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

Regulatory excellence delivered.

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

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.

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 2015 and is comprised of four modules offered over one calendar year:

• Module 1: Introduction to Global Medical Device Regulation and Quality and Compliance
• Module 2: Medical Device Regulation in the US and 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

Dr. Mrinal Musib is a lecturer in the department of Biomedical Engineering at the National University of Singapore. He has over 12 years of academic research/industrial experience in the broad domains of biomaterials and medical devices. His previous research has been funded by major pharma companies and medical device manufacturers. Dr. Musib received his bachelor’s degree in pharmaceutical technology/pharmacy and thereafter he worked for a pharma major where he was engaged in conducting/supervising clinical trials (phase IV). He earned a joint PhD degree in biomedical engineering from the University of Texas Health Science Center at San Antonio and the University of Texas at San Antonio. Thereafter he worked as a senior research scientist at the State University of New York, Downstate Medical Center, Brooklyn, USA. He has published extensively and has presented his research at various relevant conferences including Orthopedic Research Society (ORS) conference, Society for Biomaterials (SFB) conference and Biomedical Engineering Society (BMES) conferences. Prior to joining NUS, he was a consultant, Medical Information for Johnson & Johnson at its Asia-Pacific regional office in Singapore, where he helped develop a standard operating procedure (SOP) for effectively handling medical information in Asia-Pacific and ASEAN countries. Dr. Musib’s teaching interests include biomaterials, tissue engineering and ethics and his research interests include orthopaedic implants and materials, cell-nanobiomaterial interactions and drug release from biomaterials/scaffolds.

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.

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.

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 OPE³

The Office of Professional Engineering & Executive Education (OPE³) has a long history in the Faculty of Engineering having as its origins the Professional Activities Centre established in 1996. It leverages upon existing expertise within NUS, as well as external partners to develop customized programs for technical depth and engineering management & leadership development. OPE³ has also been the catalyst for the many successful conferences and seminars organized for the Faculty of Engineering. These conferences and seminars have played a significant role in the faculty’s effort to disseminate the latest engineering and technology development/information to practicing engineers. These events have also generated much interaction and networking opportunities among the faculty members, research personnel and the industry practitioners. Now as a unit of the Institute for Engineering Leadership, OPE³ continues to work towards the IEL mission of developing the potential of engineer-leaders through various education, training and networking opportunities.

About 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 2015

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

Funding
A funding amount of S$10,500 from the Singapore Workforce Development Agency will be provided to qualified participants upon successful completion of the program. To qualify, participants have to be Singapore Citizens or Singapore Permanent Residents and have achieved at least 75% attendance.

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

Application 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.
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.