AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA
MEDTECH® MALAYSIA

Medsociate
Authorised Training Provider

Industry Expert Training Series * HRD Corp Claimable Course Scheme

Software Validation Requirements and Excel Spreadsheet Validation

Training Brochure

Software Validation Requirements and Excel Spreadsheet Validation

COURSE OBJECTIVES

This course provides quality systems professionals, manufacturing engineers, and process development engineers with the knowledge and skills to perform software validation and Excel spreadsheet validation, complying with ISO 13485 and regulatory requirements.

COURSE OUTLINE

1. Software validation - ISO and regulatory requirements
2. Introduction to software validation system
3. Software validation master plan
4. Software development life cycle
5. Software testing life cycle
6. Risk assessment in software validation
7. Excel spreadsheet validation
8. Software verification and validation
9. Software change control
10. Software validation- Good Documentation Practices

DURATION

Two (2) full days

MODE OF TRAINING

Classroom Training

COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Software validation - ISO and regulatory requirements
		Introduction to software validation system
		Software validation master plan
		Software development life cycle
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Software testing life cycle
		Risk assessment in software validation
		Excel spreadsheet validation
2	9.00 am – 12.30 pm	Software verification and validation
		Design/Installation/Operational and Performance Qualification
	12.30 pm – 1.45 pm	Lunch break

Software Validation Requirements and Excel Spreadsheet Validation

	1.45 pm – 5.15 pm	Software verification and validation (Continue)
		Design/Installation/Operational and Performance Qualification
		Software change control
		Software validation - Good Documentation Practices

CONTACT

For enquiries, please email to Medsociate Sdn Bhd

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