

BME4103: BIO-SAFETY AND RISK ASSESSMENT

Effective Term

Semester A 2025/26

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 ("- for nil entry)	Allow Use of GenAI?
1	Mid-term Test	1, 2	10	-	No
2	Mini-project	2, 3, 4	20	-	Yes
3	Assignment	1, 2	10	-	Yes
4	Lab Report	3, 4	10	-	No

Continuous Assessment (%)

50

Examination (%)

50

Examination Duration (Hours)

1.5

Minimum Continuous Assessment Passing Requirement (%)

30

Minimum Examination Passing Requirement (%)

30

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