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

MGMT08060
Risk Management

Full Title	Risk Management		
Status	Uploaded to Banner	**Start Term**	2017
NFQ Level	08	**ECTS Credits**	05
Module Code	MGMT08060	**Duration**	Semester - (13 Weeks)
Grading Mode		**Department**	Physical & Life Sciences
Module Author	Seamus Lennon		
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Module Description

This module will provide an understanding of how risks are identified, quantified, evaluated, monitored and controllled in order to meet quality and regulatory requirements, including those in medical devices and pharmaceuticals.

Learning Outcomes

On completion of this module the learner will/should be able to:

1.	Interpret the regulations/standards relating to Risk Management (including ISO 31000, ISO 14971 and ICH Q9).
2.	Identify, quantify and evaluate risks, review the acceptability of those risks and instigate mitigation to minimise/remove risk.
3.	Apply various risk assessment tools and techniques such as FMECA, Fault Tree Analysis and HAZOP
4.	Discuss hazards and risks in design, systems and processes
5.	Generate links between risk management processes and key quality management processes such as change control, design and CAPA.

Indicative Syllabus

Overview of standards/regulations associated with risk, including those for general use, medical devices, pharmaceutical industries (ISO 31000, ISO 14971 and ICH Q9.

Embedding risk management throughout the product lifecycle from pre market development to post marketing product surveillance.

Identification of hazards, harm, risks in product design, processes and systems.

Conduct a risk/benefit analysis.

Quantification of risk (risk priority number).

Review of Risk Impact Assessment and Prioritization and review of risk acceptability

Overview of Risk Assessment Tools including FMECA, Fault Tree Analysis, HAZOP

Teaching and Learning Strategy

This module presents the opportunity to identify and manage risk from pre market development to post marketing surveillance taking into consideration all aspects of the product lifecycle. Students will be presented with the opportunity to design a risk management system. Student interaction and peer learning will play a big role in the delivery of material. The use of technology will enhance the teaching approach by faciliting additional means of communication as well as providing a suite of resources to support student learning.

Assessment Strategy

Learning will be assessed by a mixture of CA and final exam.

For continuous assessment, both individual and group work will form the basis for assessment. Continuous assessment will required students to prepare a risk management plan and to apply risk based thinking to various senarios through the identification, analysis, evaluation and control of risk.

The final exam will present opportunity for students to demonstrate their understanding of all learning outcomes.

Repeat Assessment Strategies
Repeat exam available

Indicative Coursework and Continuous Assessment:		**60 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assignment	Assignment - Case study - create a risk management plan	30 %	Week 12	1,2,3,4,5
Group Project	Group Project - application of risk management to case study scenarios	30 %	Week 6	2,3,5

End of Semester / Year Formal Exam:		**40 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assessment	Final Exam	40 %	Week 15	1,2,3,4,5

Part Time Delivery Mode Average Weekly Workload:			**2.00 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Not Specified	2	Weekly	2.00

Literary Resources
Quality Risk Management in the FDA-Regulated Industry by J Rodriguez-Perez, 2012. Quality Press.

Online Resources
FDA Guidance for Industry https://www.fda.gov/downloads/Drugs/Guidances/ucm073511.pdf
International medical device regulators forum; http://www.imdrf.org/documents/documents.asp
FDA Q9: Quality Risk Management- Guidance for Industry https://www.fda.gov/downloads/Drugs/Guidances/ucm073511.pdf

Other Resources
ISO 31000 – Risk Management Principles and Guidelines ISO 31010 - Risk Management - Risk Assessment Techniques *ISO 14971*- “Application of Risk Management to Medical Devices *ICH Q9* – Quality Management Risk (Pharmaceuticals)

Programme Membership
GA_SQUAG_H08 201700 Bachelor of Science (Honours) in Quality For Industry