QBD GROUP

2023 CONFERENCE

Agenda

IVDR TRACK / MDR TRACK

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IVDR TRACK - INTRODUCTION TO THE IVDR - DAY 1 (MONDAY OCT 9)

Time	Topic	Speaker
08:30 – 09:00	Registration & welcome coffee	
09:00 – 09:45	**General introduction to the IVDR**	Maurizio Suppo
09:45 – 10:30	**Classification & Conformity Assessment**	Anne Paulussen
10:30 – 10:45	Coffee break	
10:45 – 11:30	**Introduction to Technical Documentation**	Sara Van Wouwe
11:30 – 12:30	**Introduction to Clinical Evidence**	Sara Peeters
12:30 – 13:30	Lunch	
13:30 – 14:15	**Quality Management System & PRRC**	Vincent Van Fulpen & Anne-Sophie Grell
14:15 – 15:00	**Post-Market Surveillance, Vigilance and Changes**	Annelies Rotthier
15:00 – 15:15	Coffee Break	
15:15 – 16:00	**Identification & Traceability (EUDAMED, UDI)**	Kirsten Van Garsse
16:00 – 16:45	**Economic operators, importers and distributors**	Maurizio Suppo
16:45 - 17:00	**Closing**	Maurizio Suppo

IVDR TRACK - IVDR CONFERENCE - DAY 2 (TUESDAY OCT 10)

Time	Topic	Speaker
08:30 – 09:00	Registration & welcome coffee	
09:00 – 09:15	**Opening**	Maurizio Suppo
09:15 – 09:35	**Regulatory state-of-play**	Kirsten Van Garsse
09:35 – 10:15	**Bringing IVDs to the EU, UK or Swiss market**	Sara Van Wouwe
10:15 – 11:00	**How to commercialize innovative products under European Regulations?**	Steven Van Hove
11:00 – 11:20	Coffee break	
11:20 – 11:55	**Challenges & opportunities complying to the IVDR: an industry perspective**	Autumn Collasius (Qiagen)
11:55 – 12:30	**NB audit experience IVD manufacturers**	Tom Patten (NSAI)
12:30 – 13:30	Lunch	
13:30 – 14:30	**Legislative requirements for AI-based MD's**	Koen Cobbaert (Phillips)
14:35 – 15:05	**Verification & validation of AI/ML MD's**	Igor Excelmans
15:05 – 15:25	Coffee Break	
15:25 – 16:00	**Documentation required for software under the IVDR**	Pieter Bogaert
16:00 – 16:40	**Electronic IFUs**	Eline Heylen
16:40 – 17:00	**Panel discussion & closing**	Maurizio Suppo

IVDR TRACK - IVDR CONFERENCE - DAY 3 (WEDNESDAY OCT 11)

Time	Topic	Speaker
08:30 – 09:00	Registration & welcome coffee	
09:00 – 09:40	**Requirements imposed on IVDs used in clinical drug trials including CDx**	Anne Paulussen
09:40 – 10:20	**How to set up and document clinical performance evaluation studies in compliance with the IVDR?**	Stefanie Nouwen
10:20 – 11:00	**In-house developed devices and the IVDR**	Pieter Bogaert
11:00 – 11:20	Coffee break	
11:20 – 12:00	**A Notified Body's point of view on structured dialogues**	Marta Carnielli (TÜV SÜD)
12:00 – 12:30	**How does the Team NB Position Paper affect your clinical evidence?**	Sara Van Wouwe
12:30 – 13:30	Lunch	
13:30 – 14:15	**How do IVDR TD and design control requirements match?**	Annelies Rotthier
14:15 – 15:00	**Usability**	Pieter Bogaert
15:00 – 15:25	Coffee Break	
15:25 – 16:00	**How to tackle the risk management requirements of ISO14971:2019 & IVDR?**	Annelies Rotthier
16:00 – 16:30	**PMS & PMPF requirements for IVDR compliant & legacy devices**	Annelies Rotthier
16:30 – 17:00	**Panel discussion & closing**	Maurizio Suppo

MDR TRACK - INTRODUCTION TO THE MDR - DAY 1 (MONDAY OCT 9)

Time	Topic	Speaker
08:30 – 09:00	Registration & welcome coffee	
09:00 – 09:05	**Opening**	Vincent Van Fulpen
09:05 – 09:45	**Setting the scene - General introduction to MDR Classification and Conformity Assessment procedures**	Vincent Van Fulpen & Anne-Sophie Grell
09:45 – 10:30	**Design & Development**	Anne Collard
10:30 – 10:45	Coffee break	
10:45 – 11:30	**Technical Documentation**	Caroline Aernouts
11:30 – 12:30	**Clinical Evidence**	Pia Gyselen
12:30 – 13:30	Lunch	
13:30 – 14:15	**Quality Management System & PRRC**	Vincent Van Fulpen & Anne-Sophie Grell
14:15 – 15:00	**Post-Market Surveillance, Vigilance and Changes**	Annelies Rotthier
15:00 – 15:15	Coffee Break	
15:15 – 16:00	**Identification and Traceability (EUDAMED, UDI)**	Kirsten Van Garsse
16:00 – 16:45	**Economic operators, importers and distributors**	Maurizio Suppo
16:45 - 17:00	**Closing**	Maurizio Suppo

MDR TRACK - MDR CONFERENCE - DAY 2 (TUESDAY OCT 10)

Time	Topic	Speaker
08:30 – 09:00	Registration & welcome coffee	
09:00 – 09:15	**Opening**	Martijn Reniers
09:15 – 10:15	**Clinical Evaluation of AI Medical Devices**	Prof. Alan Fraser (UHW)
10:20 – 11:00	**Use case: non-conformities of NBs for an AI-based medical device**	Caroline Aernouts
11:00 – 11:20	Coffee break	
11:20 – 11:50	**Registration of hardware MD versus software MD: what is different?**	Anne-Sophie Grell
11:55 – 12:30	**Opportunities in using electronic IFUs**	Eline Heylen Dimitri Jordens
12:30 – 13:30	Lunch	
13:30 – 14:30	**Current legislative requirements for AI-based Medical Devices**	Koen Cobbaert (Philips)
14:35 – 15:05	**Verification and Validation of AI/ML Medical Devices**	Igor Excelmans
15:05 – 15:25	Coffee Break	
15:30 – 16:00	**How to commercialize innovative products under European Regulations**	Steven Van Hove
16:00 – 16:45	**Notified Body's perspective**	Representative from NB
16:45 - 17:00	**Closing**	Martijn Reniers