www.bioeng.nus.edu.sg/edu/mdra.html

Regulatory excellence delivered.

Graduate Certificate in Medical Devices Regulatory Affairs

Presented by:
Department of Biomedical Engineering, Faculty of Engineering, National University of Singapore
In partnership with the Regulatory Affairs Professionals Society

NUS National University of Singapore
Department of Biomedical Engineering
Faculty of Engineering

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

2014–2015

Build the **foundational knowledge** and **competencies** to succeed as a regulatory professional and **gain the critical thinking and application skills** to translate what you learn into the real world.

Regulatory Excellence Demanded

The regulatory function is vital to making safe and effective medical devices available worldwide. As Asia's leader for medical technology, Singapore is building an industry-ready regulatory workforce to meet the needs of companies that require professionals with knowledgeable about global industry attuned to the region's healthcare needs.

That's why the National University of Singapore Faculty of Engineering's Biomedical Engineering Department (BME) and the Regulatory Affairs Professionals Society (RAPS) have partnered to offer this exclusive Graduate Certificate in Medical Devices Regulatory Affairs.

Academic Excellence + **Real-World Expertise**

The regulatory profession is dynamic by nature, requiring unique knowledge and skills throughout the product lifecycle. To succeed, you must have a strong foundational understanding of concepts and complex frameworks, as well as the ability to think critically and apply that knowledge as the job demands.

The Graduate Certificate in Medical Devices Regulatory Affairs draws on the teaching and research excellence of NUS/BME faculty and combines the expertise of RAPS' renowned regulatory leaders from around the world to provide you with the knowledge, skills and tools to succeed. The curriculum is based on the validated competencies of working regulatory professionals and is delivered through a combination of online training, interactive seminars, peer interaction and case study-based learning—all in a flexible format that fits your busy schedule.

You Will Learn

- The history and evolution of the regulatory profession and the role of the regulatory professional throughout the product lifecycle
- Foundational knowledge and the core competencies of regulatory professionals working in industry, regulatory agencies, research and other environments
- Fundamentals of global medical device regulation, including identification of regulatory agencies and processes in major regulatory systems
- Device regulation in the US, EU, China, ASEAN and Asia-Pacific Countries
- Quality and compliance
- Critical thinking and practical application of regulatory knowledge
- Global regulatory pathways and submission processes

Who Should Enroll

- Industry professionals representing product developers, manufacturers, distributors, service providers, entrepreneurs, investors and regulators dealing with medical device products
  - Whose work responsibilities include the preparation and management of medical device pre- and postmarketing submissions to regulatory authorities in Singapore and elsewhere in ASEAN, either on behalf of domestic producers or importers
  - Who prepare regulatory submissions to authorities or Conformity Assessment Bodies in other jurisdictions outside Singapore (or ASEAN)
- Engineering or life sciences graduates in the early stages of their regulatory careers
- Professionals working for regulatory agencies

Participants are not required to reside in Singapore .

Program Structure and Learning Approach

Begins September 2014 and is comprised of four modules offered over one calendar year:

- Module 1: Introduction to Global Medical Device Regulation and Regulation in the US
- Module 2: Quality and Compliance & Medical Device Regulation in the EU
- Module 3: Medical Devices Regulation in China, ASEAN and Asia-Pacific Countries
- Module 4: Medical Device Regulatory Process Planning

Modules 1-3 are a blended format, featuring lecture-based and online learning:

- Online courses and activities through RAPS Online University
- Tutorials facilitated by NUS instructors, with peer interaction
- On-campus intensive seminars focused on the application of foundational knowledge

Module 4 is project-based. Groups prepare a presentation detailing the regulatory strategy for an identified product across a number of market pathways.

Faculty

Mrinal K. Musib, PhD, NUS Program Coordinator

Mrinal Musib earned his bachelor's degree in pharmaceutical technology from Jadavpur University, India. He then worked for Ranbaxy Pharmaceuticals as a medico-marketing executive. Musib holds a PhD in biomedical engineering from the University of Texas Health Science Center at San Antonio and the University of Texas at San Antonio. He has worked as a senior research scientist at the State University of New York, Downstate Medical Center, Brooklyn. Prior to joining the NUS Department of Biomedical Engineering, he was a consultant for Johnson & Johnson at its Asia-Pacific regional office in Singapore, where he helped develop a standard operating procedure for handling medical information in Asia-Pacific and ASEAN countries. Musib's teaching interests include biomaterials, tissue engineering, engineering ethics and cellular bioengineering. His research interests include orthopaedic implants, cell-nanobiomaterial interactions and drug release from polymeric biomaterials.

