Title: IVDR: Now Is the Time for Implementation
Date Thursday, 11 September 2020 (9:00 AM) – Friday, 12 September 2020 (3:00 PM) Eastern Time (US & Canada)

Facilitators:

- Connie Angela Del Buono, Founder, Director Regulatory & Compliance, Synoptyx Inc.
- Andreas Stange, PhD, Vice President, TÜV SÜD Japan
- Anja Wiersma, PhD Chair of Board of RAPS Netherlands Chapter, CEO of mi-CE consultancy, mi-CE consultancy

Agenda:

Day 1

8:45 AM EST	**Attendees are expected to be logged into the webinar and placed in a virtual waiting room**
9:00 AM EST	**Start of the webinar**
9:00- 9:15 AM EST	**Introduction**
9:15- 10:30 AM EST	**Current State of Play with the IVDR What do we know now that we did not know last year at this time?** • **What do we still not know?** • **What is not in your control?** • **What is in your control and what to do.**
10:30- 10:45 AM EST	**15-minute break**
10:45 – 11:30 AM EST	• **QMS Must Haves…** **Meeting the requirements for relationships with Economic Operators: Authorized Representative, Importer, Distributors** - **Short exercise** • **Person responsible for Regulatory Requirement (PRRC);** • **Expectations - Hosting the on-site Notified Body Audit (…. i.e. how to handle NB requests to take samples etc.)** • **Implementing Post Market Surveillance, Vigilance procedures Clinical Evidence and new elements - PSUR, Eudamed, Processes for PMPF**
11:30 – 12:00 PM EST	**Regulatory Strategies - Risks to consider in making your Regulatory Plan** • **Considerations for the long game; what to be aware of in determining your strategy.** • **Short exercises - case examples**
12:00 – 12:45 PM EST	**lunch**
12:45 – 2:00 PM EST	**Applying the classification Rules and Selecting a Conformity Assessment Route** • **Intended Use drives classification** **Classification drives conformity assessment strategy** ○ **Short exercises - case examples**

2:00 – 2:15 PM EST	**15-minute break**
2:15 – 2:30 PM EST	**Presentation of a Case study and homework**
2:30– 3:00 PM EST	**Panel Discussion**

Day 2

8:45 AM EST	**Attendees are expected to be logged into the webinar and placed in a virtual waiting room**
9:00 AM EST	**Start of the webinar**
9:00 – 9:15 AM	**Introduction: Day 2 overview**
9:15 – 10:30 AM EST	**Case Study Exercises** • **Classification** • **Conformity Assessment choices** • **What Regulatory Strategy and why?** • **Special considerations**
10:30 – 10:45 AM EST	**15-minute break**

10:45 – 11:30 AM EST	**Technical Documentation: Best Practices – Organization and Assembly of the Technical Documentation File**
	• **Demonstrating General Safety and Performance Requirements**
	  ○ **Application to the presented Case Study - Challenge exercises**
	• **How to approach and manage a new submission with "legacy data"**
	• **How to manage the new clinical evaluation requirements**
	  ○ **Application to the presented Case Study - Exercise**
	• **Maintaining the Technical Documentation - Living Documentation**

12:00 – 12:45 PM EST	**Lunch**
12:45 – 2:00 PM EST	**Clinical Evidence, Clinical Performance Investigation; Post-Market Performance follow up** • **Having enough clinical data** • **Clinical evaluation process and risk management, including Performance Evaluation Presentation** ○ **Group Exercise / Application to the Case Study**
2:00– 2:15 PM EST	**15-minute break**
2:15– 2:30 PM EST	**Review Group Exercise**
2:30 – 3:00 PM EST	**Panel Discussion**
3:00 PM EST	**End of meeting**