

Tamkang University Academic Year 109, 2nd Semester Course Syllabus

Course Title	ADVANCED MEDICAL DEVICES REGULATION PRACTICE	Instructor	WANG, YU-TZU
Course Class	TEBXM1A MASTER'S PROGRAM, DEPARTMENT OF MECHANICAL AND ELECTRO-MECHANICAL ENGINEERING, 1A	Details	<ul style="list-style-type: none"> ◆ General Course ◆ Selective ◆ One Semester
Relevance to SDGs	SDG9 Industry, Innovation, and Infrastructure		
Departmental Aim of Education			
<p>I. To prepare students who have a comprehensive understanding of the principles of applied sciences and engineering to be innovators in the field of mechanical and electromechanical engineering.</p> <p>II. To train emerging professionals who possess a high level of expertise and ethical standards who will become independent research and development leaders in the industry.</p> <p>III. To motivate students who will pursue continuing education as a means to stay on the cutting edge of global competitiveness and meet changes in their careers and the workplace with confidence and ease.</p>			
Subject Departmental core competences			
<p>A. Head: Knowledge of mechanical and electromechanical engineering.(ratio:20.00)</p> <p>B. Hand: Hands-on skills and practical realization.(ratio:40.00)</p> <p>C. Heart: Love of learning and innovation.(ratio:30.00)</p> <p>D. Eye: Vision of progress and improvements.(ratio:10.00)</p>			
Subject Schoolwide essential virtues			
<p>2. Information literacy. (ratio:30.00)</p> <p>5. Independent thinking. (ratio:40.00)</p> <p>7. A spirit of teamwork and dedication. (ratio:30.00)</p>			

Course Introduction	The course will introduce the international regulations and standards for medical devices and the safety testing that advanced medical devices must pass to convey the concept of the regulations and the importance of functional testing for advanced medical devices.
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The correspondences between the course's instructional objectives and the cognitive, affective, and psychomotor objectives.

Differentiate the various objective methods among the cognitive, affective and psychomotor domains of the course's instructional objectives.

- I. Cognitive : Emphasis upon the study of various kinds of knowledge in the cognition of the course's veracity, conception, procedures, outcomes, etc.
- II. Affective : Emphasis upon the study of various kinds of knowledge in the course's appeal, morals, attitude, conviction, values, etc.
- III. Psychomotor: Emphasis upon the study of the course's physical activity and technical manipulation.

No.	Teaching Objectives	objective methods
1	Biomedical engineering is a specialized discipline that combines engineering technology and clinical medicine in disease diagnosis or treatment to design and development of medical devices. This course will explore the integration technology of this interdisciplinary research simply.	Psychomotor

The correspondences of teaching objectives : core competences, essential virtues, teaching methods, and assessment

No.	Core Competences	Essential Virtues	Teaching Methods	Assessment
1	ABCD	257	Lecture, Discussion, Experience	Study Assignments, Report(including oral and written)

Course Schedule

Week	Date	Course Contents	Note
1	110/02/22 ~ 110/02/28	Observe/Define Medical Device Design Requirements I	
2	110/03/01 ~ 110/03/07	Basic Introduction to Clinical Conditions	
3	110/03/08 ~ 110/03/14	Clinical Treatment Options	

4	110/03/15 ~ 110/03/21	Treatment Options Advantages and Disadvantages	
5	110/03/22 ~ 110/03/28	In Vitro Biomechanical Testing I	
6	110/03/29 ~ 110/04/04	In Vitro Biomechanical Test II	
7	110/04/05 ~ 110/04/11	Medical Image Processing Analysis	
8	110/04/12 ~ 110/04/18	Reverse Engineering Practice	
9	110/04/19 ~ 110/04/25	Static Simulation Analysis I –Bone Screw Pullout Simulation Analysis	
10	110/04/26 ~ 110/05/02	Static simulation analysis II - Bone plate bending simulation analysis	
11	110/05/03 ~ 110/05/09	Optimal Application analysis in Medical Devices Design I	
12	110/05/10 ~ 110/05/16	Introduction to Clinical Case Reports I	
13	110/05/17 ~ 110/05/23	Introduction to Clinical Case Reports II	
14	110/05/24 ~ 110/05/30	Biomechanical Simulation Analysis I-Customized bone plate design	
15	110/05/31 ~ 110/06/06	Biomechanical Simulation Analysis II - Customized Mandibular Implants Device	
16	110/06/07 ~ 110/06/13	Porous Structures for Medical Implant Design I	
17	110/06/14 ~ 110/06/20	Porous Structures for Medical Implant Design II	
18	110/06/21 ~ 110/06/27	Final report	
Requirement			
Teaching Facility	Computer, Projector		
Textbooks and Teaching Materials	Basic Biomechanics of the Musculoskeletal System 4/e, authors: Margareta Nordin and Victor H. Frankel		
References			

Number of Assignment(s)	(Filled in by assignment instructor only)
Grading Policy	◆ Attendance : 30.0 % ◆ Mark of Usual : 20.0 % ◆ Midterm Exam : % ◆ Final Exam : 50.0 % ◆ Other () : %
Note	This syllabus may be uploaded at the website of Course Syllabus Management System at http://info.ais.tku.edu.tw/csp or through the link of Course Syllabus Upload posted on the home page of TKU Office of Academic Affairs at http://www.acad.tku.edu.tw/CS/main.php . ※ Unauthorized photocopying is illegal. Using original textbooks is advised. It is a crime to improperly photocopy others' publications.