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

Agenda

Day 1 | November 25th, 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 | November 26th, 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 | November 27th, 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.

Tutor information

Ing. Diego Falletti, BSI Vascular Team manager and Technical Expert & Scheme Manager

Diego Falletti is Vascular Team manager and Technical Expert & Scheme Manager in BSI since 2016.
He is a mechanical engineer with a solid background in the medical devices industry. He is graduated in Material Science Technology and graduated in Mechanical Engineering at Politecnico of Torino. He has an Executive MBA at Bocconi School of Management. Diego worked for 7 years at Medtronic as Program Manager Officer and for other 7 years as R&D System Engineer at Livanova, former Sorin Group.