CHEM08021
Validation and Metrology

Full Title	Validation and Metrology		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	08	**ECTS Credits**	10
Module Code	CHEM08021	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences
Module Author	Frances Martin		
Co Authors	Cormac Quigley, Rita Woodings		

Module Description

This module will provide the student with knowledge of validation and an introduction to metrology as applied in industry. The student will understand the difference between validation and calibration and the importance of each in an industry setting.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Interpret the various regulations, guidelines and standards for Validation and Calibration and understand their importance within GMP (Good Manufacturing Practice).
2.	Examine the major steps involved in Validation of manufacturing operations, including processes, equipment and automated / computerized systems.
3.	Explain the science behind Metrology and the importance of measurement traceability and Calibration within a Quality System.
4.	Describe the role of Computerised Systems and smart instruments, the data they create in the laboratory and how Computerised System Validation (CSV) is carried out
5.	Evaluate laboratory data use, storage and failure handling practices to ensure data integrity in laboratory Computerised Systems and instruments.
6.	Develop an outline approach to an analytical method validation with reference to the ICH Q2 guidance.

Indicative Syllabus

Explore regulatory text and associated guidance documents pertaining to validation and associated activities and examine regulatory findings to develop understanding of the regulators perspective in this area.

Describe the different types of validation required in industry, including facility, process, equipment, computerised system and test method validation and analyse the reason for each type in terms of potential product impact.

Management of computerised systems, instrumentation and electronic records / data throughout their lifecycles, including IQ, OQ and PQ.

Explain requirements specifications and procedures to perform analytical method Validation for assay, impurities and limit tests.

Understand the difference between systems and instruments, and the difference between Validation and Calibration.

Consistency, accuracy and reliability of instrumentation and of measurement results.

Quality system integration points in validation and calibration, e.g. GDP, risk management and change control.

Use workshop sessions to write validation documents, e.g. protocols, reports, and understand the importance of clear technical expression.

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.

Assessment Strategy

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

Final exam (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:		**60 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Open Book Exam	Knowledge quizzes	30 %	OnGoing	1,2,3,4
Assignment	Project work	30 %	OnGoing	4,5,6

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

Blended Delivery Mode Average Weekly Workload:			**5.00 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Online	3	Weekly	3.00
Tutorial	Discussion / Q&A session	Not Specified	2	Fortnightly	1.00
Other	Workshops	Not Specified	2	Fortnightly	1.00

Journal Resources

Online Resources

https://www.fda.gov/

https://www.hpra.ie/

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

https://www.ich.org/

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

Other Resources

Additional Information

Programme Membership

GA_SAACG_L08 202000 Higher Diploma in Science in Advanced Analytical Chemistry