Subject Description Form

Subject Code	BME21153
Subject Title	**Medical Device Regulation**
Credit Value	3
Level	2
Co-Requisite	ENG3XXX Engineering Professionals in Society II *(pending approval)*
Objectives	This subject provides students with the regulatory knowledge on the medical technologies which demand risk-based regulation to ensure safe and proper use applied to mankind. The course will investigate basic regulatory controls as well as extended regulatory controls and the context of risk-based modelling approach. This subject will provide different regulatory control mechanisms and introduce the models of medical device regulation of developed countries as well as the developments in many Asian countries. Alongside, regulatory controls relevant to the safety, efficacy and quality controls of medical devices will form the knowledge base for the students as foundation in medical device regulation.
Intended Learning Outcomes	Upon completion of the subject, students will be able to: a. Apprehend the global and national health technology policies, assessment, regulation and harmonization; and can interpret the essence of medical technology management and regulation practice; b. Understand terms, definitions and regulatory terminologies of medical device. c. Appreciate the risk-based approach on medical device and technology application in healthcare environment. d. Apprehend regulation controls of medical device of risk-based approach and the characteristics of medical devices with regard to safety, efficacy and quality. e. Develop in-depth knowledge on regulatory controls such as use of standards, quality management, risk management, good clinical practice and international electrical safety standard for medical devices; f. Apprehend the major regulatory control systems for medical devices of developed countries such as USA, EU and China; and enhance knowledge on control frameworks in Hong Kong and ASEAN. g. Develop self-learning initiatives and integrate learned knowledge for problem solving.

Contribution to Programme Outcomes (Refer to Part I Section 10)	▪ Programme Outcome 3: Demonstrate an ability to design a system, component, or process relevant to Biomedical Engineering (BME) to meet desired needs within realistic constraints, such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability. (Teach and Measure) ▪ Programme Outcome 5: Demonstrate an ability to understand the impact of BME solution in a global and societal context, especially the importance of health, safety and environmental considerations to both workers and the general public (Teach, Practice and Measure) ▪ Programme Outcome 10: Demonstrate an understanding of professional and ethical responsibility (Teach, Practice and Measure) ▪ Programme Outcome 12: Demonstrate an ability to recognize the need for and to engage in life-long learning understanding of professional and ethical responsibility (Teach, Practice and Measure) ▪ Programme Outcome 14: Demonstrate an understanding of entrepreneur-ship and leadership. (Teach and Measure)
Subject Synopsis / Indicative Syllabus	The general scope of the syllabus will include: ▪ Need for Regulation Controls: Regulation overview & guiding principles ▪ Basic terminologies in Medical Device Regulation: MD Definition, MD Risk Classification, Nomenclature System and Use of standards ▪ GHTF Medical Device Risk-based Regulation Model; ▪ Quality Management System ISO 13485 and Risk Management System ISO 14971 ▪ Medical device regulation, general overview, regulation and harmonization; ▪ Regulatory controls such as good clinical practice and international electrical safety standard for medical devices ▪ Medical device regulation: US FDA, EU and China; ▪ Medical device regulations: Hong Kong and ASEAN; ▪ Regulation Case study: AHWP Playbook ▪ Case study for medical device product registration to Medical Device Administrative Control System (MDACS) of the Medical Device Division (MDD) of Department of Health, HKSAR Government.
Teaching and Learning Methodology	There will be lectures, case studies and specialty seminars.

Assessment Methods in Alignment with Intended Learning Outcomes

Specific assessment methods/tasks	% weighting	Intended subject learning outcomes to be assessed (Please tick as appropriate)							
		a	b	c	d	e	f	g	
1. Minor Quiz & Assignments	40%	√	√	√	√			√	
2. Case Study Project	30%			√	√	√	√		
3. Final Quiz	30%	√	√	√	√	√	√	√	
Total	100%								

Explanation of the appropriateness of the assessment methods in assessing the intended learning outcomes:

Different assignments will be used to guide the students toward the learning objectives of the subject contents. Mini-project (case study and oral presentation) is used to facilitate students in applying learned knowledge to solve real-life problems. Students are expected to demonstrate their knowledge through the assignments, mini-project and quizzes.

Student Study Effort Expected		
	Class contact:	
	▪ Lectures	30 Hrs.
	▪ Speciality Seminars	12 Hrs.
	▪ Presentations	3 Hrs.
	Other student study effort:	
	▪ Self-study	72 Hrs.
	Total student study effort	117 Hrs.

Reading List and References	**Regulatory References** ▪ International Medical Device Regulators Forum (IMDRF), guidance documents under Global Harmonization Task Force (GHTF) archive ▪ US FDA Medical Devices, http://www.fda.gov/MedicalDevices/ ▪ EU Medical Device Regulation and In-Vitro Diagnostics Regulation ▪ Asian Harmonization Working Party (AHWP), http://ahwp.info/ ▪ Hong Kong Medical Device Division (MDD) website and guidance document; ▪ NMPA China regulations on medical devices ▪ ASEAN Medical Device Directive (AMDD) **Technical References** ▪ International Electrochemical Commission (IEC) www.iec.ch ▪ EU Med Dev Guidance http://ec.europa.eu/growth/sectors/medical-devices/guidance_en ▪ International Standards Organization ISO website www.iso.org ▪ Association for the Advancement of Medical Instrumentation (AAMI) website www.aami.org ▪ International standard IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ▪ International standard ISO 13485 (Medical devices – Quality Management Systems – Requirements for Regulatory Purposes) ▪ International standard ISO 14971 (Medical devices –Application of Risk Management to Medical Devices)
Date of Last Major Revision	28 December 2021
Date of Last Minor Revision	20 August 2025