This Version is No Longer Current
The latest version of this module is available here

MODULE DESCRIPTOR

Module Title

Quality Assurance & Regulations For Industry

Reference	AS3147	Version	2
Created	February 2018	SCQF Level	SCQF 9
Approved	February 2018	SCQF Points	15
Amended	July 2018	ECTS Points	7.5

Aims of Module

To provide the student with the ability to understand the importance of quality assurance and quality regulations within organisations, and explore approaches to the assurance and improvement of quality.

Learning Outcomes for Module

On completion of this module, students are expected to be able to:

1	Discuss the role of quality, quality systems, and their relevance in bioindustry.
2	Discuss quality tools and techniques which are employed to assess and improve quality in an organisation.
3	Define the purpose of audit, and evaluate the different types of audit.

Indicative Module Content

Definitions of Quality; The role of Quality in industry; Cost of poor quality; Reliable results; Calibration; Quality control; Quality assurance; Quality system; Reference materials and method of validation; Traceability; Measurement of uncertainty; Good laboratory practice; Standard operating procedures; Measuring and monitoring Quality; Quality systems; Laboratory accreditation; ISO 9000/9001; ISO 15189; ISO 13845; Cultures of quality; Audit; Continuous quality improvement; External Quality assessment; Corrective action plan; Understanding and complying with FDA and CE marking requirements; Lifecycle of a medical device/pharmaceutical product.

Module Delivery

A combined approach utilising formal lectures, seminars, directed reading and tutorials.

Indicative Student Workload	Full Time	Part Time
Contact Hours	30	N/A
Non-Contact Hours	120	N/A
Placement/Work-Based Learning Experience [Notional] Hours	N/A	N/A
TOTAL	150	N/A
Actual Placement hours for professional, statutory or regulatory body		

Module Ref:	AS3147 v2

ASSESSMENT PLAN

If a major/minor model is used and box is ticked, % weightings below are indicative only.

Component 1

Type:	Coursework	Weighting:	100%	Outcomes Assessed:	1, 2, 3
Description:	The module will be assessed by a coursework evaluating the outcome of two horizontal audits.				

MODULE PERFORMANCE DESCRIPTOR

Explanatory Text

This module is assessed using the one component detailed in the Assessment Plan. To pass this module, candidates must achieve a Module Grade D or better.

Module Grade	Minimum Requirements to achieve Module Grade:
A	Final aggregate mark of 70% or greater
B	Final aggregate mark of between 60-69%
C	Final aggregate mark of between 50-59%
D	Final aggregate mark of between 40-49%
E	MARGINAL FAIL. Final aggregate of between 35-39%
F	FAIL. A mark of less than 35%
NS	Non-submission of work by published deadline or non-attendance for examination

Module Requirements

Prerequisites for Module	Successful completion of Stage 2 of the BSc (Hons) Applied Bioscience, MEng Electronic and Biomedical Technology, MEng Mechanical and Biomedical Technology. Successful admission to the MSc Biomedical Technology, or equivalent.
Corequisites for module	None.
Precluded Modules	None.

INDICATIVE BIBLIOGRAPHY

1	HOYLE, D. *ISO 9000 Quality Systems Handbook - updated for the ISO 9001: 2015 Standard.* Current Edition.: Routledge.
2	Beckford, J. *Quality: a critical introduction.* Current Edition.: Routledge.
3	OAKLAND, JS. *Total quality management and operational excellence.* Current Edition.: Routledge.
4	Detailed lists are provided by academic staff to reflect the subject matter.