Casey Chan, MD

Casey Chan has more than 25 years of experience as an orthopaedic surgeon, inventor, researcher and entrepreneur. He has brought a number of innovations from concept to the standard of surgical care, including a vacuum-mixing system for total joint replacements and a suture passer for arthroscopic surgery. He is an adjunct professor at NUS, with appointments in the Department of Orthopaedic Surgery and the Department of Biomedical Engineering, a Fellow of the American Academy of Orthopedic Surgeons and a Fellow of the Canadian Academy of Sport and Exercise Medicine. His experience as director of the Technology Transfer Office and as senior director of NUS Enterprise provides Chan with unique executive and management skills. He is on the governing board of the Mechanobiology Research Center of Excellence, Singapore. He holds a master's degree of Applied Science in Aerospace Engineering and a doctor of medicine degree, both from the University of Toronto.

Leo Hwa Liang, PhD

Leo Hwa Liang is an assistant professor for the Department of Biomedical Engineering at NUS. He has more than 15 years of research expertise in biofluid mechanics, developing various novel medical devices such as mitral percutaneous heart valves, carotid stents, artificial liver assist devices and left ventricular assist devices. Liang has published more than 50 international peer reviewed journal articles and appeared at more than 70 international conferences. He received his bachelor's degree in mechanical engineering from the University of Leeds, UK, and master's of engineering in mechanical and production engineering from Nanyang Technological University, Singapore. At Georgia Tech in the US, he pursued a master's in science (mechanical engineering) and a PhD in bioengineering. At NUS, he teaches modules on biomedical engineering designs focusing on the product development process, including medtech regulatory affairs, patent analysis, risk analysis and more.

Dieter Wilhelm Trau, PhD

Dieter Trau is an associate professor at the Department of Biomedical Engineering and the Department of Chemical & Biomolecular Engineering at the National University of Singapore (NUS). He is the co-founder and CSO of AyoxxA Biosystems Group in Singapore and Cologne, Germany. He started his entrepreneurial activities as a founder of two life-science companies started in 1995 and 2000. Trau holds a PhD in Chemistry from the Hong Kong University of Science and Technology and an engineering degree from the University of Applied Sciences in Juelich/Aachen, Germany. He was a visiting assistant professor at HKUST and since 2004 has been an academic staff at NUS. Trau is the author of more than 40 international peer-reviewed research papers and inventor of 15+ patent families, resulting in more than 60 patent applications, of which 20 are granted and commercialized by different companies

Desmond Y.R. Chong, PhD

Desmond Chong is a senior lecturer in the Engineering Design and Innovation Centre (EDIC) and the Department of Biomedical Engineering, NUS. He received his bachelor's of engineering (mechanical) and master's of engineering (by research), both from the Nanyang Technological University, Singapore, and a PhD in orthopaedic biomechanics from the Imperial College London. Prior to joining NUS, he was with Motorola Electronics Singapore, United Test & Assembly Center (UTAC) Singapore and the Institute of Materials Research & Engineering (IMRE), A*STAR, Singapore. His research interests are in biomechanics, computational modelling and experimentation, design of biomedical and orthopaedic devices, gait and human motion analyses and bone mechanics.

Michael Gropp, RAPS Program Coordinator

Michael Gropp has more than 30 years of engineering and regulatory affairs industry experience. He has held positions of increasing global responsibility with Eli Lilly's Medical Devices and Diagnostics Division and Guidant's Devices for Vascular Intervention group. Gropp served as Guidant's chief compliance officer from 1996-2000, when he took the position of vice president, global regulatory and public policy in Brussels. Gropp was vice president, global regulatory strategy with Medtronic from November 2006 until May 2013. He served as special representative for international affairs at AdvaMed and chair of the Eucomed International Affairs Task Force. Gropp was a member of the GHTF Steering Committee from 2000–12 and led work on medical device regulatory harmonization in the APEC Life Sciences Innovation Forum. He also was co-chair of GMTA, a group of national medical technology associations focused on international policy advocacy. In October 2010, Gropp received the RAPS Richard E. Greco Award for his work to harmonize global medical device regulations and advocate for regulatory professional development. He chairs the RAPS Global Advisory Council.

