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

Medsociate
Authorised Training Provider

Industry Expert Training Series * HRDF SBL-Khas Scheme Claimable

Medical Device Manufacturing Process Validation

Training Brochure

HRDF CLAIMABLE

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. Regulatory/QMS Compliance

1.1. QSR-21 CFR Part 820/ 21 CFR Part 11

1.2. ISO 13485:2016, GHTF/SG3/N99-10:2004 (Edition 2)

2. A Brief Introduction to Validation System

2.1. Process Validation/Software Validation System/Analytical Method Validation System

2.2 Cleaning Validation System/Packaging Validation/Sterilization Validation

3. Introduction to Process Validation

3.1. Overall Validation Program Description

3.2. Validation Definition

3.3 Process Validation Decision Tree

3.4. Types of Validation

3.4.1. Prospective Validation/ Concurrent Validation

3.4.2 Retrospective Validation/Revalidation

4. Validation Master Plan

4.1. Life Cycle Approach in Process Validation

4.2. Risk Assessment in Process Validation

5. Elements of Process Validation System

5.1. Installation Qualification (IQ)/Operational Qualification (OQ)/Performance Qualification (PQ)

5.2. Maintaining State of Validation

5.3. Deviation in Process Validation

5.4. Change Control in Process Validation

MEDICAL DEVICE MANUFACTURING PROCESS VALIDATION

6. Statistical Tools & Techniques

6.1. Acceptance Sampling Plan
6.2. Measurement System Analysis
6.3. The 7 Basic QC Tools
6.4. Process Capability Analysis
6.5. Statistical Method and Data Analysis

7. Validation- Benefits and Good Documentation Practice

7.1. Good Validation Documentation Practice
7.2. Benefits of Process Validation

DURATION

Four Sessions over four days (4 hours per session)

MODE OF TRAINING

Online Training

PREREQUISITE

Knowledge of medical device manufacturing and preferably an understanding of Quality Assurance or Quality Management System or Good Manufacturing Practices.

PAYMENT AND CONFIRMATION OF REGISTRATION

Option 1: HRDF Claim under SBL-Khas Scheme

A quotation together with course outlines and course agenda will be sent to you for HRDF grant application upon confirmation of the training. Please send us the grant application number for our record upon submission.

Option 2: Self-paying

2a) Direct Bank-in or via E-Banking

An invoice will be sent to you within 3 working days upon your registration. Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice. Please email us (admin@medsociate.com) the bank-in slip / remittance slip once the payment is made.

Please refer the following bank account details:
Beneficiary Name: Medsociate Sdn Bhd
Bank Account Number: 230-302-078-2
Bank: UOB Bank
Swift Code: UOVBMYKL
For Government Sector - A Local Order (LO) or letter of approval to participate must be submitted before your registration can be confirmed.

2b) Direct Online Payment

You may choose to make credit card payment via Paypal. An invoice with payment link will be sent to your email address separately when you choose this option.

CANCELLATION / REFUND POLICY

The organisers, AMMI/ Medsociate Sdn Bhd reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded in full if the cancellation is made by AMMI/ Medsociate Sdn Bhd. No shows and cancellations made by participants/ companies within the specified period will incur the specified costs as per below schedule.

Prior to Training Date	Cancellation Charges
30 days or more	**No charges**
15-29 days	**25% of training course fee**
8 - 14 days	**50% of training course fee**
0 - 7 days	**100% of training course fee**

SUBSTITUTION

Replacement of participant is allowed at no additional cost if you are unable to attend. Please inform us of the replacement in writing at least 3 working days before the training date.

CONTACT

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