Subject Description Form

Subject Code	BME41141
Subject Title	**Medical Technology Management and Regulation**
Credit Value	3
Level	4
Prerequisite	BME31139 Biomedical Engineering Research & Design Studies II
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: 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 inhealthcare settings, such as eHealth, wearables, mobile devices and "software as medical devices"; d. Appreciate the application of engineering technology to selectedspecialties 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 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) ▪ 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 and practice) ▪ Programme Outcome 10: Demonstrate an understanding of professional and ethical responsibility (Teach and Practice) ▪ 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 and Practice) ▪ Programme Outcome 13: Demonstrate an understanding of contemporary issues (Teach and Practice) ▪ Programme Outcome 14: Demonstrate an understanding of entrepreneur-ship and leadership. (Teach)
Subject Synopsis/ Indicative Syllabus	▪ 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 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; ▪ Case study for medical device product registration to Medical Device Administrative Control System (MDACS) of the Medical Device Control

<table>
<tr><td></td><td>Office (MDCO) of Department of Health, HKSAR Government.</td></tr>
<tr><td>Teaching and Learning Methodology</td><td>There will be lectures, case studies, specialty seminars and group mini-projects.</td></tr>
<tr><td>Assessment Methods in Alignment with Intended Learning Outcomes</td><td>
<table>
<tr><td rowspan="2">Specific assessment methods/tasks</td><td rowspan="2">% weighting</td><td colspan="8">Intended subject learning outcomes to be assessed (Please tick as appropriate)</td></tr>
<tr><td>a</td><td>b</td><td>c</td><td>d</td><td>e</td><td>f</td><td>g</td><td></td></tr>
<tr><td>Assignments</td><td>40%</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></tr>
<tr><td>Quizzes</td><td>30%</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="8"></td></tr>
</table>
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.
</td></tr>
<tr><td rowspan="6">Student Study Effort Required</td><td>Class contact:</td><td></td></tr>
<tr><td>▪ Lectures</td><td>24 Hrs.</td></tr>
<tr><td>▪ Specialty seminars</td><td>12 Hrs.</td></tr>
<tr><td>▪ Presentations</td><td>3 Hrs.</td></tr>
<tr><td>▪ Other student study effort: Self-study</td><td>87 Hrs.</td></tr>
<tr><td>Total student study effort</td><td>126 Hrs.</td></tr>
</table>

Reading List and References	**Textbook** ▪ Chan A., Medical Technology Management Practice, Charles C Thomas, 2003. **References** ▪ David Y. (Ed.), Clinical Engineering, CRC Press, 2003. ▪ Dyro J. (Ed.), Clinical Engineering Handbook, Elsevier Academic Press, 2004. ▪ Geddes L.A., Medical Device Accidents and Illustrative Cases, Lawyers & Judges Pub. Co., 2002. **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 Control Office (MDCO) website and guidance document; ▪ CFDA regulations on medical devices ▪ 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 ▪ 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