VIRTUAL PROGRAM

Understand the New EU Medical Device/IVD Regulations

Agenda

3 May 2017	Week 1: Background to New EU Regulations	Speaker
11:00–11:50 am	Regulator/Notified Body Introductions • Negotiations and process for the new regulations • Overview of new MDR and IVDR • New requirements in the regulations	Paul Brooks, executive director, Regulatory Affairs Professionals Society (RAPS)
11:50 am–12:40 pm	Changes in Classification and Routes to Conformity Assessment • Classification changes expected under the MDR and IVDR • Conformity assessment routes to CE Marking	Theresa Jeary, technical manager, and Nick Baker, Lloyds Register Quality Assurance
12:40–1:00 pm	Q&A	

10 May 2017	Week 2: EU MDR Requirements	Speaker
11:00–11:50 am	MDR General Safety, Performance Requirements & Technical Documentation • MDR Annex 1 General Safety & Performance Requirements • Changes introduced by MDR Annex I • Labeling changes	Itoro Udofia, head of notified body, UL International (UK) Ltd
11:50 am–12:40 pm	MDR Clinical Requirements • MDR requirements for clinical evidence & evaluation • Covering the gaps for legacy devices • PMCF expectations	Bassil Akra, PhD, global director, TUEV SUED PS
12:40–1:00pm	Q&A	

17 May 2017	Week 3: EU IVDR Requirements	Speaker
11:00–11:50 am	IVDR General Safety, Performance Requirements & Technical Documentation • IVDR Annex I general safety & performance requirements • Changes introduced by IVDR • Labeling changes	Erica Conway, global head – in vitro diagnostic medical devices, BSI
11:50 am–12:40 pm	IVDR Performance Evaluation Requirements • IVDR requirements for clinical evidence & performance evaluation • Covering the gaps for legacy devices • PMCF expectations	Sue Spencer, head of global medical device services, UL
12:40–1:00 pm	Q&A	

24 May 2017	Week 4: Technical Documentation, Postmarket and Other	Speaker
11:00–11:30 am	Technical Documentation • Technical documentation under the new regulations • Managing legacy files	Amie Smirthwaite, BSI
11:30 am–12:00 pm	Postmarket Expectations • Postmarket surveillance requirements under new regulations • Vigilance and incident reporting under new regulations	Florianne Torset-Bonfillou, director of regulatory, education and quality - lead auditor, LNE/G-MED
12:00–12:30 pm	Post Regulation Changes • Delegated acts and further requirements that will impact manufacturers and notified bodies	Gert Bos, PhD, FRAPS, executive director & partner, Qserve Group
12:30–1:00 pm	Q&A - Panel	Gert Bos, PhD, FRAPS, executive director & partner, Qserve Group Notified Body representatives