VIRTUAL

MedDev Day

22 September 2020

All times indicated on the Agenda are CEST

10:00 - 10:25 **Welcome**

10:25 - 10:50 **The EU perspective: Latest developments in MDR implementation regulations, Common Specifications and Clinical Guidance Documents**

Dario Pirovano - *Senior Regulatory Adviser* at MedTech Europe

10:50 -11:15 **The Regulatory pathway to MDR from the perspective of a Notified Body: from the Technical documentation to pre and post-market data**

Franceso Laterza - *Regulatory Lead – Global Oversight* at BSI group

11:15 - 11:30 **Break**

11:30 - 11:55 **Lessons learnt on the journey to MDR certification and beyond**

Elizabeth Gfoeller - *Corporate Director, Regulatory Affairs* at MED-EL Elektromedizinische Geraete Gesellschaft m.b.H.

11:55 - 12:20 **Emerging challenges for aesthetic devices**

Melania Battistella - *Global Manager Aesthetic Products* at TUV SUD

12:20 - 12:40 **PRRC and Manufacturer Liability: who is liable in which case and how to mitigate personal risks**

Adem Koyuncu - *Lawyer and Medical Doctor, Partner of law firm* at Covington & Burling LLP

12:40 - 14:00 **Lunch break**

14:00 - 14:25 **Post Market Surveillance under EU MDR and its role in the device life cycle**

Ralf Labugger - *Regulatory Affairs Compliance Manager* at CROMA-PHARMA

14:25 - 14:50 **Vigilance under EU MDR: lessons learned from early implementation**

Laura Gamez - *Senior Pharmacovigilance Process Manager* at Novartis

14:50 - 15:05 **Break**

15:05 - 16:05 **Interactive Session - Clinical Evaluation Plan - A regulatory prospective**

Managed by Melania Battistella - *Global Manager Aesthetic Products* at TUV SUD

16:05 - 16:20 **Conclusion**

At the end of the Conference you can enjoy a relaxing moment with a Singing Live Entertainment

LIFE SCIENCE ACADEMY