Module 1 (BN5517) : Pre-Market Requirements and Post Market Surveillance

Dates	Thurs, 4 September 2025	Tues - Fri 9th to 12th September 2025								Thurs, 25 September 2025
Topic		Premarket Requirements for Medical Devices				Postmarket Requirements for Medical Devices				
Coverage	Registration Online 6.30pm to 7.30pm	Submission Dossier Content	Grouping rules for medical devices	Risk Management for Medical Device	Post Market Requirements	AE and FSCA case studies	Change management	Advertising and Promotional Materials Controls	2 Weeks Break	Final Quiz EA-06-02 6.30pm to 9.30pm
Activities		Workshop 9am to 6pm E7-03-09 Seminar Room 4								

Module 2 (BN5516) : Medical Device Design, Development and Testing

Dates	Sat, 4 Oct 2025	Thurs, 9 Oct 2025	Thurs, 16 Oct 2025	Sat, 25 Oct 2025		Thurs, 6 Nov 2025	Thurs, 13 Nov 2025	Thurs, 20 Nov 2025	Thurs, 27 Nov 2025
Topic	Medical Device's Product Realization Process on Design & Development Control Part 1			Medical Device's Product Realization Process on Design & Development Control Part 2					
Coverage	Part 1- Medical device's Product Realisation Process on Design & Development Control from the perspective of 21CFR Part 820 and ISO 13485:2016	Roles of DHF/DMR/DHR in D & D Control	Verification & Validation in D & D Control	Part 2 - Medical device's Product Realisation Process on Design & Development Control (cont from Part 1) and Medical Device Testing	1 Week Break	Briefing & assignment of Case studies	Risk Management/Quality management system / medical device testing	Presentation on Case study	Final Quiz E4-04-05/06/07 6.30pm to 9.30pm
Activities	Seminar ((E4-04-02)	Tutorial	Tutorial	Seminar ((E4-04-02)		Tutorial	Tutorial	Tutorial	

Module 3 (BN5515) : Clinical Design and Evaluation of Medical Devices

Date	Sat, 10 Jan 2026	Thurs, 15 Jan 2026	Thurs, 22 Jan 2026	Thurs, 31 Jan 2026		Thurs, 12 Feb 2026	Thurs, 19 Feb 2026		Thurs, 5 Mar 2026
Topic	Clinical Evaluation of Medical Devices		Assessment of Clinical Evidence						
Coverage	Introduction to Clinical Evaluation	Types of Clinical Evidence	Assessing Clinical Evidence	Literature Review & Content of Clinical Evaluation Report	1 Week Break	Assignment on CER	Presentation on CER assignment	1 Week Break	Final Quiz
Activities	Seminar (E4-04-02)	Tutorial	Tutorial	Seminar (E4-04-02)		Tutorial	Tutorial		

Module 4 (BN5518): Next-Generation Device Regulations

Dates	Thurs, 19 Mar 2026		Thurs, 2 Apr 2026		Thurs, 23 Apr 2026	Thurs, 30 Apr 2026
Topic	Project Module: Next-Generation Devices Regulations					
Coverage	Project Discussion with Faculty	2 week Self-study	Midpoint Check-in	3 Week Self-study	Final Presentation	Final Submission
Activities	Tutorial		Tutorial			

Notes:

*** Dates and timings are subject to change with prior notice**

Tutorials: 6.30pm to 9:30pm, Seminars: 8.00am to 6.00pm