

Subject Description Form

Subject Code	BME41141
Subject Title	Medical Technology Management and Regulation
Credit Value	3
Level	4
Prerequisite	BME31142 Biomedical Engineering Research and Design Studies II – Engineer for the Community or BME31147 Biomedical Engineering Innovation for the Community
Objectives	This subject provides students with the knowledge on the development of medical engineering technologies and how technology and engineering skills are applied to healthcare settings. As medical technologies are highly regulated to ensure safe and proper use applied to mankind, this subject will also introduce the regulatory models of medical device regulations of developed countries as well as the developments in Asian countries.
Intended Learning Outcomes	Upon completion of the subject, students will: <ol style="list-style-type: none">a. Apprehend the history and development of engineering technologies applied in healthcare settings;b. Understand the global and national health technology policies, assessment, regulation and harmonization; and can interpret the essence of medical technology management and regulation practice;c. Understand technology management incorporating IT technology applications and their importance in the delivery of modern health care; identify developing areas of IT application in healthcare settings, such as eHealth, wearables, mobile devices and “software as medical devices”;d. Appreciate the application of engineering technology to selected specialties such as radio-diagnostic and radio-therapy, endoscopy centre, biochemistry & laboratory, OT & ICU equipment, ophthalmic equipment, beauty therapy, MGPS, eHealth & IT applications etc.e. Develop in-depth knowledge on regulatory controls such as use of national and international 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.

<p>Contribution to Programme Outcomes (Refer to Part I Section 10)</p>	<ul style="list-style-type: none"> ▪ 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) ▪ 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 13: Demonstrate an understanding of contemporary issues (Teach, practice and measure) ▪ Programme Outcome 14: Demonstrate an understanding of entrepreneurship and leadership. (Teach)
<p>Subject Synopsis/ Indicative Syllabus</p>	<ul style="list-style-type: none"> ▪ Medical Technology Management: a general overview and history of medical technology development and impacts to healthcare services; ▪ Global Initiatives of Health Technology Assessment (HTA), Health Technology Regulation (HTR) and Health Technology Management (HTM): the interlinking relationship ▪ Innovative medical technologies: Technology assessment: role of technology assessment in technology planning, principles and practice of medical technology assessment methodology, role of clinical engineering professional in assessing medical technology; ▪ Review on selected specialty technologies, such as radio-diagnostic and radio-therapy, endoscopy centre, biochemistry & laboratory, OT & ICU equipment, ophthalmic equipment, beauty therapy, MGPS, eHealth & IT applications etc. and other areas such as dialysis, infection control, sterilization, EMC, electrical safety, MD safety, nomenclature naming systems etc. ▪ Medical device regulation, general overview, regulation and harmonization; ▪ Regulatory controls such as use of international standards, quality management, risk management, 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; ▪ Group project on selected medical device technology / regulation; ▪ 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, specialty seminars and group mini-projects.																																																																							
Assessment Methods in Alignment with Intended Learning Outcomes	<table border="1" data-bbox="467 352 1446 814"> <thead> <tr> <th rowspan="2">Specific assessment methods/tasks</th> <th rowspan="2">% weighting</th> <th colspan="8">Intended subject learning outcomes to be assessed (Please tick as appropriate)</th> </tr> <tr> <th>a</th> <th>b</th> <th>c</th> <th>d</th> <th>e</th> <th>f</th> <th>g</th> <th></th> </tr> </thead> <tbody> <tr> <td>Assignments</td> <td>40%</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td></td> </tr> <tr> <td>Mini-project</td> <td>30%</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td></td> <td></td> <td>√</td> <td></td> </tr> <tr> <td>Quizzes</td> <td>30%</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td>√</td> <td></td> </tr> <tr> <td>Total</td> <td>100%</td> <td colspan="9"></td> </tr> </tbody> </table> <p data-bbox="459 898 1419 968"><i>Explanation of the appropriateness of the assessment methods in assessing the intended learning outcomes:</i></p> <p data-bbox="459 993 1435 1205">Different assignments (assignment / tutorial / mid-term quiz / test) 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.</p>										Specific assessment methods/tasks	% weighting	Intended subject learning outcomes to be assessed (Please tick as appropriate)								a	b	c	d	e	f	g		Assignments	40%	√	√	√	√	√	√	√	√		Mini-project	30%	√	√	√	√	√			√		Quizzes	30%	√	√	√	√	√	√	√	√		Total	100%									
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Student Study Effort Required	Class contact:																																																																							
	▪ Lectures					24 Hrs.																																																																		
	▪ Specialty seminars					12 Hrs.																																																																		
	▪ Presentations					3 Hrs.																																																																		
	▪ Other student study effort: Self-study					78 Hrs.																																																																		
	Total student study effort					117 Hrs.																																																																		

Reading List and References

Textbook

- Healthcare Technology Management - A Systematic Approach
By Francis Hegarty, John Amooore, Paul Blackett, Justin McCarthy, Richard Scott, 1st Edition CRC Press First Published 2017
- Healthcare Technology Management Systems, Towards a New Organizational Model for Health Services, 1st Edition - July 17, 2017
Authors: Rossana Rivas, Luis Vilcahuamán, Elsevier Academic Press.
- Medical Device Regulations, A Complete Guide, 1st Edition - January 13, 2022 Author: Aakash Deep, Elsevier Academic Press.
- The Future of Medical Device Regulation, Innovation and Protection, Edited by I. Glenn Cohen, Harvard Law School, Massachusetts, Timo Minssen, University of Copenhagen, W. Nicholson Price II, University of Michigan, Ann Arbor, Christopher Robertson, Boston University, Carmel Shachar, Harvard Law School, Massachusetts
Publisher: Cambridge University Press, March 2022

References

- Clinical Engineering: A Handbook for Clinical and Biomedical Engineers 1st Edition by Azzam Taktak (Editor), Paul Ganney (Editor), David Long (Editor) Academic Press; 1st edition (January 24, 2014)
- Clinical Engineering: From Devices to Systems, Roberto Miniati, Ernesto Iadanza, FABRIZIO DORI, Academic Press, 23 Dec 2015
- Clinical Engineering Handbook 2nd Edition - December 4, 2019, Elsevier Academic Press, Editor: Ernesto Iadanza

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; <https://www.mdd.gov.hk/>
- National Medical Products Administration (NMPA), China regulations on medical devices, <http://english.nmpa.gov.cn/>
- ASEAN Medical Device Directive (AMDD)

Technical References

- International Electrochemical Commission (IEC) website www.iec.ch
- EU Med Dev Guidance http://ec.europa.eu/growth/sectors/medical-devices/guidance_en

	<ul style="list-style-type: none"> ▪ 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	15 May 2018
Date of Last Minor Revision	11 July 2022