AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA
Medtech Malaysia

Medsociate
Medsociate Sdn Bhd

Industry Expert Training Series * HRDF SBL Scheme Claimable

Medical Device Manufacturing Process Validation

Course Brochure

MEDICAL DEVICE MANUFACTURING PROCESS VALIDATION

INTRODUCTION

The global medical device market is governed by various quality system requirements and regulations of different countries. Medical device manufacturers need to perform process validation in order to comply with regulatory requirements and ensure business success

COURSE OBJECTIVES

This course provides regulatory/quality systems professionals, manufacturing engineers, and process development engineers with the knowledge and skills needed to comply with the process validation requirements of the FDA's Quality System Regulation, ISO 13485 and the GHTF Validation guidance N99-10 while offering information on how to implement an effective validation program.

COURSE OUTLINE

1. Overview of Process Validation System
    - QMS Compliance- ISO 13485:2016/FDA 21CFR Part 820
    - Benefits of Process Validation System
    - Challenges in Process Validation System

2. Types of Validation System.
    - Prospective Validation System
    - Concurrent Validation
    - Retrospective system

3. Elements of Process Validation System
    - Validation Master Plan
    - Installation/Operational/Performance Qualification
    - Protocol/ Report
    - Revalidation Activities
    - Challenge Test

4. Statistical Tools and Techniques in Process Validation
    - Statistical Process Control/Process Capability

5. Brief Overview of Validation System
    - Software Validation System
    - Cleaning Validation System
    - Analytical Method Validation System
    - Packaging Validation
    - Sterilization Validation

TARGET AUDIENCE

Quality managers, quality engineers and quality technicians involved in the development and manufacturing of medical devices. Professionals directly involved in regulatory affairs, quality assurance, process development or manufacturing.

PRE-REQUISITE

Familiarity with ISO 13485 and/or 21 CFR 280 is preferable but not mandatory

DURATION

Two (2) full days

TRAINER'S PROFILE

Ms PS Gan, a Bachelor of Science in Chemistry graduate, has more than 10 years of practical and managerial experience having held local and overseas positions as Quality Management Representative in a multinational company. Her expertise covers implementation of quality management system, risk management, process validation and ISO audits.

COURSE REGISTRATION DETAILS

Course fees, payment details and online registration log-in will be provided once the course is open for registration.

CONTACT

For enquiries, please email to admin@medsociate.com
Medsociate Sdn Bhd
(HRDF Approved Training Provider - Registration No. 4195)
(AMMI Authorized Training Provider and Secretariat)
Tel: +6010 4040 662 Fax: +603 2178 4347