Module 14:

Design Development and Certification of Medical Devices

LOCATION: London, UK and Online

Module Leader(s): Dr Helen Erwood and Jason Collins

Date:

DAY ONE:

Time	Activity	Speaker
	Registration and coffee	
	Housekeeping and Introduction Overview of the regulatory environment MDR, IVDR and Notified Body changes	Helen Erwood and Jason Collins ESPL Regulatory
	Lecture 1: Principles of the Design and Development of Medical Devices: • An overview and introduction to the design and development "toolkit". • The importance of ISO standards in device development (ISO13485 / ISO14971 / ISO10993 etc.)	Helen Erwood ESPL Regulatory
	Refreshment Break	
	Case Study 1: **The Design and Development Target** • How the target product profile (TPP) fits into the design programme • Relevance of the Essential Requirements checklist to design and development of a new device	Jason Collins ESPL Regulatory
	Lecture 2: Risk Assessment: what is it? • A practical look at how this fits into device design and development	Helen Erwood ESPL Regulatory

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DAY TWO: Date:

Time	Activity	Speaker
	Review of Day 1	Jason Collins ESPL Regulatory
	Lecture 3: **The influence of materials in Medical Device Design**	Helen Erwood / Chris Erwood Jason Collins
	Refreshment break	
	Lecture 4: **Design Planning and Design Control** • INPUTS and OUTPUTS When should DESIGN CONTROL take effect?	Jonathon Bradshaw OOONO Medical A/S
	Interactive Session: **Statistical Considerations in Medical Device Clinical Investigations**	Andrew Mills Exploristics
	Lunch	
	Lecture 5: Rapid Prototyping – the Challenges of Designing and Testing Prototypes	Jonathon Bradshaw OOONO Medical A/S
	Interactive session: **Packaging for Medical Devices** • Factors to consider in packaging design • How packaging helps to maintain product integrity	Helen Erwood ESPL Regulatory
	Refreshment Break	
	Lecture 6: Human factors and usability testing during development • Human factors studies	Greg Thay Thay Medical Limited
	Lecture 7: Diverging approaches to MD requirements – EEA and UK	
	Case study 2: Inputs, Outputs and Design Control	Jonathon Bradshaw Greg Thay Helen Erwood

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DAY THREE

Date:

	Introduction/overview of the day: Review of case study 2	**Helen Erwood** **ESPL Regulatory**
	Lecture 8: Certification: Documenting data to Support New Device files • Reporting design and development data for regulatory assessment. • Are requirements really different globally?	Jason Collins ESPL Regulatory
	Refreshment break	
	Lecture 9: Biological Assessments Relevant to Medical Devices	Stuart Freeman Farino Consulting
	Lecture 10: Notified Body Expectations • Common Issues with design and development data	James Newman BSI
	LUNCH	
	Lecture 11: Sterilisation of Medical Devices: The trials and tribulations of trying to sterilise the unsterilisable!	Helen Erwood ESPL Consulting
	Interactive session: Digital Health and Software a different development approach and a look at machine learning	Chris Erwood ESPL Consulting
	Refreshment Break	

	Lecture 12: Post-marketing Design/Development Activities • Clinical follow-up • Life Cycle Management of device design: optimisation after launch	
	Case Study 3: Post-Marketing Design Changes Including Packaging and Sterilisation	Helen Erwood / Jason Collins ESPL Regulatory
	Close	