



# Software Validation Requirements and Excel Spreadsheet Validation

Training Brochure

# SOFTWARE VALIDATION REQUIREMENTS AND EXCEL SPREADSHEET VALIDATION

## INTRODUCTION / OBJECTIVES

Software Validation Requirements and Excel Spreadsheet Validation is a formalized, documented process for testing computer software and systems. The FDA and other regulatory bodies require Software and Excel Spreadsheet Validation to demonstrate that computer systems are in compliance with all regulations for electronic data management systems. Software and excel spreadsheets used in GMP or GLP environments, as with any computer system, the regulatory bodies expects measures to be in place to ensure system data are controlled and protected and to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. This training session shall explore the requirements for Software and Excel spreadsheets used in production or the quality system and case studies on how verification/validation can be accomplished.

## COURSE OUTLINE

### 1. Overview of Excel Validation System

- 1.1. Regulatory and QMS Requirements
- 1.2. Introduction to GAMP 5 requirements
- 1.3. 21 CFR Part 11 Regulations

### 2. Types of Software/Computer Validation System

- 2.1. Computer System
- 2.2. Information System
- 2.3. Control System
- 2.4. Design system

### 3. Software Category

- 3.1. Category 1 – Operating System
- 3.2. Category 3 - Standard Software Packages
- 3.3. Category 4 - Configurable Software Systems
- 3.4. Category 5 – Custom Built or Bespoke Systems

### 4. Excel Spreadsheet Development Lifecycle

- 4.1. Project Planning.
- 4.2. Design
- 4.3. Development
- 4.4. Integration and Test
- 4.5. Installation and Acceptance

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## 5. Elements of Excel Spreadsheet Verification and Validation

- 5.1. Validation Master Plan
- 5.2. User Requirement Specification (URS)
- 5.3. Functional Requirement Specification (FRS)
- 5.4. Design Specification (DS)
- 5.5. Installation Qualification (IQ)
- 5.6. Operational Qualification (OQ)
- 5.7. Performance Qualification (PQ)

## 6. Case Studies + Discussion

- 6.1. The “V” Model and how to apply it to software
- 6.2. Development of URS, FS, DS & Test Cases
- 6.3. Development of IQ, OQ and PQ protocols
- 6.4. Development of IQ, OQ and PQ report

## DURATION

**4 half-day** course running from 8.30AM – 12.30PM or 1.30PM – 5.30PM. Please refer to the training calendar in the website for the actual slot.

## MODE OF TRAINING

Remote Online Training

## TARGET AUDIENCE

Regulatory/quality systems professionals, manufacturing engineers, and process development engineers

## TRAINER’S PROFILE

Mr. Gobu Devarajan possesses Master 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 twenty five 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. MDD 93/42/EEC, CMDCAS and JPAL

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### 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

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### 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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