Programme - Wednesday, June 22

SECTION 1 - INTRODUCTION TO IVDR		
10.00-10.15	**General introduction** **Presentation includes some theory and practical examples on:** • History, • short overview • IH-IVD's & CE-IVD - Identify devices within scope & risk classification of IVDR	*Els Dequeker, Leuven, Belgium*
10.15-10.35	**Role of the European Commission & Competent Authority**	*Olga Tkachenko, Brussels, Belgium*
	Role of different organizations:	
10.35-10.47	**Role of Notified Bodies & Role of Reference laboratories**	*Anja Wiersma, Valburg The Netherlands*
10.48-11.00	**Role of Stakeholders as observers - Biomed Alliance**	*Elizabeth Macintyre, Paris, France*
11.00-11.20	*Questions*	
11.20-13.00	*Break*	

SECTION 2 - IVDR – IMPACT ON A DIAGNOSTIC LABORATORY

13.00-13.30	**In-house test and hospital exemption – What does this mean?** - Explanation of article 5.5 (a-i) - What about ISO 15189? - Key requirements concerning conformity assessment • Technical documentation • General Safety and performance Requirement • How to combine with existing QMS documents and validation data	*Els Dequeker, Leuven, Belgium*
13.30-14.00	**MDCG documents for IVDR – some insights:** - How are the guidelines established? - Snapshot of guidelines for IVDR	*Jeroen Poels, Brussels, Belgium*
14.00-14.20	*Questions*	
14.20-15.00	*Break*	

SECTION 3 - IVDR - OBTAIN REGULATORY COMPLIANCE FOR IH-IVD'S

	National initiatives:	
15.00-15.15	**The Netherlands – TF IVDR Clinical Chemistry - Department of Pathology, Princess Máxima Center for Pediatric Oncology, Utrecht, The Netherlands**	*Claudia Ruivenkamp, Utrecht, The Netherlands*
	Practical examples - Open questions:	
15.15-15.35	**Implementing the IVDR in a diagnostic laboratory - a practical approach**	*Isabel Dombrink, Kiel, Germany*
15.35-15.55	**Software as an IVD medical device - how to comply to IVDR**	*Oliver Eidel, Berlin, Germany*
15.55-16.30	*Panel discussion - Questions and answers*	

How to participate?

Participation is free of charge, however registration is mandatory.
The webinar will be held on a Zoom platform.

Register now

Contact

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