Implementation of the Medical Device Regulation (MDR) for CE Marking Training Course

Agenda

Day 1 | July 8th, 2019

Time	Topic
09.00	Benefits to you, welcome and introductions
	Boundaries: Conflicts of interest and structure
	Course aims and objectives
	General obligations • Who is responsible? • Items for Technical documentation • Conformity assessment
	Scope of the MDR • Relation of the MDR to other Union legislations • Definition: Medical device and accessories
	Determine risk class and applicable 'NBOG' codes • Applying the rules • Different codes for Medical Devices
	Select conformity assessment procedure • Quality system assessment
	Amend and maintain QMS • ISO 13485: A stairway to MDR
	Identify applicable safety and performance requirements
	Day 1 review and questions
16.30	Close of day

Day 2 | July 9th, 2019

Time	Topic
09.00	Welcome to day 2
	Identify applicable safety and performance requirements continued • How long must devices stay safe and effective? • Risk management process • Demonstration of conformity • Labelling
	Assemble Technical Documentation • Use of symbols for information • Pillars of the technical documentation • Content of a technical documentation under MDR • Good Laboratory Practice (GLP) • Clinical evidence and development plan • Clinical investigation report
	Apply conformity assessment procedure
	Day 2 review and questions
17.00	Close of day

Day 3 | July 10th, 2019

Time	Topic
09.00	Welcome to day 3
	Apply conformity assessment procedure continued • Submission of technical documentation • Surveillance of technical documentation • Evaluation of changes • Strategy for regulatory compliance (concept)
	Assign Unique Identifications • European database on medical devices • Difference in meaning • Dealing with EUDAMED
	Complete DoC (Declaration of Conformity) and affix CE mark • Statements for devices • CE mark
	Post Market Surveillance (PMS) • Plans needed for the MDR • Periodic Safety Update Report (PSUR) • Summary of Safety and Performance (SSCP) • Alarming issues • Lines of communication • Vigilance reporting
	Recap and transition arrangements
	Review of course and final questions
16.30	End of course

• Two short breaks will be taken at suitably convenient times in the morning and afternoon.

• Forty five minutes will be given for a lunch break.

• Additional breaks may be taken as long as agreed by delegates and tutor, and all learning objectives are met.