APPROVED

PHAR S8016: Biopharmaceutical Therapeutics

Module Details

Module Code:	PHAR S8016
Full Title:	Biopharmaceutical Therapeutics APPROVED
Valid From::	Semester 1 - 2018/19 (September 2018)
Language of Instruction:	English
Duration:	1 Semester
Credits::	7.5
Module Owner::	Ronan Bree
Departments:	Unknown
Module Description:	The aim of this module is to provide students with knowledge of the range and scope of traditional pharmaceuticals of biological origin, and of the underpinning scientific principles and procedures involved in their development, production and biological effect.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Compare the key differences between traditional pharmaceuticals of biological origin, synthetic pharmaceuticals and modern recombinant biopharmaceuticals/biosimilars.
MLO2	Grasp the mechanism of action of common and emerging biotherapeutics.
MLO3	Explain the development and production of a selected range of biological products.
MLO4	Assimilate the concept of the biological effects of biotherapeutics through receptor binding and internal cell signalling processes.
MLO5	Create and communicate formal mini-project reports on biotherapeutic based applications.

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

CONTENT
n/a

• Introduction / Historical perspective
What is a Biopharmaceutical?: Chemical (synthetic) versus traditional biological products versus biopharmaceutical . The early use of biological extracts in medicine, the development of immunisation. A brief survey of traditional pharmaceuticals of biological origin and of the sources, production and medical applications of modern therapeutic substances extracted from non-recombinant biological sources (e.g. plant derived pharmaceuticals). The impact of recombinant DNA technology and expression systems pharmaceutical biotechnology. Chinese Hamster Ovary cells – the current leader. Biopharmaceuticals and general safety issues. The impact of biosimilars.

• Cytokines as biotherapeutics
Chemical messenger overview. Focus on the two families of Interleukins (IL-2 in particular) and Interferons as biopharmaceuticals. Focus on the cytokine molecules themselves, their receptors, the signalling pathways employed (e.g. JAK-STAT) and the biological effect involved. Mechanisms of cytokine inhibition will also be considered.

• Growth Factors and their value as biopharmaceuticals.
General overview of the growth factor families; Insulin like growth factors, haematopoietic growth factors (e.g Erythropoietin), epidermal growth factors, platelet-derived growth factors etc. and their role in the recombinant biopharmaceutical industry. Primary focus on erythropoietin (production, mechanism of action, glycosylation etc.)

• Therapeutic use of Antibodies
A brief review of immunology. Overview of the clinical applications of monoclonal antibodies; passive immunisation, diagnostic imaging and therapeutic applications. Tumour associated antigens and antibody-based strategies for tumour detection/destruction. Selected examples of monoclonal antibodies approved for medical use. The use of monoclonal antibodies as probes. Polyclonal antibody preparations: production of antisera and purified immunoglobulins. Applications in passive immunisation. Anti-inflammatory treatments. Radio-immuno conjugation, toxin-immuno conjugation and enzyme-immuno conjugation play critical roles in targeted therapies. The selection of the conjugate is critical depending on the target. The generation and mechanism of actions of these compounds will be discussed in detail.

• Hormones
A brief revision of the main hormone systems of the human body. Biochemistry, production and medical applications of selected proteinaceous hormones. Overview of the metabolic synthesis, general biochemistry and therapeutic applications of peptide regulatory factors. A similar overview of steroid hormones and also therapeutic analogues; their use in therapy and in contraception. Hormones produced by genetic engineering. Internal Cell Signalling pathways are also covered in detail, looking at phosphorylation, tyrosine kinases, IP3, DAG and G proteins.

• Emerging biological technologies
An introductory review of novel biopharmaceutical products including emerging vaccine technology, cell and nucleic acid based therapies. The principles of manipulating gene expression to inhibit or overexpress genes of interest to induce a therapeutic effect. The use of modern gene therapy to achieve altered gene expression. Overview of areas including stem cell differentiation, anti-inflammatory exosome secretion and modern vaccine design technology. Selected examples of the use of emerging therapeutics in the clinical setting.

