TRAINING COURSE

15 JUNE 2021

THE CLINICAL EVALUATION IN THE NEW MDR 2017/745

ECM Medical Devices Division organises a training course focused on the comprehension of the regulatory requirements related to Clinical Evaluation, according to the new Regulation (EU) 2017/745.

MAIN TOPICS

- Requirements on clinical evaluation, from Directive 92/42/EEC to Regulation (EU) 2017/745
- Requirements and contents of MEDDEV 2.7.1 rev.04
- Requirements and contents of MEDDEV 2.12-2 on PMCF
- Documentation for clinical evaluation: drafting and updating
- Links with the requirements of EN ISO 13485:2016
- Post-Marketing Surveillance and Vigilance

SPEAKERS

Dr. Marianna Mastroroberto - Clinical Expert
Eng. Maurizio Sacchero - Lead Auditor

TARGET

The course is addressed to professionals in charge as Person Responsible for Regolatory Compliance (PRRC), experts in regulatory affairs, quality assurance, physicians, clinical experts, designers and engineers in the medical sector.

WHEN AND WHERE

The Course will take place on **Tuesday 15 June 2021** and will last 8 hours.
E-learning mode: it will be possible to attend the Course "The Clinical Evaluation in the new MDR 2017/745" remotely online.

For information:
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