

National University of Sciences and Technology

Course Description

Course Title
Medical Devices Design
and Standards

Course Code
BMES-812

Credit Hours
3 - 0

TEXT BOOK:

- Scripts from: IPO/WHO, MDR, FDA, ISO
- John G Webster "medical instrumentation application and design" 5th Ed. (latest edition).

REFERENCE BOOK

• N/a

COURSE OBJECTIVES:

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 biofluid device, and to understand how to meet regulatory requirements. Patent defense and intellectual property protection will be introduced.

COURSE OUTLINES

- Medical devices from Global prospective
- Design of Medical Devices
- Medical Device Classification
- Intellectual property
- Clinical Research
- Electrical Standards

ASSESSMENTS

Description	Percentage Weightage (%)
Assignments	05-10%
Quizzes	10-15%
Mid Semester Exams	30-40%
End Semester Exam	40-50%