ZPHA C3100: Pharmaceutical Processing and Process Analytical Technologies

Module Title:	Pharmaceutical Processing and Process Analytical Technologies
Language of Instruction:	English

Credits:	5

NFQ Level:	7

Module Delivered In	2 programme(s)

Teaching & Learning Strategies:	The module will be taught in two 2-hour theory lectures per week and ten 3-hour practicals per semester. Blended learning approaches will be incorporated. Lectures will provide a structured framework to enable fulfilment of the learning outcomes. Industry-relevant case studies will be included. Learners will work in a supervised laboratory environment while being encouraged to develop their ability to work independently and their problem-solving skills. Access to on-line resources will be encouraged.

Module Aim:	The aim of this module is to give students an overview of the scientific principles underpinning pharmaceutical manufacturing processes, the principles of process control and monitoring, and the principles and implementation of Process Analytical Technology (PAT).

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Describe and apply the principles of process control and compare and select sensors and actuators for process control applications.
LO2	Describe important processing steps in pharmaceutical manufacturing, compare the features of different reactor types, explain the properties and functions of excipients used in tablet formulations.
LO3	Describe the theory and application of chemometrics, select chemometric data models, develop and validate models such as design spaces and data bases for use in PAT in-line or at-line process monitoring.

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.*
No requirements listed

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Module Content & Assessment

Indicative Content
PAT Process technology Processing: Process control: Basic principles, on/off control, feedback and feedforward control, PID control, case studies. Sensors and actuators: Sensors for pressure, flow, and liquid level; Pumps and valves; Chemical sensors for process monitoring. Chemical reactors: Reactor types – batch reactors, plug flow reactors, continuous stirred-tank reactors, semi-batch reactors; Non-ideal flow and residence time distribution; Scale-up issues. Important processes in pharmaceutical manufacturing: Crystallisation, Filtration, Centrifugation, Drying, Milling, Blending. Tablet production processes: Properties and functions of tableting excipients; Wet and dry granulation; Tableting machines. PAT: Chemo-metrics, to introduce the learner to the theory and application of chemo-metrics, concepts and strategies. To illustrate how using multivariate statistics, applied mathematics and computer science in combination can lead to the ability to measure chemical and biological processes or issues in real time. (Sampling) To demonstrate how and when to sample a chemical or biological process. As well as define how sampling techniques such as bootstrap permutation and cross-validation can be used to verify the performance of PAT analytical methods. To provide the learner with the skills and ability to use spectroscopic data to produce mathematical models. As well as the rationale to select appropriate data models, calibrate instrumentation and identify outliers or spurious data points. Finally the process and procedures required to develop and validate PAT methods will be described and demonstrated in both theoretical and laboratory settings.

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

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	n/a	1,2,3	10.00	Week 8

No Project

Practical				
Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	Laboratory experimental procedures and concepts will be documented by the learner and their ability to practically perform the experiment and theoretically evaluate the results of the experiment and demonstrate the understanding of the scientific concepts involved will be assessed.	1,3	40.00	Every Week

End of Module Formal Examination				
Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	Formal exam	1,2,3	50.00	End-of-Semester

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

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Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Lecture	12 Weeks per Stage	4.00
Laboratory	12 Weeks per Stage	2.50
Estimated Learner Hours	15 Weeks per Stage	3.13
	Total Hours	125.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_SAPHA_B	Bachelor of Science (Honours) in Pharmaceutics and Drug Formulation	6	Mandatory
CW_SAASC_D	Bachelor of Science in Analytical Science	6	Mandatory