



The MDR and IVDR: Ready, Get Set, Go!

9 June 2017 | 7:30 am–4:45 pm PDT

7:30 am	Registration Check In and Networking Continental Breakfast
8:30 am	Welcome and Introductions <ul style="list-style-type: none"> • Cherry Mun, chair, RAPS San Francisco Bay Area Chapter • Dishita Purohit, chair, ASQ Northern California Biomedical Discussion Group
8:45 am	MDR Roadmap – Part I: Brief Overview of MDD/AIMD → MDR Requirements; Impact on Key Stakeholders; Step-by-Step Transition Plan for Industry <ul style="list-style-type: none"> • Oliver Christ, CEO, PROSYSTEM AG
10:00 am	Break
10:15 am	MDR Roadmap – Part II: Impact of New EU Regulations on Notified Bodies; MDR Certification Timelines; Practical Guide to Compliance With MDR Technical Documentation Requirements <ul style="list-style-type: none"> • Julien Senac, PhD, certification project manager, LNE/G-MED North America
11:30 am	Panel Discussion: Facilitated by Paul Brooks, executive director, RAPS <ul style="list-style-type: none"> • Oliver Christ, CEO, PROSYSTEM AG • Julien Senac, PhD, certification project manager, LNE/G-MED North America Ibim Tariah, PhD, technical director, BSI Medical Device (BSI liaison with European Regulatory Authorities)
12:00 pm	Lunch Buffet
1:00 pm	IVDR Roadmap: Brief Overview of IVDD → IVDR Requirements; IVDR Certification Timelines; Perspective From a Notified Body Auditor: Tips to Prepare for a Successful Audit Under New EU Regulations <ul style="list-style-type: none"> • Connie Del Buono, Synoptyx Inc., Auditor for DEKRA
2:00 pm	Break
2:15 pm	Risk Management and Mitigation per ISO 13485:2016 <ul style="list-style-type: none"> • Nitin Mehta, TÜV SÜD America
2:45 pm	Notified Body Perspectives: Brief Overview of Notified Body Accreditation Process; What to Do If Your Notified Body Doesn't Make the List <p>Ibim Tariah, PhD, technical director, BSI Medical Device</p>
3:30 pm	Final Comments: Tying It All Together: MDR/IVDR and ISO 13485:2016 <ul style="list-style-type: none"> • Barry Craner, principal, CQA-Associates
3:45 pm	Final Panel Discussion: All Speakers <ul style="list-style-type: none"> • Facilitate by Barry Craner, principal, CQA-Associates
4:30 pm	Closing Remarks: <ul style="list-style-type: none"> • Paul Brooks, executive director, RAPS
4:45 pm	Adjournment

5:00-6:00 pm	Networking Reception
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