MANU08003
Regulatory Affairs

Full Title	Regulatory Affairs		
Status	Uploaded to Banner	**Start Term**	2017
NFQ Level	08	**ECTS Credits**	05
Module Code	MANU08003	**Duration**	Stage - (26 Weeks)
Grading Mode		**Department**	Physical & Life Sciences
Module Author	Seamus Lennon		
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Module Description

This module will provide a deep understanding on the regulatory pathways for medical devices and pharmaceuticals in Europe, the US and also have an introduction into accessing other global markets.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Explain the differences in product registration requirements for medical devices and pharmaceuticals when seeking market approval in the EU and the US.
2.	Evaluate how and why the regulatory environment for medical devices has changed in Europe over the last few years.
3.	Explain the various types of technical documentation required when seeking market approval for medical devices and pharmaceuticals in the US and the EU.
4.	Explain the EU and US regulatory requirements when conducting clinical evaluation/investigations for Medical Devices and for pharmaceuticals
5.	Compare and contrast post marketing surveillance requirements in US and Europe for medical devices and pharmaceuticals
6.	Evaluate the regulatory considerations when seeking marketing approval in global markets including Japan, Canada and Australia.

Indicative Syllabus

1. Overview of regulatory pathways including recent changes associated with classification, clinical requirements, conformity assessment and the role of economic operators.
2. Evaluating the regulatory requirements for medical devices and pharmaceuticals in Europe, the US, and other global markets including Japan, Canada, Australia
3. Overivew of regulations for combination products
4. The design of a technical submission required for regulatory approval.
5. Clinical investigations - planning, identifying roles, risks, and number of subjects, purpose of investigation making reference to European or US regulations/standards.
6. Post marketing surveillance

Teaching and Learning Strategy

Notes will be provided in advance for student preparation. Lectures will involve peer learning, discussions, debates, group work, presentations. The use of technology will enhance dialogue and delivery to enable both face to face delivery and online interactions.

Assessment Strategy

CA and final exam

Continuous assessment in this modules presents many opportunities for individual and group work that would include the application of theory in the form of the creation of documention to support the preparation of technical submissions, cinical investigation plan, and post-market surveillance plans.

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 - case study - create a technical submission	30 %	Week 9	1,3,4,5,6
Assignment	Group project - Clinical investigation and surveillance	30 %	Week 14	1,2,3,4,5,6

End of Semester / Year Formal Exam:		**40 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assessment	Final Exam	40 %	Week 15	1,2,3,4,5,6

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

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

Literary Resources

FDA Website for CDRH and CDER
European Directives/ Regulation for Medical Devices
Directive/Regulations for Pharmaceuticals including Directive 2001/83/EC and EudraLex Volume 4
Guidance Documents including MEDDEV's and FDA guidance documents

Other Resources

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

Programme Membership

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