BITC S7005: Biotherapeutics

Module Details

Module Code:	BITC S7005
Full Title:	Biotherapeutics APPROVED
Valid From:	Semester 1 - 2013/14 (September 2013)
Language of Instruction:	
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.
MLO2	Grasp the mechanism of action of common 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 manage a team-based presentation project on a popular biotherapeutic.

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.

• 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 and the biological effect involved. Mechanisms of cytokine inhibition will also be considered.

• Growth Factors and their value as biopharmaceuticals.
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.

• 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.

• Vaccine Technology
Introductory review of traditional vaccine preparations, their production and uses. Traditional vaccine preparations based upon: live attenuated bacteria, dead/inactivated bacteria, live attenuated viruses, inactivated viruses, toxoids, pathogen-derived antigens. Recombinant sub-unit vaccines; range, use and advantages/disadvantages, when compared to non-recombinant vaccine preparations. Survey of adjuvants, their mode of action, properties and uses.

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 Classroom Response Systems (CRS) 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 will also be employed. These will include 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 eBrary service (access to more than 50,000 multidisciplinary e-books), 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 the delivery of both lecture 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. These are designed to facilitate group work in problem solving situations. These assessments are built in to the lecture and practical components.

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. Screencast and Podcast tutorials will also 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 who may not possess fluent English.

ASSESSMENT STRATEGY
n/a

Practical/Skills Evaluation
Practical / Skill set tests / Lab write-up 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 using excel for graphing / trend line generation etc.). The requirement to submit regular laboratory reports 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 assignment worth 20% of the module. Early in the semester, students will be provided with a list of common biotherapeutics. Working in teams of 3, each group will select their biotherapeutic of choice. They will then have approximately 5 weeks to prepare a 15 minute presentation (covering details on the indication being treated, the function and mechanism of action of the chosen biotherapeutic approach)followed by a question/answer session. Each team member will contribute to the presentation. The group will submit a concise abstract summarising their work/findings. Peer marking regarding student contribution will also take place in each team. This CA is designed on enhancing group work, people skills, presentation skills, in addition to literature review. All of these skills, in addition to seeing other groups' presentations will assist in the developing each students' understanding of the biotherapeutic/biopharmaceutical industry further. In essence, peer learning will be in place when students are watching the other groups' presentations.

Module Assessment

Assessment Breakdown	%
Course Work	20.00%
Practical	30.00%
Final Examination	50.00%

Module Special Regulation

Assessments

Full Time

Course Work

Assessment Type	Continuous Assessment	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	Week 9	**Learning Outcome**	2,3,4,5
Duration in minutes	0		

Assessment Description
Students will perform one assignment worth 20% of the module. Team presentations will be delivered to the class/lecturer team on a blockbuster biotherapeutic. Students will be assessed on their presentation styles, the content, the organisation and level of understanding. A submitted abstract will also be graded and peer marking will occur amongst the team members. Feedback will be provided to the students on their presentations. Further details presented in the 'indicative content' section.

No Project

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	30
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	1,2,3
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.). Summative practical laboratory reports will be submitted during the module for grading. Further details are presented in the indicative content section of this document.

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	50
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

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 workload.

Module Resources

Recommended Book Resources

Walsh, G.. (2003), 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. (2012), Molecular Cell Biology, 6th and 7th. WH Freeman.

Whitehouse, D. and Rapley, R.. (2011), Molecular and Cellular Therapeutics, Wiley-Blackwell, (Available on Dundalk IT Dawsonera online collection).

Roitt, I.M.. (2011), Essential Immunology, 12th. Wiley-Blackwell Science, (Available on the Dundalk IT online eBrary collection).

Bernhard Moser, Gordon L. Letts, Kuldeep Neote. (2006), Chemokine biology : basic research and clinical application, Birkhauser, (available on Dundalk IT Dawsonera online collection).

Berg, Tymoczko and Stryer.. (2012), Biochemistry, 6th and 7th editions. WH Freeman.

Singh, Manmohan Srivastava, Indresh K.. (2011), Development of Vaccines : From Discovery to Clinical Testing, Wiley, (available on Dundalk IT Dawsonera online collection).

David Frank (edt). (2012), Signaling Pathways in Cancer Pathogenesis and Therapy, 1. Springer Verlag, (available on Dundalk IT Dawsonera online collection).

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.. (2004), Hugo and Russell's Pharmaceutical Microbiology., 7th (8th edition available on DkIT eBrary). Blackwell Science.

Mohammad A. Tabrizi, Gadi G. Bornstein, Scott L. Klakamp (edt). (2012), Development of Antibody-Based Therapeutics, 1. Springer Verlag, (available on Dundalk IT Dawsonera online collection).

Supplementary Book Resources

Michael Butler et al. (2011), Comprehensive Biotechnology, 2nd. Elsevier, (available on Dundalk IT Dawsonera online collection).

Rodney J.Y. Ho, Milo Gibaldi. (2004), Biotechnology and biopharmaceuticals : transforming proteins and genes into drugs, Liss (Alan) Inc, (available on Dundalk IT Dawsonera online collection).

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, (available on Dundalk IT Dawsonera online collection).

This module does not have any article/paper resources

Other Resources

[Textbook collection online with DkIT], Access online textbooks through DkIT's dawsonera and eBrary collection (go to DkiT library site to begin).

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

[Website], Centocor, Monoclonal Antibody Production,,
http://www.centocor.com

[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], Irish Medical Board,,
http://www.imb.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

[Link], Library Catalogue,
http://tinyurl.com/pkzce6l

[Link], Library Catalogue,
http://tinyurl.com/kj4et7f