MODULE DESCRIPTIONS

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

This introductory course provides key foundational information related to the global regulation of medical devices. Additionally, the role of the global regulatory professional will be examined in the context of these regulatory frameworks. Covering pertinent subtopics such as harmonization, ethics and legal perspectives, the course will prepare students for more in-depth examinations of submissions and the development of regulatory strategy.

This course will also provide foundational information related to the concepts of regulatory compliance and quality in the context of the global regulatory framework. The module will increase the students' understanding of the critical role quality and regulatory compliance have in supporting good regulatory practice.

Following are the topics that will be covered:

1. Role of the Regulatory Affairs Professional
2. Professional Ethics
3. Medical Devices Lifecycle and Definition
4. Conformity Assessment of Medical Devices
5. Overview of Quality Management System

Module 2 (BN5512): Medical Device Regulation in the United States and European Union

The module delves into medical device regulation in the United States (U.S.), with an emphasis on the product lifecycle and an extended examination of the submissions process in the U.S. Key sub-topics include interactions with the US Food and Drug Administration (FDA), submission types (e.g., PMAs and 510(k)s) and Post-Market requirements

This course also provides a comprehensive review of medical device regulation in the European Union (E.U.), with an emphasis on the product lifecycle and an extended examination of the conformity assessment pathways in the E.U. Key sub-topics include an overview of Medical Device Regulation (MDR) and In-vitro Diagnostics Medical Device Regulation (IVDR), roles & responsibilities of various stakeholders, and the conformity assessment pathways.

Following are the topics that will be covered:

1. Overview of US Medical Device Regulation
2. Overview of Quality System Regulations (QSR) and Quality Management System Regulation (QMSR)
3. Regulatory Submission Pathways
4. Post-Market Surveillance and Vigilance
5. Overview of Medical Device Regulation (MDR) and In-vitro Diagnostic Medical Device Regulation (IVDR)
6. Conformity Assessment Pathways

Module 3 (BN5513): Medical Device Regulation in ASEAN Countries, China, and the Asia Pacific

This course provides a comprehensive review of medical device regulation in the ASEAN countries, China and the Asia-Pacific. The emergence of harmonization in the ASEAN community will be discussed and students will see how harmonization efforts translate into regulatory requirements. Overview of the ASEAN Medical Device Directive (AMDD) and current regulations in the respective ASEAN markets will be a key focus for this part of the course.

Students will also explore important background information regarding China's regulatory framework for medical devices. The course will provide a thorough review of the product risk classification, registration procedure, standards, and communication with National Medical Products Administration (NMPA).

The Asia Pacific region is a key focus of regulatory professionals based in Singapore and presents a unique healthcare environment with a diverse collection of medical device regulations for each country. This module provides a broad overview of basic regulatory processes across Japan, Korea, Taiwan, India, and Australia. Similarities and differences among each system will be examined.

Following are the topics that will be covered:

1. Overview of ASEAN Medical Device Directives (AMDD) and Regulations in ASEAN Countries
2. Overview of Medical Device Regulation in China
3. Overview of Medical Device Regulation in Japan
4. Overview of Medical Device Regulation in Korea
5. Overview of Medical Device Regulation in Taiwan
6. Overview of Medical Device Regulation in India
7. Overview of Medical Device Regulation in Australia

Module 4 (BN5514): Medical Device Regulatory Process Planning

In this module, the students take a prototype through a regulatory pathway in one of the regions such as EU, Asia Pacific, ASEAN and China based upon their understanding of the medical device regulatory process. Students will have both team and individual activities and deliverables for this module culminating in a simulated submission to be carried out by student teams.

The project module brings together the knowledge acquired from the earlier 3 modules i.e. Module 1, Module 2 and Module 3. This enables the students to apply the concepts learned and take a medical device prototype through a region-specific regulatory pathway. The possible regions include the USA, the EU, Asia Pacific, ASEAN countries and China.