

MedDev Day

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- 08:30 - 08:50 **Registration and Welcome coffee**
- 08:50 - 09:00 **Welcome from the scientific board**
- 09:00 - 09:30 **The current understanding of Industry of the developments in the implementation of the Medical Devices Regulation**
Dario Pirovano - *Senior Regulatory Adviser* at MedTech Europe
- 09:30 - 10:00 **Latest developments in Notified Bodies designation**
Dipl.-Ing. Hans-Heiner Junker - *Senior International Affairs Manager* at TÜV SÜD Product
- 10:00 - 10:30 **The road to MDR compliance: role and set-up of the clinical team**
Edo Knijff - *Sr. Clinical Affairs Manager* at Orthofix
- 10:30 - 11:00 **The New MDR: Safety By Design And By Vigilance**
Jan Bart Hak - *Head Medical Device Team* at ProPharma Group
- 11:00 - 11:30 **Coffee break**
- 11:30 - 12:00 **ISO 14155 revised version: implications and possible effects of the MDR**
Danielle Giroud - *Founder & CEO* at MD-Clinicals & WMDO
- 12:00 - 12:45 **The new Clinical Evaluation Process: approaches and strategies**
Fabio Macchi - *Medical Device Design & development Manager, Clinical Evaluation Manager* at Helsinn Healthcare SA
- 12:45 - 13:00 **Q&A session**
- 13:00 - 14:00 **Networking lunch**
- 14:00 - 15:00 **How to approach clinical evaluation plan? Be ready for 2020**
Cristina Cavalli - *Quality & Regulatory Affairs Manager* at Relife Srl
- 15:00 - 15:30 **Coffee break**
- 15:30 - 16:00 **Validation of Machine Learning based diagnostic devices and biomarkers**
Rajat Mukherjee - *Senior Director, Principal Consultant, Data Science and Strategic Consulting* at Cytel Inc.
- 16:00 - 16:30 **Data collection for post market surveillance: methods and lessons learned from pharma**
Massoud Toussi - *Global pharmacoepidemiology and drug safety lead* at IQVIA
- 16:30 - 16:45 **Q&A session and Conclusion**