Module 15: Clinical Evaluation of Medical Devices

LOCATION: REMOTE

Module Leader(s):

Dates: June 5th, June 12th, June 19th 2pm to 5:30pm

Date: Friday June 5th 2020

Time	Activity	Speaker
13.45 – 14:00	Connection	Adrian Keene
14:00-15:00	**Lecture 1: From EU MDD 93.42 to EU Medical Device Regulation 2017/745:** Impact overview for Clinical Evaluation	NAMSA Adrian Keene
15:00-16:00	**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
16:00 – 16.15	**Refreshment break**	
16.15 -17.15	**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
17.15 – 17:30	Wrap up day	Adrian Keene

Date: **Friday June 12th 2020**

Time	Activity	Speaker
13:45-14:00	**Connection and opening**	Adrian Keene
14:00-15:00	**Lecture 3: The Place of Clinical Evaluation Within Device Live-Cycle and Technical Documentation**	NAMSA – Adrian Keene
15:00-16:00	**Lecture 4: Clinical evaluation for marketed devices – the relationship with post market information** • PMS / PMCF • PSUR • SSCP	NAMSA –Jane Arnold Round
16:15-16:30	**Break**	
16.30 – 17.30	**Case Study Discussion**	NAMSA – Adrian Keene
17.30	**Close day**	NAMSA – Adrian Keene

Date: Friday June 19th 2020

13:45-14:00	**Connection and Opening**	Adrian Keene
14:00-15:00	**Lecture 5: The Equivalence Assessment under MDR: When and how can this be leveraged?**	NAMSA Matt Royle
15.00 – 16.00	**Lecture 6 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 – Sandra Welch /Dan Whitter
16:000 – 16:15	**Break**	
16.15 – 17.15	**Lecture 7: Clinical Global Strategy Requirements – Focus on US FDA Specifics**	NAMSA Jason Kreszack
17.15 – 17.30	**Final Review and Close of Module**	Adrian Keene Module Leader NAMSA