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, 28 Nov 2024	
Topic	Premarket Requirements for Medical Devices			Premarket Requirements for Medical Devices						
Coverage	Postmarket	Risk Management and PMS	Advertising and Promotional Materials Controls	Premarket consideration for new device technology	Regulatory Intelligence and Strategy	Regulatory Intelligence and Strategy	Presentation on Premarket Assignment	1 Week Break	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: 8.00am to 6.00pm