ENGI06050
Regulatory Affairs (TK)

Full Title	Regulatory Affairs (TK)		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	06	**ECTS Credits**	05
Module Code	ENGI06050	**Duration**	Stage - (26 Weeks)
Grading Mode	Numeric	**Department**	Mechanical & Industrial Eng
Module Author	Carine Gachon		

Module Description

This module will deal with the Quality Assurance systems and quality management principles needed in manufacturing and specifically in the building of automated machines and automated systems.

The course will cover both European Union (EU) and US regulations and related agencies.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Discuss the role of quality management in Manufacturing and the constraint linked to its implementation.
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.	Investigate and discuss the role of automation in quality control.
4.	Discuss the regulatory requirements that affect the development of automated systems and their impact on the design.

Indicative Syllabus

Introduction to quality Systems

- Quality Control,
- Quality Assurance,
- Total Quality Management,
- Quality standards and specification,
- Process control

Manufacturing quality

- Quality Tools, Statistical Process Control and Sampling Plans
- The role of automation in quality control

Standards and regulations for machine building

- Type of standards (A, B, and C)
- B standards such as EN60204-1 and EN ISO 13849-1
- C standards such as EN ISO 10218-1 and EN ISO 10218-2
- Directive 2006/42/EC
- Principles of Validation and CE marking

Teaching and Learning Strategy

The module is delivered online with a mixture of synchronous and asynchronous delivery. Students will follow Kolb's experiential learning cycle through the extension of this module in the Industry module. Having learnt the theory, they will analyse the quality tools used in their company before considering their impact as part of the Industry module.

Assessment Strategy

The assessment strategy will be divided in three sections. The continuous assessment taking place during the delivery of the module. An end

of term exam (summer) covering the theory and a final assignment submitted in autumn where students will analyse the quality tools used in their company.

Repeat Assessment Strategies

A repeat exam will be offered and students can resubmit their continuous assessment where feasible.

Indicative Coursework and Continuous Assessment:		**50 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assessment	CA	20 %	Week 13	1,2
Practical Evaluation	Practical	10 %	OnGoing	2
Assignment	Industry Assignment on Quality Tools	20 %	End of Term	2

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

Blended Delivery Mode Average Weekly Workload:			**2.00 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Online Learning	Online delivery	Not Specified	2	Weekly	2.00

Recommended Reading Book List

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

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

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

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

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

Other Resources

FDA QSR and QSIT

GHTF Reports

Programme Membership

GA_EAURG_B07 202000 Bachelor of Engineering in Automation & Robotics
GA_EAURG_C06 202000 Higher Certificate in Engineering in Automation & Robotics
GA_EAURG_B07 202100 Bachelor of Engineering in Automation and Robotics
GA_EAURG_C06 202100 Higher Certificate in Engineering in Automation and Robotics