Title:	Validation of Quality Systems APPROVED
Long Title:	Validation of Quality Systems

Module Code:	CHEM8012	**Duration:**	1 Semester

Credits:	5
NFQ Level:	Advanced
Field of Study:	Chemistry
Valid From:	Semester 1 - 2020/21 (September 2020)
Module Delivered in	1 programme(s)
Module Coordinator:	Donagh OMahony
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Module Description:	In this module students will learn about the validation of systems in a GMP environment. Students will become proficient in Computer Systems Validation within a Quality Management System in context of highly regulated industries, such as pharmaceutical manufacturing and medical device industries.

Learning Outcomes	
On successful completion of this module the learner will be able to:	
LO1	Understand the fundamentals of a validation process
LO2	Demonstrate an understanding of the principles of Computer Systems Validation
LO3	Exercise appropriate judgement and a mastery of skills in applying a Risk Based approach for validation
LO4	Demonstrate the ability to critically review and analyse the regulatory requirements of validation
LO5	Demonstrate the ability to use advanced skills to evaluate and plan a computer systems validation exercise with relevant documentation requirements

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 MTU 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
Overview of Validation Basic principles and requirements of validation including Process (Batch, Continuous Manufacturing and Continuous Process Verification), Cleaning, Utilities, Analytical Method and Computer Systems Validation. Regulatory guidance on validation.
Systems and Environments An overview of the types of systems for Validation (Test/Non-Production, QC systems, Manufacturing, IT), Validation Environments (Development, Quality Assurance, Production, Non-Production). Activities performed in each environment.
Regulatory Requirements Review of the regulatory requirements, requirements of 21CFR part 11 and Annex 11, background and purpose of part 11, audit trail requirements, security & access levels, Electronic records/Electronic Signatures (ERES), passwords, unique IDs, auto logout. Spreadsheet Validation. Highlight differences and similarities of 21CFR11 and Annex 11. Review of Warning Letters.
Validation overview for Computer Systems Validation Risk-based approach, V-model for CSV (GAMP), GAMP as applied to Computer Systems, GAMP Principles. Backup and restoration, disaster recovery, Change Control, Business Continuity, Source code review, computer systems support and maintenance, computer systems delivery, risk evaluation, periodic review, physical and logical security.
Data Integrity ALCOA+ Principles, segregation of duties, practical approach to audit trail review, data lifecycle diagrams, data Integrity assessments, falsification of data, requirements of QC Systems / Manufacturing Systems / IT Systems, additional controls for weak audit trails.

Assessment Breakdown	%
Course Work	100.00%

Course Work

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	Multiple Choice Questions / Short Answer Questions	1,2,4	30.0	Week 6
Other	Produce a report (approx 3000 words) and a presentation on an assigned case study.	3,5	40.0	Week 10
Project	Project assignment on the role of CSV in record intergrity.	1,3,4,5	30.0	Sem End

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	Theory	1.0	Every Week	1.00
Tutorial	Application of theory and principles, teamwork problem solving	1.0	Every Week	1.00
Independent & Directed Learning (Non-contact)	Lecturer and Self-directed Study	5.0	Every Week	5.00
			Total Hours	7.00
			Total Weekly Learner Workload	7.00
			Total Weekly Contact Hours	2.00

Workload: Part Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Theory	1.0	Every Week	1.00
Tutorial	Application of Theory and principles, teamwork problem solving	1.0	Every Week	1.00
Independent & Directed Learning (Non-contact)	Lecturer and Self Directed Study	5.0	Every Week	5.00
			Total Hours	7.00
			Total Weekly Learner Workload	7.00
			Total Weekly Contact Hours	2.00

Module Resources

Recommended Book Resources

- **Orlando Lopez 2018, *Pharmaceutical and Medical Devices Manufacturing Computer Systems Validation* [ISBN: 9781138041189]**
- **John R. Sharp 2005, *Good pharmaceutical manufacturing practice: rationale and compliance* [ISBN: 0849319943]**

Supplementary Book Resources

- **ISPE 2008, *The GAMP Guide for Validation of Automated Systems* [ISBN: 1931879613]**
- **Anurag S Rathore, Gail K. Sofer 2012, *Process validation in manufacturing of biopharmaceuticals* [ISBN: 9781439850930]**
- **Syed Imtiaz Haider, Erfan Syed Asif 2018, *Quality control training manual; comprehensive training guide for API, finished pharmaceutical and biotechnologies laboratories* [ISBN: 1138077526]**

This module does not have any article/paper resources

Other Resources

- **Website: *Food and Drug Administration***
  http://www.fda.gov
- **Website: *Health Products Regulatory Authority***
  http://www.hpra.ie
- **Website: *EU GMP Guidelines***
  https://ec.europa.eu/health/documents/eu dralex/vol-4_en
- **Website: *International Medical Device Regulators Forum***
  http://www.imdrf.org
- **Website: *International Council for Harmonisation***
  http://www.ich.org

Module Delivered in

Programme Code	Programme	Semester	Delivery
CR_SQSDA_8	Higher Diploma in Science in Quality Systems Validation with Data Analytics	1	Mandatory