RAPS San Francisco Chapter

ASQ Biomedical Division
The Global Voice of Quality™

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** • **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 • **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 • **Julien Senac, PhD**, certification project manager, LNE/G-MED North America
11:30 am	**Panel Discussion**: **Facilitated by Paul Brooks, executive director, RAPS** • **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 • **Connie Del Buono**, Synoptyx Inc., Auditor for DEKRA
2:00 pm	**Break**
2:15 pm	**Risk Management and Mitigation per ISO 13485:2016** • **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 **Ibim Tariah, PhD**, technical director, BSI Medical Device
3:30 pm	**Final Comments and Panel Discussion: Tying It All Together: MDR/IVDR and ISO 13485:2016** • **Paul Brooks,** executive director, RAPS • **Barry Craner,** principal, CQA-Associates
3:45 pm	**Final Panel Discussion: All Speakers** • **Facilitate by Barry Craner, principal, CQA-Associates**
4:30 pm	**Closing Remarks:** • **Paul Brooks,** executive director, RAPS
4:45 pm	**Adjournment**

5:00-6:00 pm	**Networking Reception**