

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 - 14:05 **INTERACTIVE SESSION**
Patient Safety during pandemic situation - Sharing lessons learned
- 14:05 - 14:30 **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
- 14:30 - 14:50 **Break**
- 14:50 - 15:15 **Can artificial intelligence change our fundamental approach to safety signal detection and how far is it today?**
Martin Holm-Petersen - *CEO* at Insife
- 15:15 - 15:40 **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
- 15:40 **Conclusion**