Module 20: Regulation of Electrical, Electronic and Software Devices

Date: 2-4 December 2025

LOCATION: TOPRA OFFICE, LONDON, UK and ONLINE

Module Leader(s): Richard Vincins

Day 1: Tuesday 2 December 2025

Time	Activity	Speaker
	Registration	
	Welcome & Introduction to the Module Lecture 1: Definition of electronic devices and "active" devices, hardware components, software, accessories, and replaceable parts	Richard Vincins, Module Leader
	Lecture 2: Design controls; critical components	Richard Vincins, Oriel STAT A MATRIX
	Afternoon break	
	Lecture 3: Manufacturing aspects; storage, handling, use, and environment	Richard Vincins, Oriel STAT A MATRIX
	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 Vincins, Oriel STAT A MATRIX
	Lecture 5: IEC 60601-1-2 for EMD; review of country compliance requirements	Richard Vincins, Oriel STAT A MATRIX
	Workshop: Definition of electrical and electronic devices	

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Day 2: Wednesday 3 December 2025

Time	Activity	Speaker
	Lecture 6: Other IEC & ISO standards (home use, usability); Collateral and Particular standards	Richard Vincins, Oriel STAT A MATRIX
	Lecture 7: Safety and essential performance; risk management including normal and fault conditions	Richard Vincins, Oriel STAT A MATRIX
	Morning break	
	Lecture 8: Marking, safety guards, labelling, instructions; batteries related to safety	Richard Vincins, Oriel STAT A MATRIX
	Lunch	
	Workshop: Intended Use, Hazards, and Harms with Electrical Devices	
	Lecture 9: Usability and human factors related to IEC 62366; combination products	Richard Vincins, Oriel STAT A MATRIX
	Lecture 10: Software Development Life Cycle (SDLC) and phases of software development; PEMS	Richard Vincins, Oriel STAT A MATRIX

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Day 3: Thursday 4 December 2025

	Lecture 11: Software as a Medical Device (SaMD)	David Grainger, MHRA
	Morning break	
	Lecture 12: Linking software to electromechanical devices; operation and validation	Richard Vincins, Oriel STAT A MATRIX
	Lecture 13: IEC 62304 and FDA Guidance for Software in Submissions; comparison and contrast	Richard Vincins, Oriel STAT A MATRIX
	Lunch	
	Lecture 14: Risk management, cybersecurity, connectivity; SOUP and configuration management	Miguel Amador, EIT Health InnoStars
	Afternoon break	
	Workshop: Software Applications and Testing Requirements	
	Conclusion and summary	Richard Vincins, Oriel STAT A MATRIX