LAWS C3603: Medical Device Standards and Regulations

Module Title:	Medical Device Standards and Regulations
Language of Instruction:	English

Credits:	5

NFQ Level:	7

Module Delivered In	2 programme(s)

Teaching & Learning Strategies:	(a) Teaching will be conducted using lectures and tutorial sessions. (b) The Institute's VLE will be used to evaluate the students' understanding of the basic concepts during each section using online quizzes. (c) Case study materials and assignments will be incorporated into the learning and assessment strategy. (d) At various stages of the module, students will be directed to online materials and resources and will also have to conduct independent research on specific topics for purpose of completing the assignments. (e) These case studies will serve to reinforce the theoretical knowledge and understanding of regulations, standards, and practices with respect to real-world applications, experiences, and scenarios for industry.

Module Aim:	The aim of this module is to provide the student with knowledge and understanding in relation to the regulations, standards and practices of medical devices from an international perspective. The module focuses on the general regulations of medical devices, quality management systems, the approval process for different jurisdictions, risk assessment management, safety and clinical testing approaches, and finally, product development methodologies for medical devices.

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Discuss the general regulations of medical devices.
LO2	Examine the quality management systems for medical device manufacture.
LO3	Compare the approval process for new medical devices in different jurisdictions.
LO4	Interpret risk assessment management, safety and clinical testing approaches for new medical devices.
LO5	Evaluate the product development methodologies for medical devices.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is recommended before enrolment in this module.*
No recommendations listed
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module.*
No incompatible modules listed
Co-requisite Modules
No Co-requisite modules listed
Requirements *This is prior learning (or a practical skill) that is mandatory before enrolment in this module is allowed.*
No requirements listed

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Module Content & Assessment

Indicative Content
Introduction: (i) Medical devices: definitions and types (ii) market trend (iii) general regulations, and (iv) background to the switch from Medical Device Directives (MDD) for Medical Device Regulation (MDR) and In-vitro Diagnostic Medical Devices Regulation (IVDR).
Quality Management Systems: (i) Manufacturing practice for excellence (ii) ISO 13485 (iii) comparison of ISO and cGMP, and (iv) FDA CFR820.
Approval Process for New Medical Devices: (i) European Union (ii) the United States (iii) China, and (iv) other jurisdictions.
Risk Assessment Management: (i) Risk analysis and techniques (ii) risk acceptability, and (iii) risk management reporting.
Safety Testing: (i) Absence of toxic substance (ii) biocompatibility tests (iii) cytotoxicity, sensitization, and irritation (iv) Acute (Systematic), subacute, subchronic, and chronic toxicity (v) genotoxicity, carcinogenicity, and reproductive and development toxicity (vi) implantation (vii) hemocompatibility (viii) biodegradation (ix) sterility tests (x) transportation tests (xi) electrical tests (xii) mechanical tests (xiii) outsourcing (third party) laboratory testing.
Clinical Testing: (i) Role of clinical testing, (ii) creating and implementing clinical tests, (iii) clinical practices for excellence, and (iv) documentation of findings.
Product development methodologies: (i) Initiation, (ii) planning, (iii) execution, monitoring, and control (iv) verification and validation (v) review meetings and evaluation of product development progress.

Assessment Breakdown	%
Continuous Assessment	60.00%
Project	40.00%

Continuous Assessment

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Examination	Class Assessment	1,2,3	30.00	Week 7
Examination	Class Assessment	4,5	30.00	Week 14

Project

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Project	Assignment Exercise	2,3	40.00	n/a

No Practical

No End of Module Formal Examination

SETU Carlow Campus reserves the right to alter the nature and timings of assessment

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Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Lecture	Every Week	3.00
Independent Learning	Every Week	3.00
	Total Hours	6.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_EEBEE_B	Bachelor of Engineering (Honours) in Biomedical Electronics	6	Mandatory
CW_EEBEE_D	Bachelor of Engineering in Biomedical Electronics	6	Mandatory