

COURSE TITLE

VALIDATION PRACTICES & CHANGE CONTROL

Course Date

28 & 29 March 2019

Course Fee

\$963.00 per pax (inclusive of GST)

Course Duration

9am to 5pm

Course Venue

Temasek Polytechnic

Introduction

Validation is an essential part of Good Manufacturing Practices (GMP). Validation of processes and systems is fundamental to establishing confidence that the manufactured products will consistently meet the product specifications.

Change Control is one of the most critical elements in a firm's Quality Management System. Change Control demonstrates to regulatory authorities that validated systems remain under control during and after system changes.

This module introduces the principles of validation as per PIC/S and to extend the principles to practical outcomes. The participants will be provided with case studies to determine when to activate Change Control, as well as to develop a procedure for processing a change request.

Targeted Audience

This course has been designed for professionals involved in approving validation plans, effecting change control and quality system implementation. It also applies to anyone interested in GMP and the latest trends and methodologies in validation that are rapidly becoming industry standards.

Course Outline

- Validation Principles and Regulations
- Validation Master Plans and Documents
- Preparing Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) Protocols
- Protocol Execution
- Deviation Management
- Change Control: what is and when to use?
- Is Change Control the same as Document Control?
- Developing a Change Control procedure
- Designing and evaluating a Change Request
- Consideration when implementing Change Control

To apply, please click [HERE](#).

Course code: ZIU