MDR | IVDR
Training
Nov. 28-29 2019

TRAINING PROGRAM

November 28-29, 2019
Dom Pedro Lisboa
Lisbon, Portugal

JOIN US ON THE FIRST TAILORED MDR/IVDR CONFERENCE WITH THE OPPORTUNITY TO GET REAL SUPPORT ON YOUR REGULATORY CHALLENGES

WHY SHOULD YOU JOIN

- THE PROGRAM BEEN DESIGNED BASED ON INPUTS FROM INDUSTRY
- THE EVENT IS OFFERED FOR VERY ATTRACTIVE AFFORDABLE PRICES
- YOU WILL BE GIVEN THE OPPORTUNITY TO GET FREE CONSULTANCY ON YOUR REGULATORY CHALLENGES

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Thursday November 28th

09:00 – 10:00 **Registration**

10:00 – 10:10 **OPENING SESSION and WELCOME**
Introduction of Trainer Team
Mrs. Tiffani Jorgensen

10:10 – 11:10 **SESSION 1: Changes to MDD/AIMD - Overview**

- Comparison of MDD/AIMD to MDR and timelines
- Gap analysis
- Implementation of MDR (QMS and Technical File)
- Changes to classifications
- Clinical requirements
- Post-market activities
- New submission pathway
- MDR audit and impact to QMS
- Questions and answers

Trainer: **Dr. Toni Jorgensen**

11:10 – 11:30 **Coffee Break**

11:30 – 12:00 **SESSION 2: Selection of a Notified Body**

- Role of the Notified Body
- Changes to the Notified Body
- Selection criteria
- What are you paying for?
- Communication to your Notified Body
- Questions and answer

Trainer: **Dr. Toni Jorgensen**

12:00 – 12:45 **SESSION 3: Working with Contract Manufacturers**

- Using contract manufacturers vs. in-house production
- What to consider when selecting a contract manufacturer or design developer
- Quality agreements
- Supplier inspections
- Establishing specifications
- Establishing a DMR and maintaining a DHR
- Notified Body inspection at your contract manufacturing site and how to prepare your contractor
- Questions and answers

Trainer: **Dr. Toni Jorgensen**

12:45 – 13:45 **Lunch Break**

13:45 – 14:30 **SESSION 4: Document Control System and Electronic Signature**

- How to create a lean document control system
- Regulatory compliance with electronic signatures
- Benefit of using electronic signature
- Questions and answers

Trainer: **Dr. Gor Lebedev**

14:30 – 15:00 **SESSION 5: Qualified Person and Authorized Representative**

- New requirements
- Skills and responsibility
- Questions and answers

Trainer: **Dr. Petra Kaars-Wiele**

15:00 – 15:30 **Coffee Break**

15:30 – 16:00 **SESSION 6: Economic Operators and Working with Distributors**

- New requirements
- Responsibility
- Quality agreement
- Inspections
- Questions and answers

Trainer: **Dr. Petra Kaars-Wiele**

16:00 – 16:45 **SESSION 7: Software Validation**

- Standard requirements ISO 62304
- How to create an optimized technical environment for medical software development and validation
- Questions and answers

