CORSO DI FORMAZIONE

LEGACY DEVICES

COME PREPARARSI ALLA TRANSIZIONE MDD/MDR SFRUTTANDO I DATI DI POST MARKET NEL PERIODO TRANSITORIO

Organismo Notificato n.1282
Laboratorio di Prova accreditato n.1515L
www.entecerma.it

ARGOMENTI TRATTATI

Il corso descriverà come applicare i requisiti richiesti dall'**art. 120** del MDR ai dispositivi già certificati MDD, cercando di capire come poter ottimizzare le strategie regolatorie al fine di produrre evidenze cliniche adeguate.

- La Linea Guida MDCG 2021-25 *"Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC"*
- La Linea Guida MDCG 2020-6 *"Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC - A guide for manufacturers and notified bodies"*
- Come progettare in maniera efficace un PMS Plan secondo la norma ISO/TR 20416:2020 *"Medical devices - Post-market surveillance for manufacturers"*
- Gli strumenti per il fabbricante.

PROGRAMMA

Il corso sarà articolato in **due moduli** da 4 ore ciascuno, a cui sarà possibile aderire separatamente:

- **MODULO 1 - TECNICO/NORMATIVO:** approfondimento tecnico/conoscitivo sul Regolamento (EU) 2017/745 e le linee guida elaborate dal MDCG
- **MODULO 2 - SPERIMENTALE:** cenni normativi + esercitazione pratica sulle attività di sorveglianza post-market

Il corso si svolgerà in **e-learning**: sarà possibile partecipare online da remoto.

DOCENTE

Dr. Marianna Mastroroberto - Responsabile Clinico Ente Certificazione Macchine

PER INFORMAZIONI:
Diego Stevanella - Sales Manager Medical Devices
ph. (+39) 393 2471040 - diego.s@entecerma.it

TRAINING COURSE

LEGACY DEVICES

HOW TO PREPARE FOR THE MDD/MDR TRANSITION BY USING POST-MARKET DATA IN THE TRANSITION PERIOD

Notified Body no.1282
Accredited Testing Lab no.1515L
www.entecerma.it

MAIN TOPICS

The course will outline how to apply the requirements of MDR **Art. 120** to devices that are already MDD-certified, seeking to understand how regulatory strategies can be optimized to produce adequate clinical evidence.

- The Guideline MDCG 2021-25 *"Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC"*
- The Guideline MDCG 2020-6 *"Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC - A guide for manufacturers and notified bodies"*
- How to efficiently develop a PMS Plan according to standard ISO/TR 20416:2020 *"Medical devices - Post-market surveillance for manufacturers"*
- The tools for the manufacturer.

PROGRAM

The course will be divided into two 4-hours modules , which can be attended separately:

- **MODULE 1 - TECHNICAL/NORMATIVE:** technical/knowledge in-depth study on the Regulation (EU) 2017/745 and the MDCG guidelines
- **MODULE 2 - EXPERIMENTAL:** regulatory overview + practical training on post-market surveillance activities

The course will be held in **e-learning** mode: it will be possible to participate online remotely.

SPEAKER

Dr. Marianna Mastroroberto - Clinical Manager Ente Certificazione Macchine

FOR INFORMATION:
Diego Stevanella - Sales Manager Medical Devices
ph. (+39) 393 2471040 - diego.s@entecerma.it