Instructors are faculty from **NUS, a top-ranked university** and **renowned regulatory leaders** with **global expertise**.

Michael Flood, BE FIEAust CPEng

Michael Flood, BE FIEAust CPEng (Biomedical), began his career in medical devices in the late 1970s with qualifications in engineering. Through his career, he has seen all sides of the medical devices industry, commencing with a number of years in technical management and marketing for an Australian manufacturer, nearly 10 years with a State Health Department Biomedical Engineering Unit, and more recently with the Therapeutic Goods Administration. Having left TGA in mid-2010, he has established a consultancy practice in Australia – Locus Consulting, specializing in regulatory affairs, international regulatory training for economies introducing devices regulations, health technology assessment and biomedical engineering.

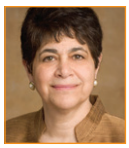
Jack Moore

Jack Moore has more than 30 years of industry experience spanning the globe. He currently is director of regulatory affairs and compliance for BD, where he oversees all aspects of regulatory affairs and compliance with all quality and regulatory requirements throughout the Greater Asia Region. Prior to BD, Moore was quality director and Asia-Pacific regulatory affairs director for Boston Scientific. He also has held positions of increased responsibility with Medline Industries, Baxter Healthcare and General Electric Plastics. Moore worked closely with the Global Harmonization Task Force (GHTF, now IMDRF) in developing GHTF guidelines. He also has worked with and supported the Asia Harmonization Working Party (AHWP) to help foster its growth since 1998.

Annie Yin Qiman, PhD

Yin Qiman (Annie Yin) is regulatory affairs director at Medtronic, where she is responsible for regulatory affairs, clinical research, compliance and operation, intelligence and strategy within China. She has more than 16 years of experience in pharmaceutical, medical device and in vitro diagnostic industries, including regulatory affairs, clinical research, quality, compliance and operations. Before joining Medtronic, Yin worked with Eli Lilly, Roche Pharma R&D Center, Sanofi-Aventis and Beckman Coulter. Before her regulatory affairs career, Yin served as a pharmacist in a hospital. She is an active member of several professional societies, including ISO technical committees and RAPS. Yin earned her bachelor's degree in pharmacology, secondary bachelor degree in information system technology and doctorate in business administration.

Susan Alpert, PhD, MD, FRAPS



Susan Alpert, PhD, MD was most recently the senior vice president, chief regulatory officer of Medtronic and was responsible for all Medtronic global regulatory efforts. Prior to joining Medtronic, Alpert served as vice president of regulatory sciences for C.R. Bard Inc. She also previously worked at FDA where she held a variety of positions in the centers dealing with drugs, devices and radiological health, and foods, including six years as the director of the Office of Device Evaluation. Alpert is a microbiologist and a pediatrician with a specialty in infectious diseases and has practical experience in laboratory research and clinical trials.

Rainer Voelksen, FRAPS

Rainer Voelkson works in the Swiss Federal Office of Public Health, overseeing implementation of the upcoming new European medical device and IVD regulations and the integration of the new requirements into Swiss law. He previously worked for Swissmedic, the Competent Authority for all therapeutic products, as well as the Australian Therapeutic Goods Administration. Voelkson also helped build and strengthen the Asia-Pacific regulatory network for Synthes, while based in Sydney, Australia, and served as executive for regulatory and quality affairs for GE Healthcare in Paris, with responsibilities for harmonizing regulatory strategies and postmarket activities in Europe, the Middle East and Asia-Pacific. By training, Voelkson is a marine biologist, having studied in Oldenburg, Germany and Brest, France.

