

MODULE DESCRIPTIONS

Module 1 (BN5515): Clinical Design and Evaluation of Medical Device

This course provides a comprehensive review of clinical design and evaluation for medical devices. It focuses on the roles of clinical evaluations in product development including the roles of various pivotal trials and the postmarket study. The students will also learn to design a clinical study taking into consideration the various aspect of the study like the ethics, treatment regimen, study population, the product effectiveness and safety endpoints etc. In additional, the course will guide the students through a rigorous and systematic review of and integration of clinical data follow by the drafting of a clinical evaluation report. The course will also include the understanding of the clinical investigations application process and reimbursement.

Module 2 (BN5516): Medical Device Design, Development and Testing

This course provides a comprehensive coverage of the initial phases of the product lifecycle, mainly the design, development and testing of the medical device. Not part of the ISO13485 or 21 CFR 820, but they constitute a crucial parts of the product lifecycle. Here the students will explore the ideation process considering a myriad of factors including the product market size, the competing products, the regulatory pathway, intellectual property issues, reimbursement model etc. The course will also cover the understanding of various testing standards (US ASTM, China YY, EU ISO etc) for verification and validation of different medical devices.

Module 3 (BN5517): Pre-Market Requirements and Post Market Surveillance

Premarket approval is conducted by appropriate regulatory authorities and Conformity Assessment Bodies to evaluate the safety and effectiveness of medical devices prior to marketing. The process may vary from jurisdiction to jurisdiction. The students will learn about the essential principles of safety & performance of medical devices including various design and manufacturing parameters and requirements. Obligations of a medical device manufacturer to conform to regulatory requirements continue throughout the medical device's lifecycle including during the post-market phase. All such manufacturers are required to implement an effective postmarket surveillance/vigilance system. This module will outline the various strategies and components of such post-market surveillance systems including vigilance reporting, handling of customer complaints and product recalls.

Module 4 (BN5518): Next-Generation Devices Regulations

This module involves supervised self-study in the field of medical device regulatory science. The work will typically entail the assignment of medical devices developed using novel advanced technologies so that the student will spend the semester to explore the challenges of regulation of such devices and to develop innovative framework requirement for regulatory approval. During the course, the student will be presented with different confronted with scenarios including product design failure, clinical trials mishaps, IP issues, manufacturing non-compliance. These scenarios present to the student real-life case studies that challenges the student ability to solve/remedy the problems.