Medical Device Regulation Seminar

Syllabus, Rev.1

EU Regulation	
Module	Topics
Session Kick-Off	• Reflections from the last session, Introduction • Learning objectives
Introduction	• Standard Conformity and Regulatory Compliance • MDD to MDR – Why?
EU Regulation Overview	• European Union (EU) Regulation • Regulatory Change • Transition timeline • Main Changes overview • Pathway to the EU Medical Device Market
EU MDR	• Classifications + exercise • QMS requirements under the MDR • Technical files • Conformity Assessment routs • Economic Operators • PRRC • UDI • EUDAMED • Post Market Surveillance, Clinical Data, Vigilance • Lessons Learned Supporting MDR Transition • Bonus session – Labeling, Translation, Brexit – UK
Session Wrap-Up	• Feedback • Reflection for the next session
Home exercise	• Home exercise