

# Test Method Validation

Training Brochure



# TEST METHOD 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 test method validation 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 test method validation requirements of the FDA's Quality System Regulation, EU MDR 2017/745, ISO 13485 and other regulatory requirements on how to implement an effective validation program.

## COURSE OUTLINE

### 1. Regulatory/QMS Compliance

- 1.1 QSR-21 CFR Part 820
- 1.2 ISO 13485:2016, ISO 9001:2015
- 1.3 EU Medical Device Regulation (EU MDR 2017/745)

### 2. A Brief Overview to Test Method Validation

- 2.1. Test Method Validation System

### 3. Test Method Validation Master Plan

- 3.1 Overall validation program description
- 3.2 Life cycle approach
- 3.3 Risk assessment

### 4. Introduction to Test Method Validation

- 4.1. Overall Validation Program Description
- 4.2. Validation Definition
- 4.3. Types of Validation
  - 4.3.1. Prospective Validation/ Concurrent Validation
  - 4.3.2 Retrospective Validation/Revalidation

### 5. Test Method Validation Essential Characteristics

- 5.1. Accuracy
- 5.2. Precision
- 5.3. Specificity
- 5.4. Limit of Detection
- 5.5. Limit of Quantification
- 5.6. Linearity
- 5.7. Range
- 5.8. Robustness

### 6. Elements of Test Method Validation/Software Validation

- 6.1. User Requirements Specification

- 6.2. Functional Requirements Specification
- 6.3. Design Specification
- 6.4. Installation Qualification (IQ)
- 6.5. Operational Qualification (OQ)
- 6.6. Performance Qualification (PQ)
- 6.7. Maintaining State of Validation
- 6.8. Deviation in Test Method Validation
- 6.9. Change Control in Test Method Validation

## **7. Statistical Tools & Techniques**

- 7.1. Gage Repeatability and Reproducibility
- 7.2. Measurement System Analysis
- 7.3. The 7 Basic QC Tools
- 7.4. Process Capability Analysis
- 7.5. Statistical Method and Data Analysis

## **8. Test Method Validation- Benefits and Good Documentation Practice**

- 8.1. Good Validation Documentation Practice
- 8.2. Benefits of Test Method Validation

### **DURATION**

2 Full days

### **MODE OF TRAINING**

Remote Online Training

### **PREREQUISITE**

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

### **TRAINER'S PROFILE**

Mr. Gobu Devarajan possesses master's degree in Electrical and Electronic Engineering and Certified Manager of Quality/Organizational Excellence (CMQ/OE, Certified Quality Auditor (CQA) from American Society of Quality (ASQ). Certified Six Sigma Green Belt.

He has more than thirty years of working experience with extensive knowledge in the field of Quality Engineering, Statistical Analysis and Quality System Requirements. He possesses excellent communication and presentation skills. He is capable of designing, conducting training programs and perform gap analysis according to QSR (21 CFR Part 820), ISO 13485, ISO 9001, ISO 16949 and ISO 14971. EU MDR 2017/745, MDSAP and JPAL

## **PAYMENT AND CONFIRMATION OF REGISTRATION**

### **Option 1: HRDCorp Claim under SBL-Khas Scheme**

A quotation together with course outlines and course agenda will be sent to you for HRDCorp 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: UOVBMKYL

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.

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

## **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**

For enquiries, please email to Medsociate Sdn Bhd

Authorised training provider of AMMI

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