MODULE DESCRIPTOR

Module Title

Quality Assurance, Regulation and Medical Ethics

Reference	ASM148	Version	1
Created	March 2018	SCQF Level	SCQF 11
Approved	March 2018	SCQF Points	15
Amended		ECTS Points	7.5

Aims of Module

To enable the student to understand quality assurance and regulations within organisations to improve quality. To provide the students with a theoretical knowledge of medical ethics. To enable the student to understand the importance of medical ethics in relation to the use of biomedical technology.

Learning Outcomes for Module

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

1	Critically discuss quality tools and techniques which are employed to assess and improve quality in an organisation.
2	Critically discuss the importance of medical ethics framework in the context of biomedical technology.
3	Demonstrate a critical understanding of the use of quality audit procedures.

Indicative Module Content

Definitions of Quality; The role of Quality in industry; Cost of poor quality; Calibration; Quality control; Quality assurance; Quality system; Reference materials and method of validation; Traceability; Good laboratory practice; 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. Medical ethics; relevance of ethics in the use and testing of medical devices.

Module Delivery

This module is delivered with a mix of lectures and tutorials supplemented by directed reading and seminars.

Module Ref:	ASM148 v1

Indicative Student Workload	Full Time	Part Time
Contact Hours	24	N/A
Non-Contact Hours	126	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		

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:	A quality management report for a particular device.				

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 mark of 70% or greater
B	Final mark of between 60-69%
C	Final mark of between 50-59%
D	Final mark of between 40-49%
E	MARGINAL FAIL. Final mark 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	None.
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	SAVAR, M. *Quality Assurance and Management.* Current Edition.: InTech.
3	SCHWARTZ, L, PREECE, PE, HENDRY, RA. *Medical Ethics: A Case-Based Approach.* 2002. Saunders Elsevier
4	Detailed lists are provided by academic staff to reflect the subject matter.