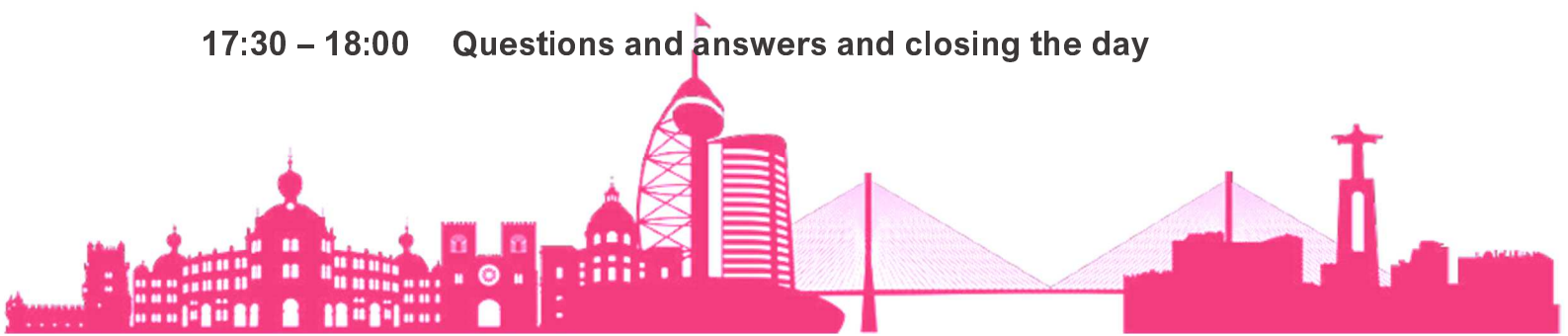
Trainer: **Dr. Gor Lebedev**

16:45 – 17:30 **SESSION 8: Labeling and Translation**

- Standard requirements ISO 15223
- What need to be on your label and what is different to today's labeling
- Responsibility of the Legal Manufacturer
- UDI

Trainer: **Dr. Petra Kaars-Wiele**

17:30 – 18:00 **Questions and answers and closing the day**



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Friday November 29th

08:00 – 08:30 **Registration for Day 2**

08:30 – 09:15 **SESSION 9: Changes to IVDD- Overview**

- The revision of the Directive to a Regulation
- Comparison of IVDD to IVDR and timelines
- Gap analysis and implementation strategy
- Changes to classification
- STED
- European Data Base and manufacturers responsibilities
- Clinical evidence
- Questions and answers

Trainer: **Dr. Petra Kaars-Wiele**

09:15 – 9:45 **SESSION 10: Regulatory and Clinical Strategy**

- How to write a strategy
- What should a strategy contain?
- How to verify your strategy?
- Can my strategy be reviewed by both a Notified Body and FDA?
- What your strategy can be used for?

Trainer: **Dr. Toni Jorgensen**

09:45 – 11:00 **SESSION 11: Clinical Evidence, Clinical Evaluation, and Post-Market Clinical Follow-up studies**

- New requirements
- Clinical requirements for IVDs and MDs
- Clinical plan (Clinical Evaluation Plan and PMCF Plan)
- Reports
- Questions and answers

Trainer: **Dr. Toni Jorgensen / Dr. Petra Kaars-Wiele**

11:00 – 11:30 **Coffee Break**

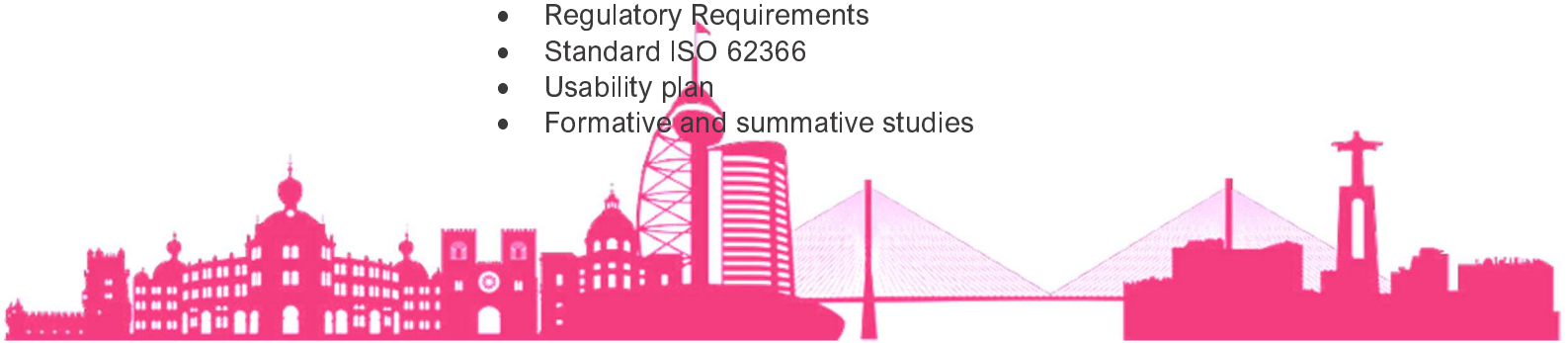
11:30 – 12:00 **SESSION 12: Data Protection**

- Regulation requirements
- Implementation and technical solutions
- Questions and answers

Trainer: **Dr. Gor Lebedev**

12:00 – 12:30 **SESSION 13: Usability**

- Regulatory Requirements
- Standard ISO 62366
- Usability plan
- Formative and summative studies



