Module 19: Regulation of In Vitro Diagnostic Medical Devices
1 - 3 June 2021

LOCATION: TOPRA OFFICE, LONDON, UK

Module Leader(s): Nancy Consterdine

Date: 1 - 3 June 2021

Tuesday 1st June 2021

Time	Activity	Speaker
13.00 13.30	Registration and coffee	
13.30 – 14.00	**Introduction and Housekeeping**	Stuart Angell IVDeology
14.00 – 15.00	**Lecture 1: Setting the Scene – EU Focus** A regulatory and Industry Perspective To include UK CA	Stephen Lee ABHI Stuart Angell IVDeology
15.05 -16.00	**Lecture 2: Classification of IVD Devices**	Stephen Lee ABHI
16.05 – 17.00	**Lecture 3: Conformity Assessment:** What are the different routes and how does a manufacturer select the route which is appropriate for their device?	Gill Morgan
17.05 – 18.00	**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?	Stuart Angell IVDeology

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Date: **Wednesday 2nd June 2021**

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	
09.30 – 10.30	**Case Study:** Apply learnings on classification, conformity assessment and QMS in a group setting using real life examples	Stuart Angell Nancy Consterdine
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 – 13.00	**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?	Maurizio Suppo
13.00 – 13.45	Lunch	
13.45 – 14.45	**Lecture 7: Post Market Surveillance, Vigilance and FSCA**	Stephen Lee ABHI
14.45 – 15.45	**Case Study including tea and coffee** Apply learnings on PMS, vigilance and FSCA in a group setting using real life examples	Stephen Lee ABHI
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 IVDeology

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?	TBC

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Date: Thursday 3rd June 2021

09.00 – 09.30	**Review of day 2** Interactive session to reflect on learnings from day 2, answer any questions and confirm understanding	Nancy Consterdine IVDeology
09.30 – 10.30	**Case Study** Apply learnings on performance data & product claims in a group setting using real life examples	
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	Nancy Consterdine IVDeology Possibly Simon Richards
12.30 – 13.15	**LUNCH**	
13.15 – 14.15	**Lecture 11: Other Legislation** Beyond IVDR. What about REACH, RoHS WEEE, GDPR, Machinery Directive and more	Nancy Consterdine IVDeology
14.15 – 14.45	**Refreshment Break**	
14.45 – 15.45	**Lecture 12: Companion Diagnostics and the IVDR** What this means for co-development and personalised medicine	Shirley Hopper MHRA Confirmed
15.45	Close of Module	