Module 19:

Date: 20-22 October 2025

LOCATION: LONDON, UK and ONLINE

Module Leader(s): Nancy Consterdine & Stuart Angell

Day 1:

Time	Activity	Speaker
	Welcome and Introduction to Module	Stuart Angell, IVDeology
	Lecture 1: Setting the Scene – EU Focus A regulatory and Industry Perspective To include UK CA	Stuart Angell, IVDeology
	Lecture 2: Classification of IVD Devices	Nancy Consterdine, IVDeology
	Afternoon break	
	Lecture 3: Conformity Assessment: What are the different routes and how does a manufacturer select the route which is appropriate for their device?	Nancy Consterdine, IVDeology
	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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Day 2:

Time	Activity	Speaker
	Review of Day 1: Interactive session to reflect on learnings from day 1, answer any questions and confirm understanding	Stuart Angell, IVDeology Nancy Consterdine, IVDeology
	Case Study: Apply learnings on classification, conformity assessment and QMS in a group setting using real life examples	Stuart Angell, IVDeology Nancy Consterdine, IVDeology
	Morning break	
	Lecture 5: Technical Documentation What is it? How should it be compiled? What is STED? How to write a DoC. To include EU IVDR	Ben Jacoby, Cambridge RA
	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
	Lunch	
	Lecture 7: Post Market Surveillance, Vigilance and FSCA	Stephen Lee, ABHI
	Case Study: (Includes afternoon break) Apply learnings on PMS, vigilance and FSCA in a group setting using real life examples	Stephen Lee, ABHI
	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
	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?	Nancy Consterdine, IVDeology

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Day 3:

Time	Activity	Speaker
	Review of day 2 Interactive session to reflect on learnings from day 2, answer any questions and confirm understanding	Nancy Consterdine, IVDeology
	Case Study: Apply learnings on performance data & product claims in a group setting using real life examples	Nancy Consterdine, IVDeology
	Morning break	
	Lecture 10: Other Regulated Markets Which are they? How are they different? How can we drive harmonisation? Who are IMDRF	Nancy Consterdine, IVDeology / Maurizio Suppo
	Lunch	
	Lecture 11: Other Legislation Beyond IVDR. What about REACH, RoHS WEEE, GDPR, Machinery Directive and more	Nancy Consterdine, IVDeology
	Afternoon break	
	Lecture 12: Companion Diagnostics and the IVDR What this means for co-development and personalised medicine	Maurizio Suppo
	Close of Module	