LEARNING & TEACHING RESOURCES
n/a

Format of lecture series
Lecture delivery will comprise a range of methodology including on-line movie animations, visual demonstrations, large diagrams for illustration purposes as well as information and slide handouts. Novel methods using smartphone web/app based quizzes will also be utilised. Course material and revision quizzes will be made readily available on a virtual learning environment (VLE) for student access. The combination of these methods will facilitate in re-enforcing the student's understanding of some of the technical and mechanistic processes involved. Various aligned classroom assessment techniques may also be employed. These may include aspects such as the background knowledge probe, the one minute paper, small group interaction and discussion, question & answer sessions, team presentations to class colleagues, pop-quizzes and open ended questioning. Access to course textbooks will be provided through the DkIT eBook service, which will allow students 24/7 access to suitable reading material. A range of self-assessment, self-reflection and peer learning exercises will be built in to deliveries of both lectures and practical sessions.

Methodology/Practical exercises will be performed to learn the principles of working in the biotherapeutic field.
The following list is designed to serve as a resource of ideas for suitable practicals to illustrate key concepts and techniques. Many of the practicals and associated techniques are applicable to a range of biopharmaceutical products and so have a broad spectrum of merit. 1. Vitamin C determination in fruit/vegetables 2. Determination of the Rh factor using PCR 3. Pregnancy test using an Enzyme Linked Immunosorbent Assay (ELISA) 4. Student designed Enzyme-linked metabolite assay kits. 5. Generation of a recombinant protein drug using E.coli as an inducible expression system. 6. Identification of selected compounds by HPLC. 7. PCR applications in the biopharmaceutical sector.

Formative Assessments
Throughout the semester, students will be provided with formative assessments both in lectures and in laboratory environments.

Virtual Learning Environment (VLE)
All lecture notes will be provided to the students through a VLE. This VLE will also be used for access to helpful YouTube video clips and peer reviewed publications of interest to the course. Students will have 24/7 access to the VLE allowing them to download and study at their own pace and in their own time. Where helpful, screencast and video resources will be made available to the students to download and listen to in their own time. This will facilitate learning and understanding for all students, but in particular the international students.

ASSESSMENT STRATEGY
n/a

Practical/Skills Evaluation
Practical / Skill set tests / Lab mini-project reports. In the practical sessions, students will focus on improving their practical skill set, while also dealing with obtaining and analysing data in addition to drawing conclusions from the data. Students will also perform formative skill set tests (used to maintain and improve their practical skill set) e.g. pipette tests, graph tests, data handling test, data interpretation tests etc.) all generated to assist understanding and improve technique. Students will work on an interactive lab manual, which will contain in-class exercises for review. Group (Peer-assisted learning) work will be encouraged. Technology use will also be encouraged throughout (for example in some cases pre-practical videos and smartphone based quizzes will be used, the use of excel for graphing / trend line generation etc.). The requirement to submit laboratory mini-project reports and perform formative tests is intended to act as serious encouragement for students to focus on the laboratory work. Marks for these reports will be based on students' ability to record primary data, calculate derivatives from these, display these data, comment on their meaning in the context of the actual experiment and associated theory, and discuss limitations to the experiment and the results obtained.

Continuous Assessment
Students will perform one class test assignment worth 10% of the module. This will assist students in their engagement with course content from the module to date and assist preparations and revision for the final exam.

Module Assessment

Assessment Breakdown	%
Course Work	10.00%
Practical	30.00%
Final Examination	60.00%

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	S1 Week 9	**Learning Outcome**	1,2,3,4
Duration in minutes	0		

Assessment Description
Students will perform one class test assignment worth 10% of the module. This will assist students in their engagement with course content from the module to date and assist preparations and revision for the final exam.

No Project

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	30
Marks Out Of	0	**Pass Mark**	0
Timing	Every Week	**Learning Outcome**	2,3,5
Duration in minutes	0		

Assessment Description
Students will participate in weekly laboratory-based practical sessions in which formative assessments will be performed in interactive group settings (e.g. problem based learning, quizzes, protocol review exercises, worksheet completion etc.). Two summative mini-project practical reports will be submitted during the module (each worth 15%).