- Questions and answers

Trainer: **Dr. Toni Jorgensen**

12:30 – 13:30 **Lunch Break**

13:30 – 14:30 **SESSION 14: Verification and validation**

- How to create a V+V plan
- How to use harmonized standards
- Sample size
- How to complete a report
- Example of a V+V plan
- Questions and answers

Trainer: **Dr. Toni Jorgensen**

14:30 – 15:15 **Session 15: Post-Market Surveillance**

- Requirements and responsibilities
- Post-Market surveillance plan and report
- How to collect post-market data and where
- Questions and answers

Trainer: **Dr. Toni Joergensen**

15:15 – 15:45 **Coffee Break**

15:45 – 16:15 **SESSION 16: Vigilance Reporting**

- New requirements of reporting medical events and field actions
- Communication with Competent Authorities

Trainer: **Dr. Petra Kaars-Wiele**

16:15 – 16:45 **Session 17: Combination Devices**

- Regulatory requirements
- Primary mode of action
- How to perform a submission
- Drug Master File
- Timelines to market
- Post CE-Mark considerations
- Questions and answers

Trainer: **Dr. Toni Joergensen**

16:45 – 17:30 **Session 18: Questions, Answers and Conclusions**

End of the training

IMPORTANT TO REMEMBER: USE ONE OF THE BENEFITS OF THIS PROGRAM - GET YOUR REGULATORY CHALLENGES OR QUESTIONS DISCUSSED WITH AN EXPERT FOR NO ADDITIONAL COST

Note:

*** Participants who are interested in a private consultation on IVD matters, may request a session in the morning**

**** Participants who are interested in a private consultation on MD matters, may request a session in the afternoon**

***** Participants who are interested in any consultation, may request a session between 8 and 10 p.m.**

SPEAKERS

Dr. Petra Kaars-Wiele

Petra graduated from the University of Goettingen/Germany with Diploma in 1980 and with Ph.D. in 1983. She joined Abbott Laboratories in the same year.
Petra has more than 35 years of experience in Regulatory Affairs and Quality Systems for Medical Devices, currently responsible for all international regulatory matters, medical event reporting, risk management, managing translation for 29 languages and labeling activities at Abbott Diagnostics Division. She has experience in building Quality Management System according ISO 9001 and ISO 13485 and has passed a lead auditor training in 1997. Since then she has used that knowledge in training, setting up a QMS or consulting in that field internally and externally.
Petra is retired from Abbott since April 2019 and is working as an independent Consultant.

Dr. Toni Kennet Jørgensen

Toni studied Chemistry and software development and initiated his PhD work in South Africa in in organic chemistry, He worked in the medical device industry for 20 years, working in function responsible for compliance (Regulatory affairs, Quality Assurance and Clinical Affairs). He worked in 8 countries for company such as Johnson & Johnson and Medtronic in leading roles. In Switzerland he was the VP of Corporate Regulatory Affairs and Compliance leading a group of 50 professional experts in Regulatory Affairs.
The last 5 years he dedicated shared experience with mainly smaller start-up companies, creating clinical, regulatory and quality strategies. He supported in finding financial and human resources for companies to obtain market access to Europe and USA.
He is the founder of MDRAC a consulting service and MDRAT a training service in the medical device area. He has been a regular presenter in Europe, USA and Asia in both the industry and for regulators, such as FDA, AHWP, SGA, DIA and Informa Life Science.

Dr. Gor Lebedev

Gor received his PhD in microelectronics and signal processing from the University of Grenoble in 2012. He is a recognized expert in the field of complex data analysis and more particularly in machine learning with 8 patents to his name. Since 2015 he has been working in the field of medical devices with a strong emphasis on digital aspects such as the use of artificial intelligence algorithms in MDs, optimization of medical software development processes and software validation.
Currently Gor is working at Sensome, a French startup that develops cutting-edge technology and disruptive devices in the neurovascular field. He coordinates the digital engineering team that develops application, embedded and cloud solutions for next-generation connected medical devices. Meanwhile he has co-developed an entire document management system tailored to Sensome's needs. Thanks to his expertise in ISO 13485 and IEC 62304 he has been able to build development and validation processes that are both fast and ensure the highest quality of the final products.