



CQE Training & Consultancy Plt (Reg No. : LLP 003668 LGN)

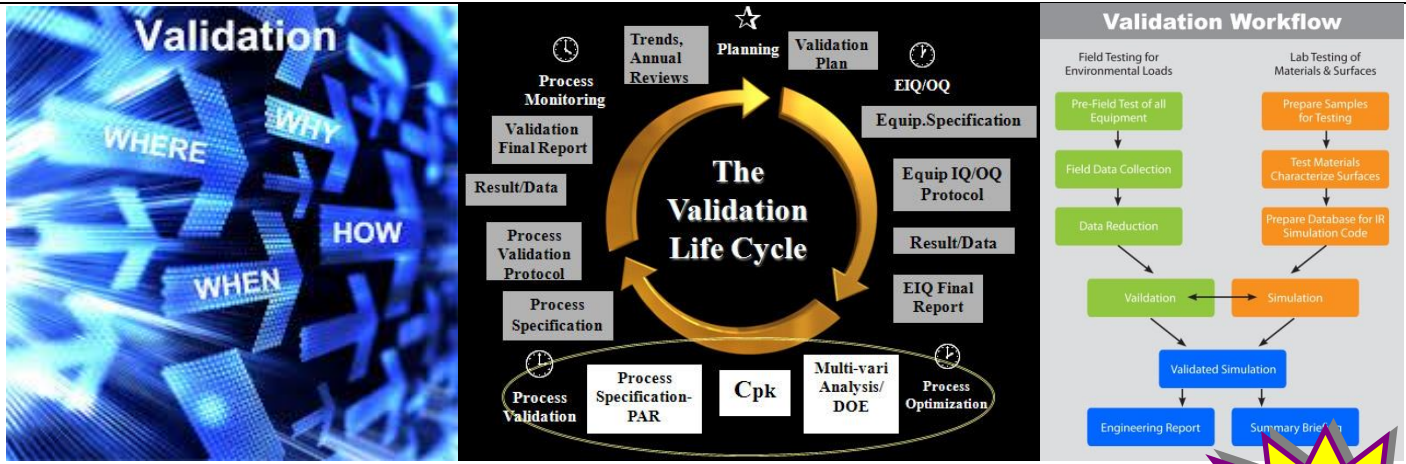
Registered Office : No. 46, Lorong Bintang, Taman Tasik Permai, 34000 Taiping, Perak. Malaysia.

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PROCESS VALIDATION TRAINING (PVT) (PUBLIC / IN-HOUSE TRAINING PROGRAMME)



**SBL
Scheme**

Introduction

With today shorter Design and Development Cycle requirements, Process Validation (PV) requirements are specified by general management system standards, as well as legal and regulations. Process Validation can be varies from retrospective, concurrent or prospective validation as an evidence of conduct, compliance to the general management system standards, legal and regulations requirements.

This course provides an introductory understanding of Process Validation for general management system standards and regulations requirements including ISO 9001, ISO 13485, IATF 16949, AS 9100, ISO 17025, ISO 22000 etc, and overview on practical statistical methodologies for its analysis and guidance for its planning, implementation and maintenance. Process Validation varies from Design Qualification, Installation Qualification, Operational Qualification and Performance Qualification will be discussed during the training session.

The training content is easy-to-understand and are suitable for companies complying with general management systems standards, legal and regulatory.

Objective

To provide delegates with proven practices and techniques that lead to Process Validation (PV) related to the Design & Development Processes:

- ✓ An introduction to the fundamentals and basic principles of process validation.
- ✓ An awareness of the international standard and regulatory requirements for Process Validation.
- ✓ Explaining how, when, where and why you should validate.
- ✓ Implementation and documentation guide.
- ✓ Statistical methods and tools used in Process Validation.
- ✓ To address on how to maintain adequate validation documentation systems and perform equipment qualifications, process validations.



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Program Contents

Day 1

• *Introduction to Process Validation*

- o Basic Principles of Process Validation
- o Regulatory and International standard Requirements for Validation (ISO 9001, ISO 13485, IATF 16949, AS 9100, ISO 22000 etc)

• *Overview of Process Validation*

- o Why and What do we validate
- o Design Qualification
- o Installation Qualification
- o Operational Qualification
- o Performance Qualification
- o Process Validation Decision
- o Validation Master Plan
- o Protocols and reports

• *Planning the Process Validation*

- o Establish validation team
- o Develop Master Validation Plan
- o Review Planning
- o Develop validation protocol

• *Conducting and Executing the Process Validation*

- o Determination of WHAT to verify / measure
- o Determination of HOW to verify / measure
- o Determination of HOW MANY to verify / measure
- o Define acceptance / rejection criteria
- o Consideration during IQ / OQ / PQ
- o Reporting

• *Maintaining Validation*

- o Monitor and control of Process Validation
- o Changes of processes and / or product
- o Periodic Revalidation
- o Use of historical Data in process validation

• *Statistical methods and tools for Process Validation*

- o Introduction of the statistical methods and tools
- o Descriptions and Objectives of the statistical methods and tools
- o Application of the statistical methods and tools

• *Examples*



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Who Should Attend

This programme is suitable for all levels of personnel involved with the process validation activities from planning, executing, reporting, reviewing, approving and maintaining the process validation.

The delegate may be someone new to process validation and aims to have a better understanding on the overall process validation activities.

Duration

1 Day

Training Methodology

The program would be conducted by using the following materials / aids :-

- ✓ Course Note
- ✓ OHP / LCD
- ✓ Group Activities
- ✓ Lecturettes





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Six Sigma Validation - IQ-OQ-PQ

