Module 15: Clinical Evaluation of Medical Devices

LOCATION: TOPRA OFFICE AND REMOTELY

Module Leader(s): Adrian Keene

Date: 23 - 25 May 2022

Monday 23rd May 2022

Time	Activity	Speaker
12:55 – 13:00	Introduction	NAMSA Adrian Keene
13:00 - 14:00	**Lecture 1: Current status of the EU Medical Device Regulation 2017/745** Impact overview for Clinical Evaluation	NAMSA Adrian Keene
14:00 - 15:00	**Lecture 2: Clinical Evaluation – moving from MEDDEV 2.7.1 Rev 4 to MDR – scope of work and who performs it**	NAMSA Jane Arnold Round
15:00 – 15:30	**Refreshment break**	
15:30 -16:30	**Lecture 2 (cont'd): Clinical Evaluation – moving from MEDDEV 2.7.1 Rev 4 to MDR – scope of work and who performs it**	NAMSA Jane Arnold Round
16:30 – 17:00	Wrap up day	Adrian Keene

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Date: **Tuesday 24th May 2022**

Time	Activity	Speaker
08:55 - 09:00	**Introduction**	Adrian Keene
09:00 - 10:00	**Lecture 3: The Place of Clinical Evaluation Within Device Live-Cycle and Technical Documentation**	NAMSA – Adrian Keene
10:00 - 10:30	Refreshment Break	
10:30 - 11:30	**Lecture 4: The Notified Body Perspective on Clinical Evaluation – the Notified Body Clinical Evaluation Assessment Report**	NAMSA – Rachel Gibbs
11:30 - 12:30	Lunch	
12.30 – 13.30	**Lecture 5: The Summary of Safety and Clinical Performance** - **how does the SSCP relate to the CER** - **challenges in drafting the SSCP to meet MDCG requirements**	NAMSA – Rachel Gibbs
13.30 – 14.30	**Case Study**	NAMSA – Adrian Keene/Jane Arnold Round
14.30 - 15:00	Refreshment Break	
15:00 - 16:00	Case Study discussion	NAMSA – Adrian Keene/Jane Arnold Round

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Date: Wednesday 25th May 2022

09:00	**Connection**	Adrian Keene
09:00-10:00	**Lecture 5: The relationship between clinical evaluation and post market surveillance/post market clinical follow-up**	NAMSA Paul Risborough
10:00 - 10:30	Refreshment Break	
10:30 – 11:30	**Lecture 6: The Equivalence Assessment under MDR: When and how can this be leveraged?**	NAMSA Paul Risborough
11:30 – 12:30	**Lunch**	
12:30 - 13:30	**Lecture 7: Clinical Investigations under MDR:** • Types of clinical studies • ISO14155 • Implication of MDR • Clinical strategy notification requirements. The role of the clinical team and regulatory governance	NAMSA Dan Whitter (remote)
13:30 - 14:30	Case study	NAMSA – Adrian Keene/Jane Arnold Round
14:30 – 15.00	Refreshment Break	
15:00 – 16:00	**Lecture 8: Clinical Global Strategy Requirements – Focus on US FDA Specifics**	NAMSA Carla Wiese (remote)
16:00 - 16:30	Wrap up	NAMSA Adrian Keene