will cover the broad approaches to the application of validation and qualification principles in the GDP/ GWP environment including equipment, systems and insulated containers.

Who should take this course?

This course has been designed for operations staff, responsible pharmacists, pharmacists and quality assurance managers within the retail, manufacturing, wholesale and distribution sectors of the pharmaceutical industry.

Course Content:

The Introduction to Cold Chain and Temperature Management will cover the following topics:

- Understanding Validation and Qualification – validation and qualification are often used to describe the same concept, we will provide a framework to understand the different definitions to allow for the appropriate application within a GDP/ GWP environment.
- Validation/ Qualification Concepts – In order to understand the application in multiple environments a principle understanding of the baseline validation/ qualification concepts will be provided.
- Equipment Validation/ Qualification – Based on the understanding of the baseline validation/ qualification principles, we will explore the appropriate approach for the application of these principles to equipment validation/ qualification.
- System Validation/ Qualification – System validation/ qualification requires a very different approach and integrates philosophical components from the IT industry. This component will provide and understanding how these philosophical differences integrate with one another into a comprehensive validation/ qualification.
- Process Validation/ Qualification – Certain GDP/ GWP components such as routes and insulated containers begin to overlap with process validation approaches. In these sections we will describe the difference in how validation/ qualification is applied in these scenarios.