BN5208 BIOMEDICAL QUALITY AND REGULATORY SYSTEMS

This module will delve deeper into regulatory strategies and approached that is a pivotal step in bringing medical devices (MD) to market and to patients. Particular emphasis would be on approval of medical devices by FDA, USA and HSA, Singapore. We will also discuss in significant details the various steps in the approval process of not only traditional medical devices like hip- and knee implants, cardiovascular stents, contact lenses etc but also of 'nontraditional' devices like invitro diagnostics (IVD), AI-MD's etc. This module will also encompass critical 'ethical issues' faced by regulators and manufacturers. The lecturer worked for Johnson and Johnson, Medical Affairs/Information in a Regional role and will bring his experience in the industry to provide further insights into how 'things' actually happen in the industry to make it a very interesting and lively learning environment. For more details you may contact Dr Mrinal Musib (biemkm@nus.edu.sg)

WHY YOU SHOULD CONSIDER THIS MODULE

This module will provide you with a better understanding of the various considerations and steps to develop a successful medical device and the importance of regulation and approval process for such devices. This module will outline the quality requirements and compliance as well as the post-market requirements for manufacturers to hasten the approval process and ensure the long-term success of implants/medical devices and decrease the chances of significant adverse events and hence recalls for such medical devices.