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

DESI08039
Design Quality Assurance

Full Title	Design Quality Assurance		
Status	Uploaded to Banner	**Start Term**	2017
NFQ Level	08	**ECTS Credits**	05
Module Code	DESI08039	**Duration**	Stage - (26 Weeks)
Grading Mode		**Department**	Physical & Life Sciences
Module Author	Seamus Lennon		
Co Authors	Marilla Keating		

Module Description

This module will give students an understanding of the four phases of design and development from product concept to manufacturing with particular focus on understanding and ensuring market needs, user requirements and regulatory compliance.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Explain the four phases of Design and Development that meet standards/regulations including relevant ISO and FDA standards and regulations.
2.	Evaluate product design to ensure compliance with requirements such as essential safety and performance requirements of US and European directives and regulations
3.	Plan new product introduction including process design and product transfer operations
4.	Conduct product design reviews, verification and validation
5.	To have an understanding of key design input requirements including software (V model), electrical safety, radiation, mechanical, usability and user interface criteria.

Indicative Syllabus

Outline the four phases of Design and Development ensuring links to regulations/standards

Identification of relevant essential/performance and safety requirements and associated method of compliance

Understanding verification and validation requirements of design

Design assurance for compatibility and compliance with requirements (such as biocompatibility, sterilization, product usability, software, mechanical, hardware, electrical safety, regulatory)

Design outputs including BOM's, operational procedures, specifications, drawings, test methods, acceptance criteria, process design and links to change management.

Teaching and Learning Strategy

This module provides the opportunity to understand the requirements of the various phases of design. Various senarios will be explored to embed student learning.

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

Assessment is by a mixture of CA and final exam.

Continuous assessment in this module will include individual and group work to ensure that students can apply the theory to practical applications which includes the preparation of an essential/performance and safety requirements checklist as well as outlining the considerations for the transfer from the design phase into the manufacuring phase.

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

Repeat Assessment Strategies

Repeat examinations available

Indicative Coursework and Continuous Assessment:		**60 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assignment	Individual project on design standards	30 %	Week 10	1,2,4,5
Assignment	Group project - case study involving the preparation of design QA documents	30 %	Week 13	1,2,3,4,5

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

FDA QSR Part 820

ISO 13485

Medical Device Directive/Regulation

FDA guidelines

Online Resources

Design Control Guidance For Medical Device Manufacturers

https://www.fda.gov/RegulatoryInformation/Guidances/ucm070627.htm

GHTF Design Control Guidance

http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-9-design-control-990629.pdf

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