Rod Ruston, RAC, FRAPS

Rod Ruston has a career which spans manufacturing, design, quality assurance and regulatory affairs. He has been working with the EU medical device regulatory from its introduction in the early 90's. He is committed to any activity which raises the identity, profile, recognition and integrity of the regulatory affairs profession, be it within government, academia, medicine, industry or consulting. He was the first Chair of the EU Examination Committee. He is a past chair of the Regulatory Affairs Certification Board, having served two terms. For the past 17 years he has been Director of Priory Analysts. Ruston lives and works in the UK.

Agenda and faculty are subject to change. Visit www.bioeng.nus.edu.sg/edu/mdra.html for the most up-to-date programme information.

About BME

The Department of Biomedical Engineering (BME) was established in 2002 in the Faculty of Engineering of the National University of Singapore, a top-ranked university. BME's talented academic staff have varied backgrounds in engineering, life sciences and medicine, many of whom have joint appointments with either the Yong Loo Lin School of Medicine, Faculty of Science, Faculty of Engineering, Mechanobiology Institute or A*STAR Research Institutes. This is a reflection of the multidisciplinary and integrative approach they take in biomedical engineering research and education.

About RAPS

RAPS

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products. Founded in 1976, RAPS helped establish the regulatory profession and continues to actively support the professional and lead the profession as a neutral, non-lobbying nonprofit organization. RAPS offers education and training, professional standards, publications, research, knowledge sharing, networking, career development opportunities and other valuable resources, including Regulatory Affairs Certification (RAC), the only post-academic professional credential to recognize regulatory excellence. RAPS is headquartered in suburban Washington, DC, with offices in Europe and Asia, and chapters and affiliates worldwide.

How to Apply

Duration
One calendar year starting September 2014

Please visit www.bioeng.nus.edu.sg/edu/mdra.html for enrollment dates.

Certificate Program Fee
S$16,050.00 (includes GST)

GST applies to individuals and Singapore registered companies

Fees must be paid in full upon acceptance to the program. Admission places will not be confirmed until payment is received. Send fees via check or bank draft made payable to "National University of Singapore." Please indicate "MDRA fee" and your name clearly on the back of the check/bank draft. Checks/bank drafts must be submitted together with the application form. Applicants who are not accepted to the program will have their checks/bank drafts returned. For payment by check, please mail to:

Office of Professional Engineering & Executive Education
Faculty of Engineering, National University of Singapore
3 Engineering Drive 2, Blk E1, #05-15, Singapore 117578

Aplication Fee
S$42.80 (includes GST)

Application Procedure
Please visit www.bioeng.nus.edu.sg/edu/mdra.html for more information.

Academic Requirements
The program is open to those with a relevant bachelor's degree or its equivalent. Candidates with relevant qualifications and related working experience may also apply for the program.

Singapore is building an industry-ready regulatory workforce to meet the needs of companies that require professionals knowledgeable about global industry attuned to Pan-Asia's healthcare needs.

Program Partners

This program was developed with the support of the following Singapore Government Agencies:

A*STAR

The Agency for Science, Technology and Research (A*STAR) is Singapore's lead public sector agency that fosters world-class scientific research and talent to drive economic growth and transform Singapore into a vibrant knowledge-based and innovation driven economy. **www.a-star.edu.sg**.

HSA

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. **www.hsa.gov.sg**.

EDB

The Singapore Economic Development Board (EDB) is the lead government agency for planning and executing strategies to enhance Singapore's position as a global business centre. **www.sedb.com**.

SPRING

SPRING Singapore is an agency under the Ministry of Trade and Industry responsible for helping Singapore enterprises grow and building trust in Singapore products and services. **www.spring.gov.sg**.

WDA

The Singapore Workforce Development Agency (WDA) aims to help workers advance in their careers and lives by developing and strengthening skills-based training for adults. **www.wda.gov.sg**.

Inquiries

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COURSE OVERVIEW

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Module 1: Introduction to Global Medical Device Regulation and Regulation in the US

This introductory course provides key foundational information related to the global regulation of medical devices with emphasis placed on ASEAN, EU and Asia-Pacific countries. 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.

