# QMS SOFTWARE VALIDATION TRAINING COURSE

## COURSE DESCRIPTION

The objective of this course is to provide learners with the knowledge and skills required to determine appropriate activities for the validation of process software used in medical device quality management systems.

## COURSE CRITERIA

**UPON COMPLETION OF THIS COURSE, LEARNERS WILL HAVE THE SKILLS AND KNOWLEDGE REQUIRED TO:**

- Determine appropriate activities for the validation of process software used in medical device quality management systems using a risk-based approach.

## PRIOR KNOWLEDGE

Before starting this course, learners are expected to have the following prior knowledge:

- Experience of risk assessments
- Experience in the use of software in a QMS
- Management systems:
  - the Plan-Do-Check-Act (PDCA) cycle;
  - the core elements of a management system and the interrelationship between management responsibility, policy, planning, implementation, measurement, review and continual improvement.

## COURSE CONTENT

### SOFTWARE AND SOFTWARE VALIDATION

- Software
- Hardware
- Why software validation?
- Scope

### CRITICAL THINKING

- Critical thinking and life cycle controls

### SOFTWARE RISK MANAGEMENT

- Risk management terms
- Risk management according to ISO 14971
- Identification of hazardous situations and estimation risks
- Categories of harm
- Hazard and hazardous situation
- Probability
- Risk evaluation
- Risk control
- Residual risks

## SGS ACADEMY


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**COURSE DURATION:** 1 day or 8 hours
**DELIVERY METHODOLOGY:** F2F & VILT
**COURSE LANGUAGE:** English
**ACCREDITATION:** SGS

### COURSE CERTIFICATION

Learners who have been in attendance for the full duration of the course will be issued with a "Certificate of Attendance".

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**DEVELOPMENT PHASE**

- Development phase
- Process requirements
- Analysis of process risk failure
- Validation planning

**MAINTENANCE PHASE**

- Maintenance phase
- Maintenance plan
- Types of maintenance
- Process changes: Change to risk control measures, Emergency change, Maintaining for intended use

**RETIREMENT PHASE**

- Retirement phase
- Issues in the retirement phase
- Documentation