

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

Date	Wed, 12 Aug 2026	Sat, 15 Aug 2026	Wed, 19 Aug 2026	Sat, 22 Aug 2026	Wed, 26 Aug 2026	Wed, 9 Sep 2026	Wed, 16 Sep 2026	1 Week Break	Wed, 30 Sep 2026	1 Week Break		
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		Final Quiz E1-06-03			
Activities	Tutorial	Seminar E4 04-02	Tutorial	Seminar E4 04-02	Tutorial	Tutorial	Tutorial					

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

Dates	Sat, 10 Oct 2026	Wed, 14 Oct 2026	Wed, 21 Oct 2026	Wed, 28 Oct 2026	Sat, 31 Oct 2026	Wed, 4 Nov 2026	Wed, 11 Nov 2026	1 Week Break	TBC	4 Week Break		
Topic	Medical Device Regulation in the United States				Medical Device Regulation in the EU							
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		Final Exam TBC			
Activities	Seminar E4 04-02	Tutorial	Tutorial	Tutorial	Seminar E4 04-02	Tutorial	Tutorial					

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

Dates	Sat, 16 Jan 2027	Wed, 20 Jan 2027	Wed, 27 Jan 2027	Sat, 30 Jan 2027	1 Week Break	Wed, 10 Feb 2027	Wed, 17 Feb 2027	Wed, 24 Feb 2027	Wed, 3 Mar 2027	3 Week Break
Topic	ASEAN Agreement on Medical Device Directive			Regulatory Framework		in Asia Pacific				
Coverage	ASEAN agreement on Medical Device Directive	ASEAN country	ASEAN country	Key Asia Pacific markets		Japan	Korea	Assignment Presentation	Final Quiz LT1	
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, 24 Mar 2027		Wed, 7 Apr 2027		Wed, 28 April 2027	Wed, 5 May 2027
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