Title:	Process Analytical Technology APPROVED
Long Title:	Process Analytical Technology

Module Code:	PHYS8017	**Duration:**	1 Semester

Credits:	5
NFQ Level:	Advanced
Field of Study:	Physics
Valid From:	Semester 1 - 2019/20 (September 2019)
Module Delivered in	3 programme(s)
Module Coordinator:	Donagh OMahony
Module Author:	David Goulding
Module Description:	Process Analytical Technologies (PAT) involves the design, analysis and control of pharmaceutical manufacturing materials and processes through on/in-line measurement of the critical process parameters and quality attributes, to generate finished products of acceptable quality. The core idea of PAT is to generate product quality information in real time. PAT focuses on the use of in-line testing using near-infrared, Raman and other physiochemical and chemometric techniques for process monitoring, rather than traditional methodologies based on temperature, pressure, flow, pH and other physical measurements.

Learning Outcomes	
On successful completion of this module the learner will be able to:	
LO1	Explain and analyse the physical principles that underpin the application of physiochemical techniques to manufacturing process control technology.
LO2	Explain and demonstrate the principles and application of chemometric techniques in PAT.
LO3	Identify, interpret and analyse spectra qualitatively and quantitatively.
LO4	Evaluate current and emerging applications of PAT.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named MTU module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).*
None
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module. You may not earn additional credit for the same learning and therefore you may not enrol in this module if you have successfully completed any modules in the incompatible list.*
None
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. You may not enrol on this module if you have not acquired the learning specified in this section.*
None

Module Content & Assessment

Indicative Content
Introduction to Process Analytical Technologies (PAT) Historical perspective, regulatory framework, application to a simple manufacturing process, data collection and analysis, measurement technology: spectroscopy, chemometrics, on-line versus off-line applications, validation, process control, future trends.
Introduction to Spectroscopy Fundamentals of spectroscopy: hydrogen spectrum, quantum numbers, selection rules. Basic elements of practical spectroscopy: sources, dispersing elements, detectors; S/N ratio, resolving power; line-widths; Fourier transforms.
Infra-Red Spectroscopy Vibrating diatomic molecule, pure vibrational spectra, anharmonicity; Rotational-vibrational spectra e.g. carbon monoxide; Techniques and instrumentation of IR spectroscopy: sources, dispersion, detector, sample preparation; Applications: chemical analysis by IR spectroscopy.
Nuclear Magnetic Resonance Spectroscopy Nuclear magnetic resonance: the chemical shift, the coupling constant; Techniques and instrumentation: pulsed NMR, other nuclei; Applications: MRI, defects in solids.
Mass Spectrometry Types to include TOF, Quadrupole and Magnetic Sector. Operating principles, resolution and sensitivity specifications. Applications including solvent drying and residual gas analysis.
Chemometrics Physiochemical data processing and analysis. Techniques studied include principal component analysis (PCA) and partial least squares regression (PLS).
PAT Applications Use of simulation software. Case Studies such as: 1) IR quality control in the food industry; 2) NIR for measurement of moisture and fat content of food; 3) NMR applications in the chemical industry; 4) Particle size distribution.

Assessment Breakdown	%
Course Work	30.00%
End of Module Formal Examination	70.00%

Course Work

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Open-book Examination	Theory assessment	1,4	15.0	Week 7
Short Answer Questions	Assessment	2,3	15.0	Week 10

End of Module Formal Examination

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	End-of-Semester Final Examination	1,2,3,4	70.0	End-of-Semester

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.

The institute reserves the right to alter the nature and timings of assessment

Module Workload

Workload: Full Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Delivery of module content	4.0	Every Week	4.00
Independent & Directed Learning (Non-contact)	Study and homework	3.0	Every Week	3.00
			Total Hours	7.00
			Total Weekly Learner Workload	7.00
			Total Weekly Contact Hours	4.00

Workload: Part Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Delivery of module content	4.0	Every Week	4.00
Independent & Directed Learning (Non-contact)	Study and homework	3.0	Every Week	3.00
			Total Hours	7.00
			Total Weekly Learner Workload	7.00
			Total Weekly Contact Hours	4.00

Module Resources

Recommended Book Resources

- **K. Bakeev 2010, *Process analytical technology: spectroscopic tools and implementation strategies for the chemical and pharmaceutical industries*, 2nd Ed., Blackwell USA [ISBN: 9781405121033]**

Supplementary Book Resources

- **H. Gunsler and H.U. Gremlich 2002, *IR Spectroscopy: An Introduction*, Wiley [ISBN: 3527288961]**
- **J. Kauppinen and J. Partanen 2001, *Fourier Transforms in Spectroscopy*, Wiley [ISBN: 3527402896]**
- **J.B. Lambert and E.P. Mazzola 2004, *NMR Spectroscopy*, Prentice-Hall [ISBN: 0130890669]**

Recommended Article/Paper Resources

- **Fonteyne, Margot; Vercruysse, Jurgen; De Leersnyder, Fien; et al. *Process Analytical Technology for continuous manufacturing of solid-dosage forms*, Analytical Chemistry, 2015, Volume 67**
- **Vargas, Jenny M; Nielsen, Sarah; Cárdenas, Vanessa; et al. 2018, *Process analytical technology in continuous manufacturing of a commercial pharmaceutical product*, International Journal of Pharmaceutics,, 538**

Other Resources

- **Website: Peter Scott 2008, *Process Analytical Technology*, AstraZeneca http://www.dissolutiontech.com/DTresour/ 0802art/article_1.htm**
- **Website: *Food and Drug Administration (FDA):* http://www.fda.gov/cder/OPS/PAT.htm**
- **Website: *European Medicines Agency (EMA)* http://www.emea.europa.eu/Inspections/PA Thome.html**
- **Website: *Bruker Optics* http://www.brukeroptics.com/pat/**

Module Delivered in

Programme Code	Programme	Semester	Delivery
CR_SCHQA_8	Bachelor of Science (Honours) in Analytical Chemistry with Quality Assurance	7	Elective
CR_SPHYS_8	Bachelor of Science (Honours) in Applied Physics and Instrumentation	1	Mandatory
CR_SESST_8	Bachelor of Science (Honours) in Environmental Science and Sustainable Technology	7	Elective