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

Part 1 - Role of the Regulatory Profession and Professional

- Evolution of the profession in the health product sector
- The body of knowledge underlying the regulatory profession
- The scope of practice of professionals working for regulators, industry and in other settings
- Professional competencies and career advancement pathways
- The role of the profession in shaping healthcare decisions and policy

Part 2 - Professional Ethics

- Fundamental ethical concepts
- Code of Ethics for regulatory professionals
- Ethical principles applied to clinical research
- Ethical principles related to compliance
- Handling ethical challenges faced by regulatory professionals

Part 3 - Medical Devices: Definition and Lifecycle

- Definition of medical devices: global perspectives
- Product classification
- Safety and performance standards
- Lifecycle stages and general regulatory perspectives
  - Product development
  - Requirements for clinical testing
  - Manufacturing
  - Product review and release
  - Postmarket stages and requirements
  - Risk management concepts
- Role of international organizations in the medical device sector

Part 4 - Overview of US Medical Device Regulation

- FDA centers with oversight of medical devices
- Introduction to device premarket review

Part 5 - Device Development, Quality Systems and Agency Interactions

- Origin of new medical devices

- Agency interactions and meetings for regulatory submissions
- Preclinical and clinical considerations
- Regulatory filing and clearance/approval
- Reimbursement
- Postmarket surveillance
- Quality System Regulation

Part 6 - Marketing Submissions

- Essential steps for getting a device to market
- 510(k)s – Types, content and format, review process, FDA action
- PMAs – Content and format, clinical considerations, product development protocol
- Review process, postapproval requirements, amendments and supplements

Part 7 - Advertising, Labeling and Promotion

- Product labeling requirements
- Promotional labeling
- FDA regulations and exceptions
- Regulation of Continuing Medical Education promotion
- General advice
- Off-label device usage by physicians

Part 8 - Postmarket Considerations and Requirements

- Medical Device Reporting (MDR) and initiatives
- Manufacturing and User Facility Device Experience (MAUDE) data
- Regulated postmarket studies
- Device modifications
- Corrections and removals

Module 2: Quality and Compliance & Medical Device Regulation in the EU

This course provides a comprehensive review of medical device regulation in the EU, with an emphasis on the product lifecycle and an extended examination of the submissions process in the EU. Key sub-topics include the *Medical Devices Directive* (*MDD*), conformity assessment pathways and the impact of harmonization efforts on the region.

This course will include a review of a sample submission. It also provides foundational information related to the concepts of compliance and quality in the context of the global regulatory framework. Emphasis is placed on Quality system regulations (QSRs), Good Manufacturing Practices (GMPs), Good Distribution Practices (GDPs), process validation, supply chain management including supplier qualification, and risk management. The module will increase the students' understanding of the critical role quality and compliance have in supporting good regulatory practices.

Part 1 - Considerations Related to Standards, Quality Assurance and Risk Management

- European standards organizations
- Harmonized standards
- ISO 14155:2011 GCPs
- ISO 13485:2003 Quality Management Systems
- ISO 14971:2007 Risk management

Part 2 - Postmarket Considerations and Requirements

- Medical Device Vigilance System
- European Databank on Medical Devices (EUDAMED)
- Risk management perspectives
- Economic perspectives

Part 3 – Quality: A Primer for the Regulatory Professional

- Principles of a Total Quality System (TQS) and a Quality Management System (QMS)
- Standard setting organizations
- CGMPs, QSRs and GDPs
- Process validation
- Quality by design (QbD)
- Design controls, production controls
- Guidance documents and standards
- Harmonized regulatory relationships for process validation

Part 4 - Compliance

- Definition of compliance and postmarket surveillance
- Postmarket elements and considerations
- Standards for compliance (global approaches)
- Auditing
- Warnings and recalls
- Monitoring
- Managing supply chains

Part 5 – Incorporation of Quality and Compliance Into Regulatory Strategy

- Risk, risk management and planning
- National and global trends in quality and compliance regulations

Part 6 - Overview of EU Medical Device Regulatory Structure

- Regulatory frameworks and bodies in the EU
- Definition of medical devices

Part 7 - *Medical Devices Directives* (*MDD*)

- Essential requirements
- Device classification
- CE Mark
- Conformity Assessment
- Creating a technical file/dossier
- Authorized representatives
- Auditing by a notified body
- Declaration of Conformity
- Clinical Evaluation requirements
- Requirements for labelling and language

