

**APPROVED****CHEM6008: Quality & Validation****Module Details**

<b>Module Code:</b>	CHEM6008
<b>Title:</b>	Quality & Validation <b>APPROVED</b>
<b>Long Title:</b>	Quality and Validation
<b>NFQ Level:</b>	Fundamental
<b>Valid From:</b>	Semester 1 - 2019/20 ( September 2019 )
<b>Duration:</b>	1 Semester
<b>Credits:</b>	5
<b>Field of Study:</b>	4421 - Chemistry
<b>Module Delivered in:</b>	<a href="#">7 programme(s)</a>
<b>Module Description:</b>	This is an introductory course aimed at those studying laboratory-based science courses, which seeks to give learners an overview of the role of quality within industry.

**Learning Outcomes**

On successful completion of this module the learner will be able to:

#	Learning Outcome Description
LO1	Explain terms and concepts relevant to quality
LO2	Describe the interrelationships among product design, materials, personnel, manufacturing processes, final output, and the inspection/testing/analysis function within manufacturing industry.
LO3	Outline regulatory requirements in modern chemical and pharmaceutical industries
LO4	Introduction to quality documentation

**Dependencies****Module Recommendations****Incompatible Modules**

No incompatible modules listed

**Co-requisite Modules**

No Co-requisite modules listed

**Requirements**

No requirements listed

**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.

**The role of quality control**

Specifications and inspection procedures. Attributes and variables. Inspection & test. Raw materials inspection. Sampling theory. The role of the testing laboratory. Acceptance testing.

**Human aspects of Quality**

The role of the human in the achievement of quality. A people based philosophy. Motivation, involvement, problem solving in teams. Introduction to problem solving tools. Empowerment. Introduction to workplace ethics.

**Regulatory Requirements**

Role of regulatory bodies. Control of the conditions of manufacture and testing. Health Products Regulatory Authority, US Food and Drug Administration, European Medicines Agency, International Conference on Harmonisation, ISO, NIST, etc.

**Documentation**

Why document? regulatory requirements, different types of documents and their roles. Elements of a documentation system.

**Validation**

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

**Module Content & Assessment**

Assessment Breakdown	%
Coursework	100.00%

**Assessments**

Coursework			
<b>Assessment Type</b>	Practical/Skills Evaluation	<b>% of Total Mark</b>	40
<b>Timing</b>	Every Second Week	<b>Learning Outcomes</b>	1,2,3,4
<b>Assessment Description</b> Approximately 4 in-class and/or homework exercises submitted during the semester, to include teamwork and participation			
<b>Assessment Type</b>	Project	<b>% of Total Mark</b>	20
<b>Timing</b>	Week 11	<b>Learning Outcomes</b>	4
<b>Assessment Description</b> Short project or written report to be submitted and orally presented near end of semester			
<b>Assessment Type</b>	Short Answer Questions	<b>% of Total Mark</b>	40
<b>Timing</b>	Sem End	<b>Learning Outcomes</b>	1,2,3,4
<b>Assessment Description</b> Written assessment of course material held in last week of the course			

No End of Module Formal Examination

**Reassessment Requirement****Repeat examination**

Reassessment of this module will consist of a repeat examination. It is possible that there will also be a requirement to be reassessed in a coursework element.

## Module Workload

Workload: Full Time					
Workload Type	Contact Type	Workload Description	Frequency	Average Weekly Learner Workload	Hours
Lecture	Contact	Theory	Every Week	2.00	2
Lab	Contact	Team exercises and group work	Every Week	1.00	1
Independent & Directed Learning (Non-contact)	Non Contact	Personal study	Every Week	4.00	4
Total Hours					7.00
Total Weekly Learner Workload					7.00
Total Weekly Contact Hours					3.00

  

Workload: Part Time					
Workload Type	Contact Type	Workload Description	Frequency	Average Weekly Learner Workload	Hours
Lecture	Contact	Theory	Every Week	2.00	2
Lab	Contact	Team exercises and group work	Every Week	1.00	1
Independent & Directed Learning (Non-contact)	Non Contact	Personal study	Every Week	4.00	4
Total Hours					7.00
Total Weekly Learner Workload					7.00
Total Weekly Contact Hours					3.00

## Module Resources

### Recommended Book Resources

Michael J. Fox. (2014), Quality Assurance Management, 3rd. Springer, U.K., [ISBN: 9781489971418].  
 Donna C. Summers,. (2009), Quality, 6th. Pearson, U.K., [ISBN: 978013441327].

### Supplementary Book Resources

Gregory B. Hutchins. (1991), Introduction to Quality, [ISBN: 0675208963].  
 Stanley Nusim. (2009), Active Pharmaceutical Ingredients, 2nd. Taylor Francis, U.s., [ISBN: 9781439803363].  
 Anna Gravells. (2016), Principles and Practices of Quality Assurance, SAGE, U.K., [ISBN: 9781473973428].

*This module does not have any article/paper resources*

### Other Resources

Website, US Food and Drug Administration (FDA). 21 CFR 210/211,  
<http://www.fda.gov>  
 Website, International Conference on Harmonisation (ICH). Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7,  
<http://www.ich.org>

## Module Delivered in

Programme Code	Programme	Semester	Delivery
CR_SCHQA_8	<a href="#">Bachelor of Science (Honours) in Analytical Chemistry with Quality Assurance</a>	-1	Elective
CR_SESST_8	<a href="#">Bachelor of Science (Honours) in Environmental Science and Sustainable Technology</a>	-1	Elective
CR_SINEN_8	<a href="#">Bachelor of Science (Honours) in Instrument Engineering</a>	-1	Elective
CR_SCHEM_7	<a href="#">Bachelor of Science in Analytical and Pharmaceutical Chemistry</a>	-1	Elective
CR_SPHYS_7	<a href="#">Bachelor of Science in Applied Physics and Instrumentation</a>	-1	Elective
CR_SPHYS_6	<a href="#">Higher Certificate in Science in Applied Physics and Instrumentation</a>	-1	Elective
CR_SCHEM_6	<a href="#">Higher Certificate in Science in Chemistry</a>	-1	Elective