APPROVED

PHAR S8Z01: Pharmaceutical and Biopharmaceutical Science

Module Details				
Module Code: PHAR S8Z01				
Full Title:	Pharmaceutical and Biopharmaceutical Science APPROVED			
Valid From::	From:: Semester 1 - 2018/19 (September 2018)			
Language of Instruction: English				
Duration:	1 Semester			
Credits::	7.5			
Module Owner::				
Departments:	Unknown			
Module Description: This module will introduce the student to a range of topics in pharmaceutical and biopharmaceutical science. Pharmaceutical science broad range of scientific disciplines that are critical to the discovery, development and manufacture of drugs and therapies.				

Module Learning Outcome				
On successful completion of this module the learner will be able to:				
#	Module Learning Outcome Description			
MLO1	Identify a wide range of organic functional groups including natural products, aromatic and heterocyclic compounds and their use as pharmaceutical sources			
MLO2	Practice safe organic chemistry laboratory skills for routine procedures and pharmaceutical synthesis			
MLO3	Examine results from scientific practical's and discuss their importance in practical reports			
MLO4	Identify and describe pharmaceutical product types, current pharmaceutical legislative requirements and regulatory authorities.			
MLO5	Discuss the lifecycle of a range of pharmaceutical drugs from discovery to marketing and describe how cGMP guidelines apply to the stages of the lifecycle.			
MLO6	Evaluate the discovery, development, production and mode of action of key protein based therapeutics.			

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 DkIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).

No recommendations listed

Module Indicative Content

Pharmaceutical Industry
This element of the module will introduce the student to the pharmaceutical industry. • Pharmaceutical legislation and regulatory authorities, FDA, MHRA, HPRA, and EMA. • GMP and the industry. Lifecycle of pharmaceutical drug products from discovery to marketing.

Pharmaceutical Chemistry

The evolution of drug discovery including synthetic drugs, chemotherapy drugs and pro-drugs. Nitrogen chemistry including aliphatic and aromatic compounds, sulphanilamide and sulfa drugs. Natural products including alkaloids, terpenes and steroids. Stereochemistry including the classification of chiral molecules and the impact of stereochemistry on pharmaceutical products.

Biopharmaceutical Science

Biopharmaceuticals are emerging as frontline medicines to combat several life-threatening and chronic diseases. This element of the module will introduce the process of leveraging a series of discoveries about biological macromolecules, including identification of their structures and elucidating their physiological roles, to permit their application as therapeutic agents. • Transforming Proteins and Genes into Drugs (application of biotechnology, biochemistry, molecular biology in drug discovery). • Therapeutic and Clinical Applications of Biopharmaceuticals: Antibodies and Derivatives; Hormones; Cytokines and Interferons. Example Case studies - Interleukins as Immunotherapeutics, - Interferon Biology and Cancer Therapy.

A range of synthetic preparations, natural product isolation and medication analysis will be undertaken to give experience of organic synthetic techniques and pharmaceutical analysis. Qualitative organic analysis, identification of simple compounds by physical and chemical tests. Extraction and purification of organic materials from natural sources. In the above preparations where applicable the students will use chromatographic and/or spectroscopic methods to check purity and identity of the products.

Module Assessment			
Assessment Breakdown	%		
Course Work	10.00%		
Project	60.00%		
Practical	30.00%		

Module Special Regulation

Assessments

Full Time On Campus

Course Work					
Assessment Type	Continuous Assessment	% of Total Mark	10		
Marks Out Of	0	Pass Mark	0		
Timing	n/a	Learning Outcome	1		
Duration in minutes	0				
Assessment Description Assignment or in-class exam in relevant area of organic Chemistry (e.g. take-home assignment on organic functional groups in pharmaceutical sources)					

Project			
Assessment Type	Project	% of Total Mark	60
Marks Out Of	0	Pass Mark	0
Timing	End-of-Semester	Learning Outcome	4,5,6
Duration in minutes	0		

Assessment Description

Students will select a (bio)pharmaceutical product type and evaluate its discovery, mode of action, development and production and using recommended resources, examine GMP requirement(s) and current legislation for the stages of its lifecycle. Students will present their findings in an ePortfolio. This assessment will allow students to engage with technology and develop a multimedia-based portfolio.

Practical				
Assessment Type	Practical/Skills Evaluation	% of Total Mark	30	
Marks Out Of	0	Pass Mark	0	
Timing	Every Week	Learning Outcome	2,3	
Duration in minutes	0			
Assessment Description A 3-hour weekly practical session will provide the student with the opportunity to back up the theory covered in formal lectures with practical experience. Each week students will indicate				

whether they have successfully completed an exercise using appropriate reports

No Final Examination

Reassessment Requirement

A 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.

Module Workload

Workload: Full Time On Campus					
Workload Type	Contact Type	Workload Description	Frequency	Average Weekly Learner Workload	Hours
Lecture	Contact	Two hours per week of face- to-face contact with lecturer.	Every Week	2.00	2
Practical	Contact	A programme of weekly 3- hour laboratory practical sessions will run concurrently with lectures.	Every Week	3.00	3
Directed Reading	Non Contact	Lecture notes, Peer-reviewed papers, Textbooks, e-Resources	Every Week	3.00	3
Independent Study	Non Contact	Independent/Group study	Every Week	3.00	3
Lecturer Supervised Learning	Contact	Guest lecturers with expertise in both traditional pharmaceutical and biopharmaceutical science will be invited to provide an overview and insight into specifics topics of relevance.	Every Week	1.00	1
Total Weekly Learner Workload				12.00	
Total Weekly Contact Hours				6.00	

This module has no Part Time On Campus workload.

Module Resources

Recommended Book Resources

Klein, D. (2012), Organic chemistry, 1st. Wiley, [ISBN: 9780471756149].

Hart, Craine, Hart. (2007), Organic chemistry - A short course, 12th. Houghton Mifflin, [ISBN: 0618215360].

Gary Walsh.. (2007), Pharmaceutical biotechnology: concepts and applications / Gary Walsh., Hoboken, N.J.: Chichester: Wiley; John Wiley [distributor].

Gary Walsh. (2003), Biopharmaceuticals: biochemistry and biotechnology, Chichester: Wiley.

Rodney Ho J.Y.. (2003), Biotechnology and biopharmaceuticals: transforming proteins and genes into drugs, New Jersey: John Wiley & Sons.

Supplementary Book Resources

Bruice, P. Organic Chemistry, 6th. Pearson, [ISBN: 9780321697684].

This module does not have any article/paper resources

Other Resources

Website, Dr Chiara Hanlon. Lecture notes and further resources, DkIT Moodle.

Website, Virtual textbook of Organic Chemistry, http://www2.chemistry.mdu.edu/faculty/re usch/VirtTxtJml/intro1.htm

Website, Database for IR information. Spectral Database for Organic Compounds (SDBS), http://sdbs.riodb.aist.go.jp/sdbs/cgi-bi n/cre_index.cgi

website, Food & Drug Administration (FDA), http://www.fda.gov/Drugs

website, European Medicines Agency (EMA), http://www.ema.europa.eu

website, Health Products Regulatory authority (HPRA),

http://www.hpra.ie

website, European Directorate for the Quality of Medicines and Healthcare',

http://www.edqm.eu

website, International Conference on Harmonisation (ICH),

http://www.ich.org
website, Eudralex - EU legislation,