

Module 1 (BN5511A) : Introduction to Global Medical Device Regulation

| Date | Sat, 16 Aug 2025 | Wed, 20 Aug 2025 | Wed, 27 Aug 2025 | Sat, 6 Sep 2025 | Wed, 10 Sep 2025 | Wed, 17 Sep 2025 | Wed, 24 Sep 2025 | Wed, 1 Oct 2025 |
|------------|---|---|---|-------------------------------------|-----------------------|--|----------------------|----------------------------|
| Topic | Introduction To Medical Device Regulation | | | Quality and Compliance | | | | |
| Coverage | Why regulate medical devices | Definition and risk classification of medical devices | Definition and risk classification of medical devices | In vitro diagnostic medical devices | Conformity Assessment | Overview of Quality Management System for RA | Review of assignment | Final Exam Venue: LT 50 |
| Activities | Seminar Venue: LT 5 | Tutorial | Tutorial | Seminar Venue: LT 5 | Tutorial | 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