Module 14:
Design Development and Certification of Medical Devices
23 - 25 March 2022

LOCATION: TOPRA OFFICE AND ONLINE

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

Date: 23rd - 25th March 2022

DAY ONE: Wednesday 23rd March 2022

Time	Activity	Speaker
13.00 13.30	Registration and coffee	
13.30 – 14.00	**Housekeeping and Introduction** Overview of the regulatory environment MDR, IVDR and Notified Body changes	Helen Erwood and Jason Collins ESPL Regulatory
14.00 – 14.45	**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
14.45 - 15.15	**Refreshment Break**	
15.15 -16.15	**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
16.15 - 17.15	**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: **Thursday 24th March 2022**

Time	Activity	Speaker
09.00 – 09.05	**Review of Day 1**	Jason Collins ESPL Regulatory
09.05 - 10.00	**Lecture 3:** **The influence of materials in Medical Device Design**	Helen Erwood / Chris Erwood Jason Collins
10.00 – 10.30	**Refreshment break**	
10.30 – 11.15	**Lecture 4:** **Design Planning and Design Control** • INPUTS and OUTPUTS When should DESIGN CONTROL take effect?	Jonathon Bradshaw Novo Nordisk
11.15 – 12.00	**Case Study** **Statistics in the Design and Development Tool Kit: why it's important.**	Denise Lee Metronomia
12.00 – 13.00	**Lunch**	
13.00 – 13.45	**Lecture 5: Rapid Prototyping – the Challenges of Designing and Testing Prototypes**	Jonathon Bradshaw Novo Nordisk
13.45 – 14.30	**Interactive session:** **Packaging for Medical Devices** • Factors to consider in packaging design • How packaging helps to maintain product integrity	Helen Erwood ESPL Regulatory
14.30 - 15.00	**Refreshment Break**	
15.00 - 15.45	**Lecture 6: Human factors and usability testing during development** • Human factors studies	Greg Thay Thay Medical Limited
15.45 – 16.30	**Lecture 7: Diverging approaches to MD requirements – EEA and UK**	Monir El Azzouzi Easy Medical Device
16.30 – 17.15	**Case study 2:** Inputs, Outputs and Design Control	Jonathon Bradshaw Greg Thay Helen Erwood

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DAY THREE

Date: Friday 25th March 2022

09.00 – 09.30	**Introduction/overview of the day: Review of case study 2**	**Helen Erwood** **ESPL Regulatory**
09.30 – 10.15	**Lecture 9: 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
10.15 – 10.45	**Refreshment break**	
10.45 – 11.30	**Lecture 11: Biological Assessments Relevant to Medical Devices**	Stuart Freeman Farino Consulting
11.30 – 12.15	**Lecture 10: Notified Body Expectations** • Common Issues with design and development data	Kevin Madden BSi
12.15 – 13.00	**LUNCH**	
13.00 - 13.45	**Lecture 12: Sterilisation of Medical Devices:** The trials and tribulations of trying to sterilise the unsterilisable!	Helen Erwood ESPL Consulting
13.45 – 14.30	**Interactive session: Software as a Medical Device:** a different development approach and a look at machine learning	Chris Erwood ESPL Consulting
14.30 – 15.00	**Refreshment Break**	

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15.00 – 15.45	**Lecture 13: Post-marketing Design/Development Activities** • Clinical follow-up • Life Cycle Management of device design: optimisation after launch	TBC
15.45 – 16.30	**Case Study 3:** Post-Marketing Design Changes Including Packaging and Sterilisation	Helen Erwood / Jason Collins ESPL Regulatory
16.30	Close	