Module 19: Regulation of In Vitro Diagnostic Medical Devices
20 – 22 February 2019

LOCATION: TOPRA OFFICE, LONDON, UK

Module Leader(s): Aaron Cousins

Date: 20 – 22 February 2019

Wednesday 20th February 2019

Time	Activity	Speaker
13.30 – 14.00	**Introduction and Housekeeping**	Aaron Cousins Beckman
14.00 – 15.00	**Lecture 1: Setting the Scene – EU Focus** An overview of Europe, the European regulatory process, the key players, the definition of an IVD, the difference legislative instruments and the role of a Regulatory professional	Aaron Cousins Beckman
15.00 – 15.15	**Refreshment break**	
15.15 -16.15	**Lecture 2: Classification of IVD Devices**	Maurizio Suppo Qarad
16.15 – 17.15	**Lecture 3: Conformity Assessment:** What are the different routes and how does a manufacturer select the route which is appropriate for their device	Maurizio Suppo Qarad
17.15 – 18.15	**Lecture 4: Quality Management System** What is an ISO 13485 QMS? Why is it needed? In which countries is it recognised? What about CMCAS? What about MDSAP?	Maurizio Suppo Qarad
18.15 – 19.00	Student Tutorial Wine Reception	

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Date: **Thursday 21st February 2019**

Time	Activity	Speaker
09.00 – 09.30	**Review of Day 1:** Interactive session to reflect on learnings from day 1, answer any questions and confirm understanding	Aaron Cousins/Maurizio Suppo
09.30 – 10.30	**Case Study:** Apply learnings on classification, conformity assessment and QMS in a group setting using real life examples	Maurizio Suppo Qarad
10.30 – 10.45	**Refreshment break**	
10.45 – 11.45	**Lecture 5: Technical Documentation** What is it? How should it be compiled? What is STED? How to write a DoC	Ben Jacoby Cambridge RA
11.45 – 12.45	**Lecture 6: Performance Data & Product Claims:** What is the difference between Scientific Validity, Analytical Performance and Clinical Performance and how should the data be collected and analysed ? What is the significance of your claim?	Liz Harrison BSI Group
12.45 – 13.30	Lunch	
14.00 – 14.30	**Lecture 7: Post Market Surveillance, Vigilance and FSCA**	Stephen Lee MHRA
14.30 – 15.30	**Case Study** Apply learnings on PMS, vigilance and FSCA in a group setting using real life examples	Stephen Lee MHRA
15.30 – 15.45	**Refreshment Break**	
15.45 – 16.45	**Lecture 8: Risk Management** What is ISO 14179? When is it needed and why? How to establish a RM policy, procedure and plan. When is a risk acceptable?	Stuart Angell Novartis

16.45 – 17.45	**Lecture 9: Registration** What is required and why? What is EUDAMED and what are the requirements on UDI? Local country requirements versus EU – what is the difference?	Gill Morgan Sestria

Date: Friday 22nd February 2019

09.00 – 09.30	**Review of day 2** Interactive session to reflect on learnings from day 2, answer any questions and confirm understanding	Aaron Cousins
09.30 – 10.30	**Case Study** Apply learnings on performance data & product claims in a group setting using real life examples	Liz Harrison BSI Group
10.30 – 10.45	**Refreshment Break**	
10.45 – 12.30	**Lecture 10: Other Regulated Markets** Which are they? How are they different? How can we drive harmonisation? Who are IMDRF	Robyn Meurant NSF
12.30 – 13.30	**LUNCH**	
13.30 – 14.30	**Lecture 11: Other Legislation** Beyond IVDR. What about REACH, RoHS WEEE, GDPR, Machinery Directive and more	Nancy Consterdine Novartis
14.30 – 15.30	**Lecture 12: Companion Diagnostics and other emerging technologies** Personalised medicine, generic testing	Liz Harrison BSI Group
15.30	Close of Module	