Module 20: Regulation of Electrical, Electronic and Software Devices
29 – 31 May 2019

LOCATION: TOPRA OFFICE, LONDON, UK

Module Leader(s):

Date: 29 September - 1 October 2021

Wednesday 29 September 2021

Time	Activity	Speaker
13.00	Registration	
13.30 -14.30	Welcome & Introduction to the Module Lecture 1: Definition of electronic devices and "active" devices, hardware components, software, accessories, and replaceable parts	Richard Vincins Course Director The Centre for Global Regulatory Compliance
14.30 – 15.00	Lecture 2: Design controls; critical components	Richard Vincins The Centre for Global Regulatory Compliance
15.00 – 15.30	**Refreshment break**	
15.30 – 16.00	Lecture 3: Manufacturing aspects; storage, handling, use, and environment	Richard Vincins The Centre for Global Regulatory Compliance
16.00 – 16.45	Lecture 4: IEC 60601-1 related to safety, risk, and usability including IEC 61010-1 for IVD instruments; 3.0 to 3.1 edition changes	Richard Stoney Medical Product Consulting Ltd
16.45 – 17.30	Lecture 5: IEC 60601-1-2 for EMD; review of country compliance requirements	Richard Stoney Medical Product Consulting Ltd
17.30 – 18.30	Workshop: Definition of electrical and electronic devices	

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Date: **Thursday 30 September 2021**

Time	Activity	Speaker
09.00 – 10.00	Lecture 6: Other IEC & ISO standards (home use, usability); Collateral and Particular standards	Richard Stoney Medical Product Consulting Ltd
10.00 – 11.00	Lecture 7: Safety and essential performance; risk management including normal and fault conditions	Richard Stoney Medical Product Consulting Ltd
11.00 – 11.30	**Refreshment Break**	
11.30 – 12.30	Lecture 8: Marking, safety guards, labelling, instructions; batteries related to safety	Richard Vincins The Centre for Global Regulatory Compliance
12.30 – 13.30	**Lunch**	
13.30 – 14.30	Workshop: Intended Use, Hazards, and Harms with Electrical Devices	
14.30 – 15.30	Lecture 9: Usability and human factors related to IEC 62366; combination products	Richard Vincins The Centre for Global Regulatory Compliance
15.30 – 17.30	Lecture 10: Software Development Life Cycle (SDLC) and phases of software development; PEMS	Richard Vincins The Centre for Global Regulatory Compliance

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Date: Friday 1st October 2021

09.00 – 10.00	Lecture 11: Software as a Medical Device (SaMD)	David Grainger MHRA
10.00 – 10.15	**Refreshment Break**	
10.15 – 11.15	Lecture 12: Linking software to electromechanical devices; operation and validation	Richard Vincins The Centre for Global Regulatory Compliance
11.15 – 12.15	Lecture 13: IEC 62304 and FDA Guidance for Software in Submissions; comparison and contrast	Richard Vincins The Centre for Global Regulatory Compliance
12.15 – 13.15	**LUNCH**	
13.15 – 14.15	Lecture 14: Risk management, cybersecurity, connectivity; SOUP and configuration management	Richard Vincins The Centre for Global Regulatory Compliance
14.15 – 14.45	**Refreshment Break**	
14.45 - 15.45	Workshop: Software Applications and Testing Requirements	
15.45 – 16.00	Conclusion and summary	Richard Vincins