ZLAW C4100: Regulatory Affairs for Pharmaceutics

Module Title:	Regulatory Affairs for Pharmaceutics
Language of Instruction:	English

Credits:	5

NFQ Level:	8

Module Delivered In	1 programme(s)

Teaching & Learning Strategies:	This programme will be delivered via lectures, class discussion, case studies, guest lecture, practical work, E-Learning, group work - collaborative and peer learning, directed and independent learning.

Module Aim:	To prepare the learner for a career in the highly regulated pharmaceutical and medical device sectors.

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Evaluate the regulatory bodies, their guidance and the application of regulations/standards, risk management across the life cycle and guidance within the pharmaceutical and medical device sectors.
LO2	Critique the content of quality management systems, auditing and how quality management systems are operated, applied, managed and reviewed and comply to multiple regulatory bodies and standards.
LO3	Examine the regulatory requirements for the design of a medical device or pharmaceutical product and appraise how clinical trials are regulated and pharmaceutical and medicinal products are evaluated prior to approval and commercialization.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is recommended before enrolment in this module.*
No recommendations listed
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module.*
No incompatible modules listed
Co-requisite Modules
No Co-requisite modules listed
Requirements *This is prior learning (or a practical skill) that is mandatory before enrolment in this module is allowed.*
No requirements listed

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Module Content & Assessment

Indicative Content
Content 1. FDA, EU, and ISO (Regulatory bodies, Regulations, standards and guidance). 2. Quality management systems and harmonization. 3. Design and development (Quality by design). 4. Clinical evaluation of medical devices and pharmaceuticals. 5. Auditing (Maintaining an audit ready status and complying with multiple regulatory standards). 6. Regulatory filings, applications ANDA and NDA. 7. Product programme management, vigilance, surveillance. 8. Risk management (Product life cycle).
Described content 1. Structure and content of guidance documents, regulatory bodies and certification / accreditation agencies. Introducing students to compliance as a discipline and way of operating in an organisation. 2. Standards EU and FDA code of regulations as well as ISO 9001 and ISO 13485. Managing compliance to regulatory bodies in regards to design and development of products. 3. Quality management systems, to develop an understanding in the student of how a medical device or pharma company manages compliance to policies procedures and standards, and manages quality and continuous improvement initiatives. 4. Clinical evaluation of drugs and medical devices this module will demonstrate the type of data required to allow a product undergo clinical evaluation and how an organisation manufactures from the perspective of small scale start up pilot programmes for release of material for clinical trials. 5. Developing auditing as a skill the student will learn how to perform internal audits and prepare for external audits from the FDA, EU, HPRA and other regulatory agencies such as the ISO or INAB. 6. Vigilance this module will illustrate how the healthcare sector manages the safety and efficacy of the products are assured and monitored once on the market. It will also describe how a company responds to customer complaints and complies with regulations regarding serious adverse events and reporting of these events to regulators and national competent authorities? 7. How risk management is applied to medical device and pharmaceuticals across the life cycle of the products. This will develop in the student an understanding of risk as a concept in drug or medical device development as well manufacturing and introduce the terminology documentation and procedures they will be required to complete and adhere to in industry.

Assessment Breakdown	%
Continuous Assessment	40.00%
End of Module Formal Examination	60.00%

Special Regulation
Learners must achieve a minimum grade (35%) on CA and Final Examination

Continuous Assessment

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Written Report	Written report on the regulatory requirements for medical device design	1	20.00	Week 12
Written Report	Report on the regulatory requirements for pharmaco-vigilance surveillance of pharmaceutical products	2	20.00	n/a

No Project

No Practical

End of Module Formal Examination

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	Final written exam	1,2,3	60.00	End-of-Semester

SETU Carlow Campus reserves the right to alter the nature and timings of assessment

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Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Lecture	12 Weeks per Stage	3.00
Independent Learning	12 Weeks per Stage	7.42
	Total Hours	125.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_SAPHA_B	Bachelor of Science (Honours) in Pharmaceutics and Drug Formulation	8	Mandatory