Subject Description Form

Subject Code	BME5151
Subject Title	Intellectual Property, Standards and Regulations of Medical Devices
Credit Value	3
Level	5
Responsible staff & Department/School	Dr Thomas LEE (BME)
Pre-requisite / Co-requisite/ Exclusion	Nil
Objectives	Quality assurance and regulatory requirements are essential aspects of every medical device development process. This subject addresses the important issues related to developing and using a safe and reliable medical device, as well as meeting regulatory requirements. This subject also discusses patent, copyright, and trademark for the intellectual property protection of medical devices.
Intended Learning Outcomes	Upon completion of the subject, students will be able to: a. Demonstrate understanding on how to the meet standards and regulatory requirements; b. Demonstrate understanding of the practical knowledge about intellectual property protection.
Contribution to Programme Outcomes (Refer to Part I Section 2)	Programme Learning Outcome (a): Acquire and apply advanced levels of knowledge and skills in BME discipline. (Teach, Practice, and Measure) Programme Learning Outcome (b): Apply critical analysis and problem-solving skills for evidence-based practice in BME discipline. (Teach, Practice, and Measure) Programme Learning Outcome (c): Demonstrate a higher level of professional competence to cope with the rapid changes in practice in BME discipline. (Teach and Practice) Programme Learning Outcome (d): Develop research skills that will help incorporate evidence-based practice in the delivery of healthcare services and industry. (Teach and Practice) Programme Learning Outcome (e): Demonstrate abilities to continuously develop in professional practice. (Teach and Practice)
Subject Synopsis/ Indicative Syllabus	▪ Medical Device Classification ▪ Patent Law, Patentability, and General Application Procedures ▪ Copyright, Design, Trademarks, and Related Legal Issues ▪ Intellectual Property Strategy and Management ▪ Quality Management System: ISO 13485 ▪ Risk Management System: ISO 14971 ▪ Medical Software: IEC 62304 ▪ Good Clinical Practice: ISO 14155 ▪ Medical Device Regulation in US: Premarket ▪ Medical Device Regulation in US: Postmarket ▪ Medical Device Regulation in EU ▪ Medical Device Regulation in HK ▪ Medical Device Regulation in China

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- Harmonization of Medical Device Regulation

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<tr><td>Teaching/Learning Methodology</td><td>
Lectures and; individual written assignments.
<table>
<tr><td rowspan="2">Teaching/learning methodology</td><td colspan="6">Intended subject learning outcomes</td></tr>
<tr><td>a</td><td>b</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Lectures</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Individual Assignments</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
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<tr><td>Assessment Methods in Alignment with Intended Learning Outcomes</td><td>
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<tr><td rowspan="2">Specific assessment methods/tasks</td><td rowspan="2">% weighting</td><td colspan="5">Intended subject learning outcomes to be assessed</td></tr>
<tr><td>a</td><td>b</td><td></td><td></td><td></td></tr>
<tr><td>Continuous Assessment:</td><td>100 %</td><td>√</td><td>√</td><td></td><td></td><td></td></tr>
<tr><td>Individual Written Assignments</td><td>100%</td><td>√</td><td>√</td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td>100 %</td><td colspan="5"></td></tr>
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Individual written assignments are used to assess the intended learning outcomes.
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<tr><td>Student Study Effort Expected</td><td>
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<tr><td>Class contact:</td><td></td></tr>
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- Lecture

</td><td>39 Hrs.</td></tr>
<tr><td>Other student study effort:</td><td></td></tr>
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- Individual written assignments

</td><td>78 Hrs.</td></tr>
<tr><td>Total student study effort</td><td>117 Hrs.</td></tr>
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<tr><td>Reading List and References</td><td>

- United States Patent and Trademark Office (https://www.uspto.gov/)
- World Intellectual Property Organization (https://www.wipo.int/portal/en/)
- International Organization for Standardization (https://www.iso.org/home.html)
- US Food and Drug Administration (https://www.fda.gov/)
- European Commission (https://ec.europa.eu/health/md_sector/overview_en)
- China National Medical Products Administration (http://www.nmpa.gov.cn)
- Hong Kong's Medical Device Division (https://www.mdd.gov.hk/en/home/index.html)

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<tr><td>Date of Last Major Revision</td><td>26 April 2021</td></tr>
<tr><td>Date of Last Minor Revision</td><td>30 June 2023</td></tr>
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