Module 1 (BN5515) : Clinical Design and Evaluation of Medical Devices

Date	Sat, 10 Aug 2024	Thurs, 15 Aug 2024	Thurs, 22 Aug 2024		Sat, 31 Aug 2024	Thurs, 5 Sept 2024	Thurs, 12 Sep 2024		Thurs, 26 Sep 2024	
Topic	**Clinical Evaluation of Medical Devices**		**Assessment of Clinical Evidence**							
Coverage	Introduction to Clinical Evaluation	Types of Clinical Evidence	Assessing Clinical Evidence	1 Week Break	Literature Review & Content of Clinical Evaluation Report	Assignment on CER	Presentation on CER assignment	2 Week Break	Final Exam	1 Week Break
Activities	Seminar	Tutorial	Tutorial		Seminar	Tutorial	Tutorial			

Module 3 (BN5517) : Pre-Market Requirements and Post Market Surveillance

Dates	Sat, 5 Oct 2024	Thurs, 10 Oct 2024	Thurs, 17 Oct 2024	Sat, 26 Oct 2024	Thurs, 31 Oct 2024	Thurs, 7 Nov 2024	Thurs, 14 Nov 2025	Thurs, 21 Nov 2024	Thurs, 28 Nov 2024	
Topic	**Premarket Requirements for Medical Devices**			**Postmarket Requirements for Medical Devices**						
Coverage	Submission Dossier Content	Grouping rules for medical devices	Risk Management for Medical Device	Post Market Requirements	1 Week Break	AE and FSCA case studies	Change management	Advertising and Promotional Materials Controls	Final Exam	4 Week Break
Activities	Seminar	Tutorial	Tutorial	Seminar		Tutorial	Tutorial	Tutorial		

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

Dates	Sat, 11 Jan 2025	Thurs, 16 Jan 2025	Thurs, 23 Jan 2025	Sat, 1 Feb 2025	Thurs, 6 Feb 2025	Thurs, 13 Feb 2025	Thurs, 20 Feb 2025		Thurs, 6 Mar 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	Briefing & assignment of Case studies	Risk Management/Quality management system / medical device testing	Presentation on Case study	1 Week Break	Final Exam
Activities	Seminar	Tutorial	Tutorial	Seminar	Tutorial	Tutorial	Tutorial		

Module 4 (BN5518): Next-Generation Device Regulations

Dates	Thurs, 13 Mar 2025		Thurs, 3 Apr 2025		Thurs, 24 Apr 2024	Thurs, 1 May 2025
Topic	**Project Module: Next-Generation Devices Regulations**					
Coverage	Project Discussion with Faculty	3 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: 9.00am to 6.00pm