Module 1 (BN5511) : Introduction to Global Medical Device Regulation

Date	Wed, 14 Aug 2024	Sat, 17 Aug 2024	Wed, 21 Aug 2024	Wed, 28 Aug 2024	Sat, 24 Aug 2024	Wed, 11 Sep 2024	Wed, 18 Sep 2024		Wed, 2 Oct 2024	
Topic	Introduction to the Global MD Regulation				Quality & Compliance					
Coverage	Administrative	Introduction to medical device regulations Elements of conformity assessment	Definition and risk classification of medical devices	Professional Ethics (case studies)	Elements of technical documents Post market surveillance	Adverse Event and Field Safety Corrective Actions	Revision	1 Week Break	Final Exam	1 Week Break
Activities	Tutorial	Seminar	Tutorial	Tutorial	Seminar	Tutorial	Tutorial			

Module 2 (BN5512) : Medical Device Regulation in the US and EU

Dates	Sat, 12 Oct 2024	Wed, 16 Oct 2024	Wed, 23 Oct 2024	Wed, 30 Oct 2024	Sat, 2 Nov 2024	Wed, 6 Nov 2024	Wed, 13 Nov 2024		Wed, 27 Nov 2024	
Topic	Medical Device Regulation in the United States				Medical Device Regulation in the					
Coverage	US regulatory framework	Routes to US market for medical device	Quality System Regulation (QSR) overview	Postmarket Considerations and Requirements	EU Regulatory Framework	Routes to CE marking	Postmarket Considerations and Requirements	1 Week Break	Final Exam	4 Week Break
Activities	Seminar	Tutorial	Tutorial	Tutorial	Seminar	Tutorial	Tutorial			

Module 3 (BN5513) : Medical Device Regulation in ASEAN and Asia-Pacific

Dates	Sat, 18 Jan 2025	Wed, 22 Jan 2025	Wed, 29 Jan 2025	Sat, 8 Feb 2025	Wed, 12 Feb 2025	Wed, 19 Feb 2025		Wed, 5 Mar 2025	Wed, 12 Mar 2025	
Topic	Postmarket Requirements for Medical Devices			Medical Device						
Coverage	ASEAN agreement on Medical Device Directive	ASEAN agreement on Medical Devic+C14e Directive	Other ASEAN countries	China, India, Taiwan, Australia, South Korea, Japan	China / South Korea	Taiwan/ Japan/ India	1 Week Break	Assignment Presentation	Final Exam	1 Week Break
Activities	Seminar	Tutorial	Tutorial	Seminar	Tutorial	Tutorial		Tutorial		

Module 4 (BN5514): Medical Device Regulatory Process Strategy and Planning

Dates	Wed, 26 Mar 2025		Wed, 9 Apr 2025		Wed, 30 April 2025	Wed, 7 May 2025
Topic	Project Module: Medical Device Regulatory Process Strategy and Planning					
Coverage	Project Discussion with Faculty	2 Week Self-study	Midpoint Check-in	3 Week Self-study	Final Presentation	Report 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