

Module Title:	Validation and Quality
Language of Instruction:	English
Credits:	5
NFQ Level:	7
Module Delivered In	1 programme(s)
Teaching & Learning Strategies:	It is envisaged that this module will prominently take place online using the college VLE Blackboard. Learners will also meet the lecturer face to face at the start of the term and during any planned workshop days during the term. Online class will take place one evening per week. Online lectures will incorporate a mixture of presentations, examples and student exercises/problem-solving, question and answer sessions, group discussions along with online resources.
Module Aim:	The aim of this module is to enable the learner to develop their understanding and knowledge of quality and validation in regulated sectors in the context of Measurement, control and automation technology.
Learning Outcomes	
<i>On successful completion of this module the learner should be able to:</i>	
LO1	Explain terms and concepts relevant to quality and their requirement within regulated industries.
LO2	Explain the principles surrounding quality management systems and how quality management systems are operated, applied, implemented and reviewed.
LO3	Demonstrate knowledge of the principles of validation and regulatory requirements in a regulated industry.
LO4	Develop basic quality/validation documentation, (such as change control, calibration failure protocols, customer complaints and surveillance programmes) for Engineering systems.
Pre-requisite learning	
Module Recommendations <i>This is prior learning (or a practical skill) that is recommended before enrolment in this module.</i>	
No recommendations listed	
Incompatible Modules <i>These are modules which have learning outcomes that are too similar to the learning outcomes of this module.</i>	
No incompatible modules listed	
Co-requisite Modules	
No Co-requisite modules listed	
Requirements <i>This is prior learning (or a practical skill) that is mandatory before enrolment in this module is allowed.</i>	
No requirements listed	

Module Content & Assessment

Indicative Content

Introduction to Quality

The meaning of quality. Measuring quality, inspection, quality control and quality assurance. The customer's specification. Quality in design, planning, purchasing, production, service.

Quality Management Systems.

Quality management systems, to develop an understanding of how a regulated company manages compliance to policies procedures and standards, and manages quality and continuous improvement initiatives. Collection of quality data and use of Statistical Process Control and control charts methods to determine product quality. Reporting and communicating quality related issues.

Validation

Documented evidence, the meaning of validation. Validation policy, validation documentation, qualification. Process validation. Cleaning validation. Analytical method validation

Regulatory bodies, Regulations, Standards and Guidance

Structure and content of guidance documents, regulatory bodies and certification / accreditation agencies. The function of audits, internally by quality departments and externally by regulatory agencies such as the FDA, EU, HPRA, ISO and INAB.

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

Continuous Assessment

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Essay	Essay on the role of Quality in regulatory environments.	1,2	10.00	Week 3
Essay	Essay on the need for Validated systems and how they are implemented.	1,2,3	10.00	Week 6
Case Studies	Case study on implementing a potential engineering change to a validated system outlining the steps required to implement the change.	3,4	20.00	Sem 1 End

No Project

No Practical

End of Module Formal Examination

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Formal Exam	Written Exam	1,2,3	60.00	End-of-Semester

Continuous Assessment

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Essay	Essay on the role of Quality in regulatory environments.	1,2	10.00	Week 3
Essay	Essay on the need for Validated systems and how they are implemented.	1,2,3	10.00	Week 6
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No Project

No Practical

End of Module Formal Examination

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Formal Exam	Written Exam	1,2,3	60.00	End-of-Semester

Module Workload

Workload: Full Time		
<i>Workload Type</i>	<i>Frequency</i>	<i>Average Weekly Learner Workload</i>
Online Learning (Moderated)	Every Week	2.00
Independent Learning Time	Every Week	7.00
Total Hours		9.00

Workload: Part Time		
<i>Workload Type</i>	<i>Frequency</i>	<i>Average Weekly Learner Workload</i>
Online Learning (Moderated)	Every Week	2.00
Independent Learning Time	Every Week	7.00
Total Hours		9.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_EMIMC_D	Batchelor of Science in Industrial Measurement and Control	1	Mandatory