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	60
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	1,2,3,4
Duration in minutes	0		

Assessment Description
End-of-Semester Final Examination

Module Workload

Workload: Full Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	3 x 1 hour lectures	Every Week	3.00	3
Practical	Contact	1 x 3 hour lab session	Every Week	3.00	3
Directed Reading	Non Contact	Notes / Paper / Textbook reading	Every Week	2.00	2
Independent Study	Non Contact	Self / group study	Every Week	5.00	5
				Total Weekly Learner Workload	13.00
				Total Weekly Contact Hours	6.00

This module has no Part Time On Campus workload.

Module Resources

Recommended Book Resources

Walsh, G.. (2013), Biopharmaceuticals - Biochemistry and Biotechnology., 2nd. J. Wiley & Sons.

Harvey Lodish; Arnold Berk, Chris A. Kaiser, Monty Krieger, Anthony Bretscher, Hidde Ploegh, Angelika Amon, Matthew P. Scott. (2016), Molecular Cell Biology, 8th. WH Freeman.

Whitehouse, D. and Rapley, R.. (2012), Molecular and Cellular Therapeutics, Wiley-Blackwell.

Roitt, I.M.. (2017), Essential Immunology, 13th. Wiley-Blackwell Science.

Bernhard Moser, Gordon L. Letts, Kuldeep Neote. (2007), Chemokine biology : basic research and clinical application, 1. Birkhauser.

Berg, Tymoczko and Stryer.. (2015), Biochemistry, 8th. WH Freeman.

Singh, Manmohan Srivastava, Indresh K.. (2011), Development of Vaccines : From Discovery to Clinical Testing, Wiley.

David Frank (edt). (2012), Signaling Pathways in Cancer Pathogenesis and Therapy, 1. Springer Verlag.

Dewick, P. M.. (2009), Medicinal Natural Products: A Biosynthetic Approach., 3rd. J. Wiley & Sons.

Hutton, J.C. & Siddle, K.. (1990), Peptide hormone secretion: a practical approach., Oxford University Press.

Denyer, S. Hodges, N. A., Gorman, S. P.. (2011), Hugo and Russell's Pharmaceutical Microbiology., 8th. Blackwell Science.

Mohammad A. Tabrizi, Gadi G. Bornstein, Scott L. Klakamp (edt). (2012), Development of Antibody-Based Therapeutics, 1. Springer Verlag.

Supplementary Book Resources

Michael Butler et al. (2011), Comprehensive Biotechnology, 2nd. Elsevier.

Rodney J.Y. Ho, Milo Gibaldi. (2013), Biotechnology and biopharmaceuticals : transforming proteins and genes into drugs, 2nd. Liss (Alan) Inc.

Rho, J.P. & Louie, S.G.. (2003), Handbook of Pharmaceutical Biotechnology., The Haworth Press Inc..

Walter Sneader. (2006), Drug discovery : a history, John Wiley & Sons Ltd.

This module does not have any article/paper resources

Other Resources

ebook collection online with DkIT, Access online textbooks through DkIT's eBook collection.

Website, British Pharmacopoeia,,
http://www.pharmacopoeia.co.uk

Website, European Biopharmaceutical Enterprises,,
http://www.ebe-biopharma.org/

Website, European Directorate for the Quality of Medicines and Healthcare,,
http://www.edqm.eu

Website, Entrez PubMed,,
http://www.ncbi.nlm.nih.gov/entrez

Website, FDA/Center for Drug Evaluation and Research,,
http://www.fda.gov/CDER

Website, Health Products Regulatory Authority (HPRA),
http://www.hpra.ie

Website, Science Direct,,
http://www.sciencedirect.com

Website, United States Food and Drug Administration,,
http://www.fda.gov

Website, United States Pharmacopoeia,,
http://www.usp.org

Website, The National Institute for Bioprocessing Research and Training (NIBRT) (http://www.nibrt.ie).