

Full Title	Quality Management Systems and Frameworks		
Status	Uploaded to Banner	Start Term	2017
NFQ Level	08	ECTS Credits	05
Module Code	MGMT08055	Duration	Semester - (13 Weeks)
Grading Mode		Department	Physical & Life Sciences
Module Author	Seamus Lennon		
Co Authors	Ita Kelly, Marilla Keating		

Module Description

The objective of this module is to ensure student understanding of quality standards, quality management systems and frameworks in order to be able to establish, implement and maintain an integrated approach to quality.

Learning Outcomes

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

1. Critically evaluate quality management system models including ISO 9001, ISO 14001, OHSAS 18001, ISO 13485, ISO/TS 16949, EudraLex - Volume 4, 21CFR Part 820, 21CFR Part 211.
2. Develop strategies for quality system management implementation and maintenance
3. Create documentation systems and structures to meet specified requirements
4. Determine the pathway to certification for ongoing registration and compliance with standards
5. Prepare a site for third party audit from certification bodies, regulatory bodies, and customers

Indicative Syllabus

Overview of Quality Management Systems, frameworks and models including ISO 9001, ISO 14001, OHSAS 18001, ISO 13485, ISO/TS 16949, EudraLex - Volume 4, 21CFR Part 820, 21CFR Part 211. Shingo prize, Excellence Ireland, EFQM

Differentiate between Quality Management Systems that are relevant to various industries and requirements

The design, implementation and maintenance of a quality management systems to meet specified requirements.

Preparation for audits from certification bodies, customers, or regulatory bodies.

Teaching and Learning Strategy

This module provides the opportunity to explore the various standards that are being used with a view to comparing and contrasting and exploring the creation of integrated systems. The diverse student profile from various industrial and experiential backgrounds will lay the foundation for the sharing of knowledge in this forum. Learning will be facilitated through group work, discussions, debate and peer learning. The support of technology will providing resources and a means of communication to enhance this learning approach.

Assessment Strategy

A mixture of CA and final exam will be used.

The continuous assessment strategy includes the evaluation of selected standards which includes comparing and contrasting and consideration of how to create integrated systems. Individual and group work will require students to demonstrate a clear understanding of relevant standards and will earn their continuous assessment marks by means of project documentation, presentations and follow up class

participation.

The final exam will present an additional opportunity for students to demonstrate knowledge across all learning outcomes.

Repeat Assessment Strategies

Repeat examination available

Indicative Coursework and Continuous Assessment:		60 %		
Form	Title	Percent	Week (Indicative)	Learning Outcomes
Assignment	Assignment - Case study - selection of standards and integration of standards	30 %	Week 11	1,2,3
Assessment	Assignment - presentation of a standard specific to a case study	30 %	Week 6	1,2,3,4

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

Recommended Reading Book List

Tricker, R., (2016). *ISO 9001:2015 for Small Businesses*. Routledge.
ISBN 1138025828 ISBN-13 9781138025820

Literary Resources

1. ISO 9001 Quality Management System - Requirements
2. ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes
3. FDA 21 CFR Part 820 QUALITY SYSTEM REGULATION
4. Part 211- Part 211 CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS
5. EU- EudraLex volume 4 GMP Guidelines
6. ISO/TS 16949 Certification for the Automotive Industry
7. ISO 14001- Environmental Management
8. OHSAS 18001 Occupation health and safety management system

Programme Membership

GA_SQUAG_H08 201700 Bachelor of Science (Honours) in Quality For Industry
GA_SQMDG_N08 201700 Certificate in Quality for the Medical Device Industry