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

SCIE07009
Regulatory Affairs & Compliance Auditing

Full Title	Regulatory Affairs & Compliance Auditing		
Status	Uploaded to Banner	**Start Term**	2015
NFQ Level	07	**ECTS Credits**	10
Module Code	SCIE07009	**Duration**	Stage - (26 Weeks)
Grading Mode		**Department**	Physical & Life Sciences
Module Author	Seamus Lennon		

Module Description

This module covers relevant pharmaceutical and medical device legislation and Good Manufacturing Practice guidelines (EU & FDA). The various approaches taken to compliance auditing are covered.

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

1.	Interpret the EU and FDA GMP guidelines and relevant ISO standards.
2.	Explain the legislative requirements during the various drug development and medical device development phases.
3.	Explain how a marketing authorization for pharmaceuticals and medical devices is obtained in the EU and the US.
4.	Detail the various approaches taken to compliance auditing.
5.	Detail a system for investigation of non-conformances, identification of root cause and corrective / preventive actions.
6.	Participate in an audit by interpreting relevant legislation and guidelines, identifying any non-conformances and recommend relevant corrective / preventive actions.

Indicative Syllabus

Pharmaceutical and Medical Device regulatory affairs – legislation and guidelines.

Quality Management systems that ensure compliance with relevant legislation and guidelines.

Marketing authorization processes for medical devices and pharmaceuticals.

Audit methodologies and tools.

Interpretation of GMP and ISO guidelines.

Case studies – performance of audits, audit reporting.

Actions to rectify non-conformances – identification of root cause, corrective actions, preventive actions.

Teaching and Learning Strategy

Material is deliverd via lectures and tutorials. Use is made of team work, presenetations, and project based work.

Assessment Strategy

Project based assessment, case studies, in class assessment

Repeat Assessment Strategies

In compliance with policy

Indicative Coursework and Continuous Assessment:		50 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assessment	Assessment	10 %	Week 10	1,2,3,4,5,6
Project	Project	15 %	Week 10	1,2,3,4,5,6
Project	Project	15 %	Week 22	1,2,3,4,5,6
Assessment	Assessment	10 %	Week 22	1,2,3,4,5,6

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

Full Time Delivery Mode Average Weekly Workload:			3.00 Hours		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Tiered Classroom	3	Weekly	3.00

Recommended Reading Book List

Tobin, J., (2011). *Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices*. Wiley-Blackwell.

Weinberg, S., (2011). *Cost-Contained Regulatory Compliance: For the Pharmaceutical, Biologics, and Medical Device Industries*. Wiley.

Literary Resources

Tobin, J & Walsh, G (2008). Medical product regulatory affairs: pharmaceuticals, diagnostics, medical devices. Wiley-Blackwell.

Weinberg, S. (2011) Cost-contained regulatory compliance: for the pharmaceutical, biological and medical device industries. Wiley

Medical devices: quality management systems: guidance on the application of ISO 13485. International Organization for Standardization. 2003.

Relevant EU and US Legislation and Guidelines.

Online Resources

International Organization for Standardization www.iso.org

Food and Drug Administration www.fda.gov

Irish Medicines Board www.imb.ie

European Medicines Agence www.emea.europa.eu

International Council for Harmonization www.ich.org

Other Resources

Medical devices: quality management systems: guidance on the application of ISO 13485. International Organization for Standardization. 2003.

Relevant EU and US Legislation and Guidelines.

Programme Membership

GA_SQRAG_S07 201500 Certificate in Science in Quality & Regulatory Affairs
GA_SQUAG_B07 201400 Bachelor of Science in Quality for Industry