CLINICAL EVALUATION
IMPLEMENTATION TRAINING COURSE

COURSE CRITERIA

UPON COMPLETION OF THIS COURSE, LEARNERS WILL HAVE:

- Knowledge of when to perform clinical investigations;
- Understand who should perform clinical evaluations;
- Competence to perform clinical evaluation

Learners will need to demonstrate acceptable performance in these areas to complete the course successfully.

COURSE CERTIFICATION

Learners will be issued with a "Certificate of Attendance".

PRIOR KNOWLEDGE

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

- ISO 14155 Clinical Investigations of medical devices for human subjects – good clinical practise;
- ISO 14971 Medical Devices: Application of risk management to medical devices;
- Optional:
  - MDR 2017/745 – basics.
  - MED DEV 2.7.1 – basics.

COURSE CONTENT

SESSION 1: REQUIREMENTS, DATA REQUIREMENTS AND PREPARATION

- Regulatory requirements for clinical evaluations
- Support from clinical data
- Clinical investigation
- Research methodology
- Sources of data
- Analysis of data
- Equivalency

SESSION 2: STAGE 4: SAFETY PERFORMANCE, REPORT WRITING, THE NEW MD AND NOTIFIED BODY EXPECTATIONS

- GHTF
- MDR
- Clinical evaluation
- Sufficient clinical data
- New Regulation on clinical evaluations

SESSION 3: POST MARKET, RISK MANAGEMENT AND MAINTENANCE

- Clinical evaluation report
- Post market surveillance and risk management
- Post market clinical studies
- Equivalence with competitor
- Pre-existing designs
- Clinical evaluation documentation
- Post-market product lifecycle

SESSION 4: APPLICATION OF CLINICAL EQUIVALENCE

- Case Studies: Workshops 8-10

SGS ACADEMY

http://www.sgs.com/en/training-services

www.facebook.com/sgsglobalacademy

train.global@sgs.com

COURSE DURATION: 2 days
DELIVERY METHODOLOGY: Face to Face
COURSE LANGUAGE: English
ACCREDITATION: SGS

COURSE DESCRIPTION

The aim of this course is to provide learners with knowledge and interpretive skills necessary to understand and implement the requirements of the new Medical Devices Regulations 2017/745 and Med Dev 2.7.1 Rev 4, Clinical Evaluation in relation to expectations for Clinical Evaluations.

Furthermore, learners will have a broader understanding of the changing landscape of regulations related to risk management with an objective of increasing patient safety.

SGS