BME4103: BIO-SAFETY AND RISK ASSESSMENT

Effective Term
Semester B 2024/25

Part I Course Overview

Course Title
Bio-safety and Risk Assessment

Subject Code
BME - Biomedical Engineering
Course Number
4103

Academic Unit
Biomedical Engineering (BME)

College/School
College of Biomedicine (BD)

Course Duration
One Semester

Credit Units
3

Level
B1, B2, B3, B4 - Bachelor's Degree

Medium of Instruction
English

Medium of Assessment
English

Prerequisites
Nil

Precursors
Nil

Equivalent Courses
Nil

Exclusive Courses
Nil

Part II Course Details

Abstract
Introduction to biosafety and medical device regulations. Overview of the biosafety work practices, equipment, and facilities for the safe and secure handling of dangerous pathogens in a laboratory setting. Related topics can be discussed,

such as rules and regulations for biolaboratory, medical devices and medical technology. Risk Assessment and Management are discussed to involve identifying, analyzing, and responding to risk factors, risk assessment focuses on detecting biohazards and analyzing all potential risks in biological laboratory, medical devices and medical technology.

Course Intended Learning Outcomes (CILOs)

	CILOs	Weighting (if app.)	DEC-A1	DEC-A2	DEC-A3
1	Describe the basic concepts of biosafety and lab safety work practice		x		
2	Analyze relevant knowledge and technologies (including lab equipment and facility design) for safe biological laboratory to handle bio-related hazards			x	
3	Analyze relevant knowledge in rules and regulations for biosafety and medical device regulations			x	
4	Apply the principles of biosafety, and medical device safety to analyze some practical problems			x	x
5	Demonstrate reflective practice in an engineering context using Risk Assessment and Management			x	x

A1: Attitude
Develop an attitude of discovery/innovation/creativity, as demonstrated by students possessing a strong sense of curiosity, asking questions actively, challenging assumptions or engaging in inquiry together with teachers.

A2: Ability
Develop the ability/skill needed to discover/innovate/create, as demonstrated by students possessing critical thinking skills to assess ideas, acquiring research skills, synthesizing knowledge across disciplines or applying academic knowledge to real-life problems.

A3: Accomplishments
Demonstrate accomplishment of discovery/innovation/creativity through producing /constructing creative works/new artefacts, effective solutions to real-life problems or new processes.

Learning and Teaching Activities (LTAs)

	LTAs	Brief Description	CILO No.	Hours/week (if applicable)
1	Lecture	Students will develop an understanding on key concepts about various biosafety levels and hazardous conditions, laboratory safety and control.	1, 2, 3, 4, 5	3 hrs/week for 12 weeks
2	Tutorial	Students will discuss some biosafety problems and questions as well as identify a group-based project.	3, 4, 5	3 hrs/week for 1 week

3	Learning Tasks of the Group-based Project	Students will participate in the learning tasks of the mini-project activities. For the mini-project, a brief outline of the work topic(s), effective teamwork and expected presentation and report-writing will be provided emphasizing opportunities for discovery and innovation inherent in this student activity.	3, 4, 5	
4	Laboratory Work	Students will engage in group activities which involve various laboratory sessions related to Biosafety.	1, 2, 3, 4	3 hrs/week for 1 week

Assessment Tasks / Activities (ATs)

	ATs	CILO No.	Weighting (%)	Remarks (e.g. Parameter for GenAI use)
1	Mid-term Test	1, 2	10	
2	Mini-project	2, 3, 4	20	
3	Assignment	1, 2	10	
4	Lab Report	3, 4	10	

Continuous Assessment (%)

50

Examination (%)

50

Examination Duration (Hours)

1.5

Additional Information for ATs

For a student to pass the course, at least 30% of the maximum mark for both coursework and examination should be obtained.

Assessment Rubrics (AR)

Assessment Task

Mid-term Test

Criterion

Ability to Explain the basic concepts of biosafety and work practice.

Excellent (A+, A, A-)

High

Good (B+, B, B-)

Significant

Fair (C+, C, C-)
Moderate

Marginal (D)
Basic

Failure (F)
Not even reaching marginal levels

Assessment Task
Mini-project

Criterion
Capacity for Self-directed Learning to understand the principles, methodology and applications of bio-safety and control.

Excellent (A+, A, A-)
High

Good (B+, B, B-)
Significant

Fair (C+, C, C-)
Moderate

Marginal (D)
Basic

Failure (F)
Not even reaching marginal levels

Assessment Task
Assignment

Criterion
Ability to Explain the basic concepts of biosafety and medical device regulations.

Excellent (A+, A, A-)
High

Good (B+, B, B-)
Significant

Fair (C+, C, C-)
Moderate

Marginal (D)
Basic

Failure (F)
Not even reaching marginal levels

Assessment Task
Lab Report

Criterion
Ability to Explain the methodology and procedures of various experimental works for biosafety and medical device regulations.

Excellent (A+, A, A-)
High

Good (B+, B, B-)
Significant

Fair (C+, C, C-)
Moderate

Marginal (D)
Basic

Failure (F)
Not even reaching marginal levels

Assessment Task
Examination

Criterion
Ability to Explain in Detail various issues and technical aspects of biosafety and medical device regulations.

Excellent (A+, A, A-)
High

Good (B+, B, B-)
Significant

Fair (C+, C, C-)
Moderate

Marginal (D)
Basic

Failure (F)
Not even reaching marginal levels

Part III Other Information

Keyword Syllabus

- Biosafety: biological safety level, risk group
- Biohazard
- Rules and Regulations for biosafety and medical devices
- Risk Assessment and Management

Reading List

Compulsory Readings

	Title
1	Fleming, Diane O. and Hunt, Debra A., Biological Safety: Principles and Practices, Amer Society for Microbiology, 4th Edition, 2006.
2	Burnette, Ryan, Biosecurity: Understanding, Assessing, and Preventing the Threat, Wiley, 2013.
3	Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo, Medical Devices: Regulations, Standards and Practices, 2005

Additional Readings

	Title
1	Nil