Module Title:	Quality Management, Experimental Design and Data Analysis
Language of Instruction:	English

Credits:	10

NFQ Level:	7

Module Delivered In	3 programme(s)

Teaching & Learning Strategies:	This module will be taught in four theory classes and four computer practical classes per week. It will be delivered using a blended learning approach. Lectures will be given to provide a structured framework for the learning outcomes and to explain concepts. Students will work in supervised and unsupervised groups. To develop a structured approach to problem solving. Access to on-line resources will be encouraged and facilitated in the computing classes. Practical sessions in SPSS will run during the schedule.

Module Aim:	The aim of this module is to give students an overview of quality management systems and develop their understanding of statistical concepts and techniques as used in science and industry.

Learning Outcomes
On successful completion of this module the learner should be able to:

LO1	Describe the process model of quality, different quality management systems, standardisation, accreditation and continuous quality improvement methodologies.
LO2	Apply statistical tools to explore the relationship between variables and be able to interpret statistical information to be able to analyse data for problem solving.
LO3	Analyse a wide range of data from experiments. using laboratory practicals to demonstrate problem solving techniques and team working to analyse and interpret data. Both statistical and quality analysis tools will be developed.
LO4	Describe key elements required for consideration in the design of experiments and analyses experimental data.
LO5	Apply the strategies involved in lean and auditing and compliance within the Pharmaceutical and food sectors
LO6	Describe and discuss the role of Quality Systems, Documentation, Validation, Compliance and how Regulatory control fits into the Pharma sector.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is recommended before enrolment in this module.*
No recommendations listed
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module.*
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.*
Successful completion of year 2 or equivalent

Module Content & Assessment

Indicative Content

Quality Management: Continuous Quality Improvement
Definitions of quality, quality control, quality assurance and quality management. Principles of a quality system, TQM and quality philosophies. Process model of quality and Quality by Design, consumer protection and product safety. Problem solving techniques for process improvement. Lean Six Sigma Methodology.

Quality Management:
Definitions of standards and standardisation. Rationale, development and structure of standards. Standards and Regulations. National and international bodies and schemes including NSAI, INAB, ISO, BRC and EIQA, method validation. Standards supporting innovation.

Quality Management: Quality Management Systems
ISO 9000 family. ISO 9001 and the seven quality management principles. Alignment of ISO 9001 with other standards, e.g. ISO 14001; Environmental Mgt Systems, ISO 22000; Food Safety Mgt Systems and ISO17025; General Requirements for the Competence of Calibration and Testing Laboratories.

Quality Management: Management
Levels of management, roles and responsibilities. Quality meetings, team building, team working, motivation, leadership and managing change. Project planning, setting objectives and meeting milestones. Producing deliverables and project evaluation.

Quality Management: Auditing
Internal and external auditing. Role of an auditor and the auditing team. Designing, planning and implementing an audit. Audit tools and checklists. Audit close out and management review.

Statistics and Experimental Design: Probability Essentials
Overview of continuous and discrete distributions including hypergeometric and negative binomial distributions. Conditional probability and Bayes Theorem.

Statistics and Experimental Design: Hypothesis testing
Review of formulation of hypotheses. Understanding p-values and statistical significance, one sample problems, confidence interval for the mean, one-sample Student's t test.

Statistics and Experimental Design:Two sample Problems
Student's t test for paired and unpaired situations. Matched and repeated measures designs.

Statistics and Experimental Design: Principles of experimental design
Principles of good data management and data visualization. Understanding and interpreting treatment effects. Introduction to experimental design. The analysis of variance (ANOVA) technique.

Statistics and Experimental Design: Many factors problems
Understand which type of analysis is appropriate to address specific research questions. Randomisation, replication and controls, use of random numbers in treatment allocation. Completely randomised design, blocking and randomised block design, Latin square designs, introduction to factorial experimental designs, two-factor ANOVA with and without replication

Assessment Breakdown	%
Continuous Assessment	10.00%
Practical	50.00%
End of Module Formal Examination	40.00%

Special Regulation

Students must achieve a minimum grade (35%) in both the practical/CA and final examination.

Continuous Assessment

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Examination	Quality management and experimental design CA exams and data analysis.	1,2,3,4,5,6	10.00	n/a

No Project

Practical

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Practical/Skills Evaluation	Computer practicals and assessments.	1,2,3,4,5,6	50.00	n/a

End of Module Formal Examination

Assessment Type	Assessment Description	Outcome addressed	% of total	Assessment Date
Formal Exam	Written examination.	1,2,3,4,5,6	40.00	End-of-Semester

SETU Carlow Campus reserves the right to alter the nature and timings of assessment

Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Lecture	12 Weeks per Stage	4.00
Practicals	12 Weeks per Stage	4.00
Estimated Learner Hours	15 Weeks per Stage	10.27
	Total Hours	250.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_SABTP_B	Bachelor of Science (Honours) in Biosciences with Biopharmaceuticals	5	Mandatory
CW_SAPHA_B	Bachelor of Science (Honours) in Pharmaceutics and Drug Formulation	5	Mandatory
CW_SAASC_D	Bachelor of Science in Analytical Science	5	Mandatory

Programme Code	Programme	Semester	Delivery
CW_SABTP_B	Bachelor of Science (Honours) in Biosciences with Biopharmaceuticals	5	Mandatory
CW_SAPHA_B	Bachelor of Science (Honours) in Pharmaceutics and Drug Formulation	5	Mandatory