Subject Description Form

Subject Code	BME41126
Subject Title	**Medical Device Regulatory and Risk Management**
Credit Value	3
Level	4
Prerequisite	Nil
Objectives	Medical device regulations are being introduced in many Asian markets. This course aims to give both factual and practical experiences on regulatory requirements and how to handle future regulatory tasks, including classification, risk management, product registration, and quality control.
Intended Learning Outcomes	Upon completion of the subject, students will be able to: a. Demonstrate deep understanding of international standards and regulatory requirements of medical devices, how these are set, and how they can be met; b. Handle regulatory tasks, including classification, risk management, product registration and quality control.
Contribution to Programme Outcomes (Refer to Part I Section 10)	▪ Programme Outcome 5: Demonstrate an ability to understand the impact of BME solutions 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. (Teach and Practice) ▪ Programme Outcome 13: Demonstrate an understanding of contemporary issues. (Teach and Practice)
Subject Synopsis/ Indicative Syllabus	▪ Global and regional regulatory organizations, regulatory comparison and key medical device regulatory definitions ▪ Medical device classification ▪ US and EU regulatory systems ▪ Hong Kong regulatory systems ▪ ISO 13485 (Medical devices – quality management systems – requirements for regulatory purposes) ▪ ISO 14971 (Medical devices – application of risk management to medical

<table>
<tr><td></td><td>devices)</td></tr>
<tr><td>Teaching and Learning Methodology</td><td>Students will be required to understand the global, regional, and local medical device regulatory requirement and trends. Students will be arranged into small groups for paper work such as preparing material submission for applications of medical device registration in Hong Kong. Guest lecturers with regulatory experience and networks will be invited to share their experience. Students finishing this course are eligible for attending related medical device regulatory examination from external bodies, e.g., BSI (British Standard Institute).</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></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Assignments</td><td>20%</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Group paper and presentation</td><td>40%</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Quizzes</td><td>40%</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:
Assignments, group paper, and presentation will be used to assess the intended learning outcomes.</td></tr>
<tr><td>Student Study Effort Expected</td><td>
<table>
<tr><td>Class contact:</td><td></td></tr>
<tr><td>▪ Lecture/seminar</td><td>39 Hrs.</td></tr>
<tr><td>Other student study effort:</td><td></td></tr>
<tr><td>▪ Self-study</td><td>55 Hrs.</td></tr>
<tr><td>▪ Preparation for assignments and project</td><td>32 Hrs.</td></tr>
<tr><td>Total student study effort</td><td>126 Hrs.</td></tr>
</table>
</td></tr>
<tr><td>Reading List and References</td><td>▪ ISO 13485 (Medical devices – quality management systems – requirements for regulatory purposes)
▪ ISO 14971 (Medical devices – application of risk management to medical devices)
▪ MDCO guidance documents</td></tr>
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	▪ AHWP guidance documents ▪ GHTF guidance documents ▪ FDA guide to inspections of quality system documents **<u>Websites</u>** ▪ MDCO, http://www.mdco.gov.hk/eindex.html ▪ FDA – Medical Devices, http://www.fda.gov/MedicalDevices/ ▪ AHWP, http://www.ahwp.info/ ▪ GHTF, http://www.ghtf.org/ ▪ BSI, http://www.bsiamerica.com/HongKongRegForum ▪ International Organization for Standardization, http://www.iso.ch/iso/
Date of Last Major Revision	14 July 2014
Date of Last Minor Revision	12 Jul 2016