CHEM08026
Introduction to Quality

Full Title	Introduction to Quality		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	08	**ECTS Credits**	05
Module Code	CHEM08026	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences
Module Author	Rita Woodings		
Co Authors	Cormac Quigley		

Module Description

This module will provide the student with knowledge of quality management systems and GMP. The student will be able to apply these GMP practices in regulated industries.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Interpret the regulations, guidelines and standards for a GMP facility and apply the fundamentals of GMP (Good Manufacturing Practice).
2.	Differentiate between QA and QC in the context of a regulated environment.
3.	Create SOP's (Standard Operating Procedures) and other technical documents using regulatory guidelines.
4.	Articulate and report quality non-conformances effectively including using the CAPA process.
5.	Explain the purpose and value of Risk Management, Equipment and Computerized System Validation and Change Control.
6.	Discuss the role of Pharmacopeias in an analytical laboratory.

Indicative Syllabus

Discuss the reason behind and historical development of regulations and regulatory jurisdictions.

Introduction to EU Eudralex Volume 4, relevant US Codes of Federal Regulations and pertinant international standards, including ISO17025.

Recognise the importance of GDP (Good Documentation Practice) and Data Integrity in a GMP regulated analytical test laboratory.

Explore risk management, validation of equipment and computerised systems, change control and CAPA and how all these disciplines are integrated in a GMP environment.

Understand the importance of auditing and training in the context of a controlled industry.

Introduction to Pharmacopeias and explain how reference standards are sourced.

Teaching and Learning Strategy

This module will be delivered as a combination of online lectures, tutorials and workshops. Moodle will be the primary learning technology for communication and accessing lecture material and learning resources.

An initial on-campus day will be used for introductions, sharing of experiences and team building.

Assessment Strategy

Continuous assessment (60%). Examples of assessment include written assignments, quizzes, report preparation and presentation.

Final examination (40%).

Repeat Assessment Strategies

Repeat assessment will be accommodated in line with GMIT Code of Practice No. 3 Student Assessment: Marks & Standards procedures and in compliance with programme board decisions.

Students who fail the theoretical component will be required to retake the theoretical exam at a subsequent exam session.

Where a student has failed the continuous assessment component of the module the nature of assessment will be linked to the need to achieve particular learning outcomes. They may be in the form of a written assessment, written assignment or other relevant assessment.

Individuals may be interviewed or asked to present their work in a formal context to validate authenticity and ownership of work.

Indicative Coursework and Continuous Assessment:		**100 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assessment	Knowledge quizzes	40 %	OnGoing	1,2,4,5,6
Group Project	Risk, CAPA & SOP Assignment	30 %	OnGoing	3,4,5
Assignment	Individual Assignment & Engagement	30 %	OnGoing	1,2,3,4,5,6

Blended Delivery Mode Average Weekly Workload:			**3.12 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Online	1.5	Weekly	1.50
Tutorial	Discussion / Q&A session	Not Specified	1	Weekly	1.00
Other	Introduction and Orientation	Not Specified	8	Once Per Module	0.62

Journal Resources

The links provided below link the student to current regulatory information in multiple jurisdictions and well as supplementary information and training resources.

Online Resources

https://www.fda.gov/

https://www.ich.org/

https://ec.europa.eu/health/documents/eudralex/

https://www.hpra.ie/

https://www.ema.europa.eu/en

https://www.usp.org

https://www.pharmacopeia.com

https://www.edqm.eu

https://www.who.int

https://www.iso.org

Other Resources

Learners are encouraged to access the websites listed within this module. Many standards are available via the GMIT on-line library. Learners will be also directed to the virtual learning environment Moodle for educational resources.

Programme Membership

GA_SAACG_L08 202000 Higher Diploma in Science in Advanced Analytical Chemistry