GMIT
INSTITIÚID TEICNEOLAÍOCHTA NA GAILLIMHE-MAIGH EO
GALWAY-MAYO INSTITUTE OF TECHNOLOGY

ENGI07066
Quality (Part-Time)

Full Title	Quality (Part-Time)		
Status	Uploaded to Banner	**Start Term**	2018
NFQ Level	07	**ECTS Credits**	10
Module Code	ENGI07066	**Duration**	36 Weeks - (36 Weeks)
Grading Mode	Numeric	**Department**	Mechanical & Industrial Eng
Module Author	Martin Conneely		
Co Authors	Padraig Audley		

Module Description

This module will deal with the Quality Assurance systems and quality management principles needed in manufacturing and service organisations.

This course will provide students with an in-depth understanding of the regulations and regulatory agencies that are specific to the medical devices industry. The course will cover both European Union (EU) and US regulations and related agencies. Topics will include the laws covering the regulation of medical devices, regulations related to the development, manufacturing and approval of medical devices, regulatory agencies and bodies responsible for implementing the regulations, how the regulations affect the marketing of medical devices.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Discuss and compare philosophies and new trends in quality management and their place in today's manufacturing and service environments including Total Quality Manageemnt (TQM)
2.	Analyse and apply a range of statistical tools to measure quality. Select appropriate methodologies of quality improvement and apply various tools and techniques for analysis of quality.
3.	Identify, describe and critique the functions of the GMP, EU and US authorities, departments, agencies and other bodies responsible for developing and implementing the laws and associated regulations for Quality and medical devices industry.
4.	Describe and critique the EU and US regulatory requirements that affect the development, manufacturing and quality of medical devices. Determine the classification of medical devices.
5.	Describe the context of Process Validation within the Quality Management System and describe the steps needed to conduct Process Validation.
6.	Decide if an adverse event should be reported and if so describe the correct reporting procedure.

Indicative Syllabus

- History and Importance of Standards,
- Quality Management Philosophies, Total Quality Mangement and gurus Deming, Juran, Crosby, Ishikawa and Feigenbaum
- Quality and organisational structure
- Total Quality Control
- Managing for quality
- Process Management, Automation and Continuous Improvement
- Cost of Quality
- Process Approach and PDCA
- Hierarch of Quality Documentation
- Quality Awards
- Quality Standards, GMP and Auditing
- Quality Tools, Statistical Process Control and Sampling Plans
- Principles of Validation

- European (EU) Medical Device Regulations
- European regulatory bodies and organizations
- Medical devices directives: Active Implantable Directive, Medical Devices Directive, In Vitro Diagnostics Directive
- ISO 13485 Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes
- ISO 14971 Risk Management for Medical Devices
- Medical Devices classification Class I, Class IIa, Class IIb, Class III
- Conformity Assessment procedures
- Vigilance systems
- FDA and CDRH - Medical device Quality System Regulation (QSR) and Quality System Inspection Technique (QSIT)

Teaching and Learning Strategy

Teaching and Learning Strategy

This module combines face-to-face, online delivery either synchronous or asynchronous, and a high level of self-learning. The majority of the theoretical content is delivered live online and recorded so students can chose to attend the session if they wish to ask questions or can download the recorded version and study in their own time. The majority of the face-to-face is ran as a tutorial where the group goes through the quality tools. Some of the face-to-face is completed as a lecture.

The learning content of the course will allow students to acquire skills which are transferrable to industry. The efficacy of these competences are proven by an Industry project. The management of this task will be demonstrated via Moodle.

Assessment Strategy

The assessment strategy of this module will be a combination of:

- Online Moodle Quiz.
- Quality Project.
- Industry Project.
- Final Exam.

The quality project is an assessment on standards for quality procedures. The student demonstrates their understanding of the quality tool and how to create a quality procedure. This assessment is a synergy between the Project management module and the Quality module.

Repeat Assessment Strategies

Repeat exam offered

Indicative Coursework and Continuous Assessment:		**50 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Multiple Choice	Online Moodle Quiz	10 %	TBA	1,2,3,4
Practical Evaluation	Industry Project	25 %	OnGoing	1,2,3,4,5,6
Assessment	Quality project	15 %	End of Semester	1,2,3,5

End of Semester / Year Formal Exam:		**50 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Closed Book Exam	CA	50 %	End of Term	1,2,3,4,5,6

Blended Delivery Mode Average Weekly Workload:			**2.50 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Online Learning	Online delivery	Not Specified	1.5	Weekly	1.50
Practical	Lab	Computer Laboratory	1	Weekly	1.00

Recommended Reading Book List

Geneva, I., (2013). *9000 International Standard for Quality Management*. ISO Geneva.

, I., (2003). *ISO 13485:2003 and Guidance document ISO/TR 14969*. ISO.

, ., *AIMD - Active Implantable Medical Devices Directive(90/385/EEC)*. EU.

, ., *MDD - Medical Devices Directive (93/42/EEC)*. EU.

, ., *IVD - In-Vitro Diagnostic Medical Devices Directive (98/79/EC)*. EU.

Journal Resources

Online Resources

Other Resources

FDA QSR and QSIT

GHTF Reports

Additional Information

Programme Membership

GA_EMANG_B07 201800 Bachelor of Engineering in Manufacturing Engineering (Part-time)