

**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, 7 Sep 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
Activities	Tutorial	Seminar	Tutorial	Tutorial	Seminar	Tutorial	Tutorial	Final Exam

**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 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	1 Week Break
Activities	Seminar	Tutorial	Tutorial	Tutorial	Seminar	Tutorial	Tutorial	Final Exam

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

Dates	Sat, 19 Jan 2025	Wed, 22 Jan 2025	Wed, 29 Jan 2025	Sat, 6 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				1 Week Break
Coverage	ASEAN agreement on Medical Device Directive	ASEAN agreement on Medical Device C14e Directive	Other ASEAN countries	China, India, Taiwan, Australia, South Korea, Japan	China / South Korea	Taiwan/ Japan/ India	Assignment Presentation	Final Exam
Activities	Seminar	Tutorial	Tutorial	Seminar	Tutorial	Tutorial	Tutorial	1 Week Break

**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
Activities	Tutorial	Tutorial	Tutorial	Final Presentation
				Report Final Submission

**Notes:**

\* Dates and timings are subject to change with prior notice

Tutorials: 6.30pm to 9.30pm, Seminars: 8.00am to 6.00pm