Title:	Strategic Quality Management APPROVED
Long Title:	Strategic Quality Management

Module Code:	CHEM9002	**Duration:**	1 Semester

Credits:	10
NFQ Level:	Expert
Field of Study:	Chemistry
Valid From:	Semester 1 - 2021/22 (September 2021)
Module Delivered in	2 programme(s)
Module Coordinator:	Donagh OMahony
Module Author:	Grainne Conneely
Module Description:	The module aims to provide the student with an in-depth understanding of the theory, practices and implementation of advanced quality methodologies such as Leadership, Six Sigma and Lean Manufacturing.

Learning Outcomes	
On successful completion of this module the learner will be able to:	
LO1	Manage and integrate the strategic elements of a quality management system
LO2	Implement the appropriate quality standards and integrate with relevant quality strategies
LO3	Create an integrated documentation system for regulatory reference documents.
LO4	Create a solution to a quality related problem as part of a industry based project involving the principles of Quality Management relevant to a regulated environment
LO5	Interpret and discuss the regulatory framework and requirements governing the validation, production, testing and procurement products in a regulated environment.
LO6	Synthesise the key factors for staff motivated in applying Six Sigma and Lean principles.
LO7	Critically evaluate validation activities, documentation and technology transfer, including integrated management systems

Pre-requisite learning

Module Recommendations
This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named CIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).

Incompatible Modules
These are modules which have learning outcomes that are too similar to the learning outcomes of this module. You may not earn additional credit for the same learning and therefore you may not enrol in this module if you have successfully completed any modules in the incompatible list.

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. You may not enrol on this module if you have not acquired the learning specified in this section.

No requirements listed

Module Content & Assessment

Indicative Content
Strategic Quality Management and Strategic Thinking Quality Evolution and Concepts, Evaluation of Strategic Management, Strategic Thinking versus Strategic Planning in Quality Departments, Roles and responsibilities.
Elements of a Quality Management System Strategies for implementation of a QMS, supplier and customer related processes, design and development, resource management, monitoring and measurement, documentation control. Key elements of QMS (CAPA, Risk management, Control of non-conformances, Change Control, Continuous Improvement, Auditing, Process control), Strategy for Risk based decision .
Quality Standards Standards, Regulatory bodies and Certification relevant to the analyst. Role of Auditing and Assessment. Laboratory Accreditation (e.g. ISO17025).
The role of the analyst in a regulated environment Phases of drug development, analytical testing at each stage. Stability testing, Regulatory and guidance documents. Laboratory controls and compliance. Dealing with non conformances (e.g. OOS).
Integrated Management Systems Analytical method selection, development, optimisation and validation requirements (ICH Q2, Eurachem documents etc). Measurement uncertainty. Technology transfer for analytical methods.
Managing for Quality Importance of the culture of an organisation for successful QMS. Employee involvement and empowerment, process management. Leadership & Management commitment to a QMS, Teamwork, continuous improvement and systematic approach to problem solving. Use of quality tools and techniques.
Six Sigma and Lean Programmes Use of Quality tools and techniques, introducing the methods and tools for interpretation of customer requirements for service design and operation (Lean thinking; Six sigma; project planning; process mapping; RCA; statistics; data visualisation; effective decision making)
Validation Role of validation in a Quality System. Systematic approach to validation of systems in a regulated environment
Data Integrity Data Integrity, ALCOA+ Principles

Assessment Breakdown	%
Course Work	100.00%

Course Work

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Project	Practical project on quality issues in an organisation.	3,4,5	40.0	Week 10
Presentation	Produce an oral presentation on the outcomes of team solving problems undertaken throughout the semester	1,2,3	60.0	Every Second Week

No End of Module Formal Examination

Reassessment Requirement
Coursework Only *This module is reassessed solely on the basis of re-submitted coursework. There is no repeat written examination.*

The institute reserves the right to alter the nature and timings of assessment

Module Workload

Workload: Full Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Lecture on course material	2.0	Every Week	2.00
Tutorial	Tutorial on course material	2.0	Every Week	2.00
Independent & Directed Learning (Non-contact)	Personal study	10.0	Every Week	10.00
			Total Hours	14.00
			Total Weekly Learner Workload	14.00
			Total Weekly Contact Hours	4.00

Workload: Part Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Lecture on course material	2.0	Every Week	2.00
Tutorial	Tutorial on course material	2.0	Every Week	2.00
Independent & Directed Learning (Non-contact)	Personal Study	10.0	Every Week	10.00
			Total Hours	14.00
			Total Weekly Learner Workload	14.00
			Total Weekly Contact Hours	4.00

Module Resources

Recommended Book Resources

- **David Hoyle 2009, *ISO 9000 Quality Systems Handbook-updated for ISO 9000:2008*, 6th Ed., Routledge [ISBN: 9781138188648]**
- **John S. Oakland 2004, *Oakland on Quality*, 3rd Ed., Routledge [ISBN: 9780750657419]**
- **D.L. Goetsch & S. Davis 2014, *Quality Management for Organisational Excellence*, Pearson U.S. [ISBN: 9781292022338]**

Supplementary Book Resources

- **National Standards Authority of Ireland, *IS EN ISO 9000:2015 Series***

This module does not have any article/paper resources

Other Resources

- **Website: *US Food and Drug Administration***
  http://www.fda.gov
- **Website: *HPRA***
  http://www.hpra.ie
- **Website: *ISO***
  http://www.iso.org
- **Website: *EMA***
  http://www.ema.europa.eu/en

Module Delivered in

Programme Code	Programme	Semester	Delivery
CR_SASIV_9	MSc in Analytical Sciences with Instrument Validation	2	Mandatory
CR_SANIV_9	Postgraduate Diploma in Analytical Sciences with Instrument Validation	2	Mandatory