Part 8 - *In Vitro Diagnostic Devices Directive* (*IVDD*) and *Active Implantable Medical Devices Directive* (*AIMDD*)

- Overview of *IVDD*
  - Essential Requirements for IVDs
  - Conformity Assessment Procedures and options
- Overview of *AIMDD*
  - Conformity Assessment Procedures and options

Module 3: Medical Device Regulation in ASEAN Countries, China and Asia-Pacific

This course provides a comprehensive review of medical device regulation in the ASEAN countries, China and Asia-Pacific. The emergence of harmonization in the ASEAN community will be discussed and students will see how harmonization efforts translate into regulatory requirements. Regulatory and submission strategy for the ASEAN market will be a key focus of this course, with a blend of practical and applied concepts to include the review of a sample submission.

Students also will explore important background information regarding China's society, culture and laws and assess how select concepts apply to healthcare system. A thorough review of the registration procedure follows, including discussions on product classification, standards and requirements, and communication with the China Food and Drug Administration (CFDA) and provincial CFDA offices. Other critical areas of discussion include postmarket requirements and regulations pertaining to combination products and IVDs.

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 will emphasize Japan, Korea, Taiwan and Australia—and provide a broad overview of basic regulatory processes across the product lifecycle. Similarities and differences among each system will be examined and their impact on regulatory strategy will be discussed, along with the role of harmonization bodies in shaping the current regulatory environment.

Part 1 - Overview of Medical Devices in ASEAN Countries

- Medical device market in ASEAN countries
- Legal and regulatory frameworks among ASEAN countries
- Harmonization efforts and stakeholders

Part 2 - *ASEAN Medical Device Directive* (*AMDD*)

- Definitions and classifications
- Clinical trials requirements
- Common Submission Dossier
- Postmarket requirements and plan development
- Status and future directions

Part 3 - Considerations for Developing a Regulatory Strategy for the ASEAN Countries

- Regulatory and economic considerations
- Communicating and interfacing with regulators
- Relevance to global regulatory strategy

Part 4 – Overview of Medical Device Regulation in China

- Promulgation of medical device regulation
- National and regional laws
- Mandatory Standards
- CFDA departments, technical organizations and key responsibilities of each
- Device classification and framework
- Ministries of health role in device regulation
- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the China Compulsory Certification (CCC Mark)

Part 5 – Medical Device Lifecycle in China

- Premarket considerations
- Clinical trials requirements
- Product registration requirements
- Testing laboratories and requirements
- Medical device manufacturing (foreign and domestic)
- Labeling requirements
- Postmarket requirements and plan development

Part 6 – Developing a Regulatory Strategy for Medical Devices in China

- Regulatory and economic considerations
- Communicating and interfacing with regulators
- Relevance to global regulatory strategy

Part 7 - South Korea

- Medical device market in Korea
- Overview of legislative and government structures, regulatory frameworks
- Medical device definition and classification
- Premarket notification/approval requirements
- Requirements to import products
- Quality management systems
- Product labeling requirements
- Postmarket surveillance (re-examination and re-evaluation)
- Adverse event reporting
- Change reporting requirements

Part 8 - Japan

- Medical device market in Japan
- Government and industry framework in Japan
- Overview of medical device regulations
- Registration pathway in Japan
- Foreign Manufacturers Accreditation requirements
- Presubmission meetings with PMDA
- Submission dossiers

Part 9 - Taiwan

- Medical device market in Taiwan
- Overview of regulatory environment in Taiwan
- Definition and classification of medical devices
- Role of distributors or local subsidiaries
- Product registration requirements and process
- Product labeling
- Quality system requirements
- Postmarket surveillance requirements

Part 10 - Australia

- Medical device market in Australia
- Regulating authority, legislation and guidances
- Definition and classification of medical devices
- Listing devices on the Australian Register of Therapeutic Goods (ARTG)
- Documentation requirements
- Conformity assessment
- Postmarket reporting requirements
- Renewal applications

Module 4: 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 on their understanding of the medical device regulatory process. Students will have both team and individual activities and deliverables for this module.

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