

BME217e Healthcare Standards and Regulations

Level: 2

Credit Units: 5 Credit Units

Language: ENGLISH

Presentation Pattern: EVERY JULY

E-Learning: BLENDED - Learning is done MAINLY online using interactive study materials in Canvas. Students receive guidance and support from online instructors via discussion forums and emails. This is supplemented with SOME face-to-face sessions. If the course has an exam component, this will be administered on-campus.

Synopsis:

The course aims to provide students with a general understanding of a healthcare regulation as it exists in Singapore with relevant emphasis on regulation that pertains to biomedical engineering. There will also be a brief overview of relevant foreign examples such as FDA, CE etc. Students would also be given an introduction into international health standards and accreditation systems.

Topics:

- International Pharmaceutical and Drug Development
- Regulation of Western Medicine in Singapore
- Goods and Manufacturing Practices (GMP)
- Validation for Drugs
- International Regulation for Medical Devices
- Classification of Medical Devices
- Healthcare standards in hospitals
- Joint Commission International (JCI) certifications
- Risk management
- Business continuity planning
- Emerging issues in Healthcare Standards and Regulations (Part 1)
- Emerging issues in Healthcare Standards and Regulations (Part 2)

Learning Outcome:

- Discuss the role and operations of regulatory bodies in Singapore and worldwide
- Examine the role of legislation, regulations, principles of cGMP and guidance in healthcare industry
- Apply knowledge of the common healthcare standards required in the industry
- Explain the use of a framework on what is required for licensing of a medical devices
- Design a checklist on audit of healthcare standards in the hospital
- Develop a risk assessment and business continuity project at workplace

Assessment Strategies (Evening Class):

Components	Description	Weightage Allocation (%)
Overall Continuous Assessment	PRE-CLASS QUIZ 1	2

Overall Continuous Assessment	PRE-CLASS QUIZ 2	2
	PRE-CLASS QUIZ 3	2
	QUIZ 1	12
	TUTOR-MARKED ASSIGNMENT 1	12
Overall Examinable Components	Written Exam	70
Total		100