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

Date	Wed, 13 Aug 2025	Sat, 16 Aug 2025	Wed, 20 Aug 2025	Sat, 23 Aug 2025	Wed, 27 Aug 2025	Wed, 10 Sep 2025	Wed, 17 Sep 2025		Wed, 1 Oct 2025	
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	Elements of technical documents Post market surveillance	Professional Ethics (case studies)	Adverse Event and Field Safety Corrective Actions	Revision	1 Week Break	Final Quiz EA 06-05	1 Week Break
Activities	Tutorial	Seminar E4 04-03	Tutorial	Seminar E4 04-03	Tutorial	Tutorial	Tutorial			

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

Dates	Sat, 11 Oct 2025	Wed, 15 Oct 2025	Wed, 22 Oct 2025	Wed, 29 Oct 2024	Sat, 1 Nov 2025	Wed, 5 Nov 2025	Wed, 12 Nov 2025		Wed, 26 Nov 2025	
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 EA 06-05	4 Week Break
Activities	Seminar E4 04-03	Tutorial	Tutorial	Tutorial	Seminar E4 04-03	Tutorial	Tutorial			

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

Dates	Sat, 17 Jan 2026	Wed, 21 Jan 2026	Wed, 4 Feb 2026	Sat, 7 Feb 2026	Wed, 11 Feb 2026		Wed, 25 Feb 2026	Wed, 4 Mar 2026	Wed, 11 Mar 2026	
Topic	ASEAN Agreement on Medical Device Directive			Regulatory Framework in						
Coverage	ASEAN agreement on Medical Device Directive	ASEAN country	ASEAN country	Key Asia Pacific markets	Japan	1 Week Break	Korea	Assignment Presentation	Final Quiz EA 06-05	1 Week Break
Activities	Seminar E4 04-03	Tutorial	Tutorial	Seminar E4 04-03	Tutorial		Tutorial	Tutorial		

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

Dates	Wed, 25 Mar 2026		Wed, 8 Apr 2026		Wed, 29 April 2026	Wed, 6 May 2026
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: 9.00am to 6.00pm