

All times indicated on the Agenda are CEST

10:00 - 10:20 **Welcome from Scientific Board**

10:20 - 10:45 **Ensuring compliance in a changing world - inspection perspectives**

Line Michan - *PV inspector at DKMA*

10:45 - 11:10 **Outcome of risk minimization measures**

Inge Zomerdijk - *Pharmacovigilance Assessor at Medicines Evaluation Board (MEB)*

11:10 - 11:30 **Break**

11:30 - 11:55 **Outsourcing in pharmacovigilance - Should anyone dare?**

Liliana Cristina Hansen - *Senior Director, Head of Pharmacovigilance at Zeland Pharma*

11:55 - 12:20 **New Medical Device Regulation in Europe – Are you ready?**

Linda Matti - *Senior Device Vigilance & Process Manager, Global Pharmacovigilance, PV Surveillance at Ferring*

12:20 - 13:20 **Lunch Break**

13:20 - 13:50 **INTERACTIVE SESSION**

Patient Safety during pandemic situation - Sharing lessons learned

13:50 - 14:15 **Using Danish registries as sources of real-world data for signal detection, validation and assessments. Examples from the Danish medicines agency (DKMA)**

Kåre Kemp - *PV unit at DKMA*

14:15 - 14:35 **Break**

14:35 - 15:00 **Can artificial intelligence change our fundamental approach to safety signal detection and how far is it today?**

Martin Holm-Petersen - *CEO at Insife*

15:00 - 15:25 **ccAI – an example of using AI/ML (Artificial Intelligence & Machine Learning) in case intake**

Alex Nam Van Nguyen Aarsø - *Sr. Project Manager at Novo Nordisk*

15:25 - 15:30 **Conclusion**