# Subject Description Form

<table>
<tr><td>Subject Code</td><td>BME5151</td></tr>
<tr><td>Subject Title</td><td>Intellectual Property, Standards and Regulations of Medical Devices</td></tr>
<tr><td>Credit Value</td><td>3</td></tr>
<tr><td>Level</td><td>5</td></tr>
<tr><td>Pre-requisite / Co-requisite/ Exclusion</td><td>Nil</td></tr>
<tr><td>Objectives</td><td>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.</td></tr>
<tr><td>Intended Learning Outcomes</td><td>Upon completion of the subject, students will be able to:<br>a. Demonstrate understanding on how to the meet standards and regulatory requirements;<br>b. Demonstrate understanding of the practical knowledge about intellectual property protection.</td></tr>
<tr><td>Subject Synopsis/ Indicative Syllabus</td><td>• Medical Device Classification<br>• Patent Law, Patentability, and General Application Procedures<br>• Copyright, Design, Trademarks, and Related Legal Issues<br>• Intellectual Property Strategy and Management<br>• Quality Management System: ISO 13485<br>• Risk Management System: ISO 14971<br>• Medical Software: IEC 62304<br>• Good Clinical Practice: ISO 14155<br>• Medical Device Regulation in US: Premarket<br>• Medical Device Regulation in US: Postmarket<br>• Medical Device Regulation in EU<br>• Medical Device Regulation in HK<br>• Medical Device Regulation in China<br>• Harmonization of Medical Device Regulation</td></tr>
<tr><td>Teaching/Learning Methodology</td><td>Lectures, individual written assignments, and individual oral presentation.
<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>
<tr><td>Individual Oral Presentation</td><td>√</td><td>√</td><td></td><td></td><td></td><td></td></tr>
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**Assessment Methods in Alignment with Intended Learning Outcomes**

| Specific assessment methods/tasks | % weighting | Intended subject learning outcomes to be assessed | | | | | |
|---|---|---|---|---|---|---|---|
| | | a | b | | | | |
| Continuous Assessment: | 100 % | √ | √ | | | | |
| Individual Written Assignments | 75% | √ | √ | | | | |
| Individual Oral Presentation | 25% | √ | √ | | | | |
| Total | 100 % | | | | | | |

Individual written assignments and individual oral presentation are used to assess the intended learning outcomes.

**Student Study Effort Expected**

| | |
|---|---|
| Class contact: | |
| • Lecture | 39 Hrs. |
| Other student study effort: | |
| • Individual written assignments | 65 Hrs. |
| • Individual oral presentation | 22 Hrs. |
| Total student study effort | 126 Hrs. |

**Reading List and References**

- 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/eindex.html)