

APPROVED

CHEM7006: QA for Chemists

Module Details	
Module Code:	CHEM7006
Title:	QA for Chemists APPROVED
Long Title:	Quality Assurance for the Chem
NFQ Level:	Intermediate
Valid From:	Semester 1 - 2019/20 (September 2019)
Duration:	1 Semester
Credits:	5
Field of Study:	4421 - Chemistry
Module Delivered in:	2 programme(s)
Module Description:	This course aims to give chemical analysts an understanding of the nature of quality and its role in the chemical industry.

Learning Outcomes	
On successful completion of this module the learner will be able to:	
#	Learning Outcome Description
LO1	Explain the role of quality within an organisation
LO2	Outline how quality applies to manufacturing and testing in the chemical and pharmaceutical industries, including the role of Good Manufacturing Practice (GMP) and Quality Management Systems (QMS).
LO3	Construct and explain charts designed to aid in the control of variability of processes
LO4	Describe the elements of quality as they apply to the analytical chemistry laboratory
Dependencies	
Module Recommendations	
13363	CHEM7006 QA for Chemists
Incompatible Modules	
No incompatible modules listed	
Co-requisite Modules	
No Co-requisite modules listed	
Requirements	
No requirements listed	

Indicative Content
Quality Basics Identifying and understanding quality. Quality in all areas: marketing, specification, design, purchasing, production, inspection, measurement, packaging, storage, service.
Quality for Process Industries The management of quality for chemical, pharmaceutical and related industries. Outline of a quality management system (e.g. ISO 9000). Regulations such as 21CFR 211 and/or ICH Q7 as they relate to: suitability of equipment, SOPs, validation of processes, traceability, laboratory controls, documentation and records, control of nonconforming product etc.
Understanding variability in processes Frequency distribution curves and their presentation. Normal distribution and standard deviation. Specification limits vs Process capability. Standardised normal curve and calculation of process capabilities. Process capability indices. Quality control charts, central limit theorem, Shewhart charts. Control charts for variables - Mean and range charts. Control charts for attributes. CUSUM charts.
Quality for the laboratory Overview of quality assurance in the analytical chemistry laboratory including such topics as: sampling, statistical principles, validation, documentation, equipment calibration & maintenance, reference materials & their traceability, internal and external QC, Laboratory accreditation, Auditing and Ethics.

Module Content & Assessment	
Assessment Breakdown	%
Coursework	100.00%

Assessments

Coursework			
Assessment Type	Short Answer Questions	% of Total Mark	15
Timing	Week 5	Learning Outcomes	1,2
Assessment Description Theory test			
Assessment Type	Essay	% of Total Mark	15
Timing	Week 8	Learning Outcomes	1,2,4
Assessment Description Complete an in-class essay on a topic which has been assigned and researched in advance			
Assessment Type	Project	% of Total Mark	20
Timing	Week 12	Learning Outcomes	1,2,4
Assessment Description Practical quality, written/verbal communications in teams - e.g. prepare a written report and/or an oral presentation on a quality topic; to be completed late semester			
Assessment Type	Other	% of Total Mark	50
Timing	Sem End	Learning Outcomes	1,2,3,4
Assessment Description 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 and discussion classes	Every Week	2.00	2
Lab	Contact	Practical skills development	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 and discussion classes	Every Week	2.00	2
Lab	Contact	Practical skills development	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

Donna C. Summers., (2009), Quality, 6th. Pearson, London, [ISBN: 9780134413273].
James Miller. (2018), Statistics and Chemometrics for Analytical Chemistry.

Supplementary Book Resources

Elizabeth Prichard and Vicki Barwick. (2007), Quality assurance in analytical chemistry, [ISBN: 0470012048].
NSAI. (2015), IS EN ISO: 9001:2015.
D.H. Besterfield. (2009), Quality control, Prentice Hall Ptr, Upper Saddle River, [ISBN: 0135000955].
Kehoe D.F.. (1996), The Fundamentals of Quality Management, [ISBN: 041262690X].
David Hoyle. (2007), Quality Management Essentials, Routledge, U.s., [ISBN: 9780750667869].

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). GMP Guide for Active Pharmaceutical Ingredients Q7 and other relevant documents, <http://www.ich.org>
Website, Eurachem. Several relevant documents, <http://www.eurachem.org>

Module Delivered in

Programme Code	Programme	Semester	Delivery
CR_SCHQA_8	Bachelor of Science (Honours) in Analytical Chemistry with Quality Assurance	-1	Mandatory
CR_SCHEM_7	Bachelor of Science in Analytical and Pharmaceutical Chemistry	-1	Mandatory