

SUBJECT DESCRIPTION FORM

Subject Title: Intellectual Property, Standards
and Regulations of Medical Devices

Subject Code: HTI5151

Credit Value: 3

Date of Submission: Feb 2007

Responsible Staff & Department: Dr. Raymond K.Y. Tong (HTI)

Pre-requisites: Nil

Recommended Background Knowledge: Have exposures to the clinical or industrial working environments of medical devices

Exclusions: Nil

Learning Approach:

Students will be required to learn to conduct patent searches, will read widely on intellectual property issues and, in specific areas, also in depth. Students will be arranged into a small group of three to four persons to write a group paper and deliver a seminar presentation. 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.

Contact hours:

Lectures/Tutorial/seminars	36 hours
Group Discussion/Presentation	6 hours
Sub-total	42 hours

Independent study hours:

Self-study	48 hours
Assignments	10 hours
Group paper/seminar presentation	42 hours
Sub-total:	100 hours
Total	142 hours

Assessment (types & weighting):

Continuous Assessment (100%)

Assignments	20%
Group paper and presentation	40%
Tests	40%

Learning Outcomes:

To give those professionals working in the development and use of medical devices and health care clinics, 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 understand how to meet regulatory requirements. Moreover, patent defence and intellectual property protection are important to protect each medical product and the company and will be introduced.

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, ISO 9000 set of standards
 8. European Standards and regulations (BSI, CEN, DIN, etc.)
 9. China and Hong Kong standards and regulations
 10. Software patent and standards
 11. Hazard, safety and risk analysis, biocompatibility, reliability and quality assurance
 12. Accessibility and flexibility for persons with disability
 13. Ethics issues on clinical research about medical devices on human subjects
-

Indicative reading list and references:

1. Fries RC, Handbook of Medical Device Design, Marcel Dekker, Inc., 2000.
2. Pressmann D, Patent it yourself, 9th edition, Nolo Press, 2002
3. Bronzino JD, The Biomedical Engineering handbook, Section XIX, Regulations and Organizations, 1995, CRC Press
4. Bronzino JD, Management of medical technology, a primer for clinical engineers, Butterworth-Heinemann, 1992.
5. Fishman S, Software development – a legal guide, Berkeley, California, Nolo Press, 1994.
6. Beauchamp TL, Childress JF, Principles of biomedical ethics, 4th edition, Oxford University Press, 1994

Websites

1. U.S. Patent Office, <http://www.uspto.gov/>
2. World Intellectual Property Organization, <http://www.wipo.org/>
3. Code of Federal Regulations, <http://www.access.gpo.gov/nara/cfr/>
4. United States Code, <http://uscode.house.gov/usc.htm>
5. FDA <http://www.fda.gov/>
6. International Organization for Standardization, <http://www.iso.ch/iso/>