# System Validation in GDP/ GWP Environment Fundamentals

## Introduction

System validation is included as a requirement in the updated SAHPRA GWP 2016 Guidelines. It is therefore key to understand what is required from a system validation and what systems should be validated.
In a world filled with acronyms and technical jargon this training will provide a simplified understandable view of what is required.

## Who should take this course?

This course has been designed for responsible pharmacists, pharmacists and quality assurance managers, IT staff 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:

- Introduction to System Validation – As system validation becomes an increasingly key component of regulatory compliance it is crucial to have broad understanding of system validation and its importance.
- Regulatory Requirements and Guidelines – In this section of the course we will work through the specific applicable regulation to understand what is expected at minimum from a system validation. An understanding of key guidance documents and how to use them will be discussed.
- System Life Cycle and Validation Approach – In order to execute an effective system validation, it is key to understand the life cycle approach, which provides a framework for the validation requirements of each phase of a system's life cycle.
- System and Validation Concepts – System Validation requires an understanding of key system concepts and how they relate to the system validation. We will work through these key concepts to understand what the practical elements need to be in place to meet system validation requirements.
- System Categories – With a core understanding of system validation, we will then elaborate on the different categories of systems and how the validation approach should be adjusted depending on the category of the system.