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	This subject aims to give those professionals working in the development and use of medical devices and health care clinics, to demonstrate understanding of the practical knowledge about intellectual property, standards and regulations, and their relationship to quality health care and associated biomedical technology. Knowledge on medical device design, product development, quality assurance, and regulatory requirements and techniques is an essential part of every medical device development process. This subject is to address the important issues related to developing and using a safe and reliable medical device, and to demonstrate understanding on how to the meet regulatory requirements. Moreover, patent defence and intellectual property protection are important to protect each medical product and the company and will be discussed.
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, such as patent.
Subject Synopsis/ Indicative Syllabus	1. Basic knowledge on intellectual property, such as patents, copyrights and trademarks 2. U.S. Patent system, European Patent Convention, China patent system, other patent systems, Patent Treaties, 3. Patent search, and patent filling procedures 4. Copyright ownership and protection 5. Technology transfer with examples of standard license agreement for technology transfer 6. Food and drug administration (FDA) regulations, U.S. Food and Drug law, Medical device Classification, medical device approval, Preparing FDA submission 7. ISO (International Organization for Standards) standards 8. European Standards and regulations (CE, MDD etc.) 9. China and Hong Kong standards and regulations 10. Hazard, safety and risk analysis, biocompatibility, reliability and quality assurance 11. Ethics issues on clinical research about medical devices on human subjects

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<tr><td>Teaching/Learning Methodology</td><td>
Students will be required to learn to conduct patent searches, they will read widely on intellectual property issues and, in specific areas, also in depth. Students will be arranged into a small group to write a group paper. For example, they will be practising writing a patent with an example of a medical device.

Guest lecturers will be invited to discuss the legal aspects and formal procedures to apply and file a patent application, and issues related to contested patents and patent defense.

Self studies, which could include complementary readings and problem 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>1. Lectures (include guest lecturers)</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
<tr><td>2. Group papers</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>
<table>
<tr><td rowspan="2">Specific assessment methods/tasks</td><td rowspan="2">% weighting</td><td colspan="6">Intended subject learning outcomes to be assessed</td></tr>
<tr><td>a</td><td>b</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1. Continuous Assessment:</td><td>100 %</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
<tr><td>a. Assessments</td><td>60%</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
<tr><td>b. Quizzes</td><td>40%</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td>100 %</td><td colspan="6"></td></tr>
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Assignments, group paper and quizzes will be used to assess the intended learning outcomes.
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<tr><td>Student Study Effort Expected</td><td>
<table>
<tr><td>Class contact:</td><td></td></tr>
<tr><td>Lecture</td><td>36 Hrs.</td></tr>
<tr><td>□ Group Discussion/Presentation</td><td>3Hrs.</td></tr>
<tr><td>Other student study effort:</td><td></td></tr>
<tr><td>□ Reading subject-related materials</td><td>53 Hrs.</td></tr>
<tr><td>□ Preparation for reports and quizzes</td><td>50Hrs.</td></tr>
<tr><td>Total student study effort</td><td>142 Hrs.</td></tr>
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<tr><td>Reading List and References</td><td>
Reading Materials:
1. Medical devices – Quality management systems – Requirements for regulatory purposes ISO13485:2003, 2003
2. Medical devices — Application of risk management to medical devices ISO14971:2007, 2007
3. Council directive 93/42/EEC concerning medical devices, 2007
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	4. Fries RC, Handbook of Medical Device Design, Marcel Dekker, Inc., 2000. 5. Pressmann D, Patent it yourself, 9th edition, Nolo Press, 2002 6. Bronzino JD, The Biomedical Engineering handbook, Section XIX, Regulations and Organizations, 1995, CRC Press Websites: 1. U.S. Patent Office, http://www.uspto.gov/ 2. World Intellectual Property Organization, http://www.wipo.org/ 3. Medical Device Control Office (Hong Kong) http://www.mdco.gov.hk/eindex.html 4. European Commission, Medical Devices Sector http://ec.europa.eu/enterprise/medical_devices/ 5. US Food and Drug Administration http://www.fda.gov/ 6. International Organization for Standardization, http://www.iso.ch/iso/