

Full Title:	Biotherapeutics
Module Code:	BITC S7005
Credits:	7.5
Valid From:	Semester 1 - 2013/14 (September 2013)
Module Delivered in	2 programme(s)
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.
Learning Outcomes:	
<i>On successful completion of this module the learner should be able to</i>	
<ol style="list-style-type: none"> 1. Compare the key differences between traditional pharmaceuticals of biological origin, synthetic pharmaceuticals and modern recombinant biopharmaceuticals. 2. Grasp the mechanism of action of common biotherapeutics. 3. Explain the development and production of a selected range of biological products. 4. Assimilate the concept of the biological effects of biotherapeutics through receptor binding and internal cell signalling processes. 5. Create and manage a team-based presentation project on a popular biotherapeutic. 	

Module Content & Assessment

Indicative Content
CONTENT n/a
<p>• 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.</p>
<p>• 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.</p>
<p>• 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.</p>
<p>• 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.</p>
<p>• 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.</p>
<p>• 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.</p>
LEARNING & TEACHING RESOURCES n/a
<p>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.</p>
<p>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.</p>
<p>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.</p>

Indicative Content
<p>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.</p>
<p>ASSESSMENT STRATEGY n/a</p>
<p>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.</p>
<p>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.</p>

Assessment Breakdown	%
Course Work	20.00%
Practical	30.00%
End of Module Formal Examination	50.00%

Full Time

Course Work							
<i>Assessment Type</i>	<i>Assessment Description</i>	<i>Outcome addressed</i>	<i>% of total</i>	<i>Marks Out Of</i>	<i>Pass Marks</i>	<i>Assessment Date</i>	<i>Duration</i>
Continuous Assessment	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.	2,3,4,5	20.00	0	0	Week 9	0

No Project

Practical							
<i>Assessment Type</i>	<i>Assessment Description</i>	<i>Outcome addressed</i>	<i>% of total</i>	<i>Marks Out Of</i>	<i>Pass Marks</i>	<i>Assessment Date</i>	<i>Duration</i>
Practical/Skills Evaluation	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.	1,2,3	30.00	0	0	n/a	0

End of Module Formal Examination							
<i>Assessment Type</i>	<i>Assessment Description</i>	<i>Outcome addressed</i>	<i>% of total</i>	<i>Marks Out Of</i>	<i>Pass Marks</i>	<i>Assessment Date</i>	<i>Duration</i>
Formal Exam	End-of-Semester Final Examination	1,2,3,4	50.00	0	0	End-of-Semester	0

DKIT reserves the right to alter the nature and timings of assessment

Module Workload & Resources

Workload: Full Time

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

This course has no Part Time workload.

Resources

Recommended Book Resources

- Walsh, G. 2003, *Biopharmaceuticals - Biochemistry and Biotechnology.*, 2nd Ed., 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 Ed., 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 Ed., 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 Ed., 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 Ed., Springer Verlag (available on Dundalk IT Dawsonera online collection)
- Dewick, P. M. 2009, *Medicinal Natural Products: A Biosynthetic Approach.*, 3rd Ed., 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) Ed., Blackwell Science
- Mohammad A. Tabrizi, Gadi G. Bornstein, Scott L. Klakamp (edt) 2012, *Development of Antibody-Based Therapeutics*, 1 Ed., Springer Verlag (available on Dundalk IT Dawsonera online collection)

Supplementary Book Resources

Resources

Recommended Book Resources

Michael Butler et al 2011, *Comprehensive Biotechnology*, 2nd Ed., 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>

Module Delivered in

Programme Code	Programme	Semester	Delivery
DK_SAPBI_7	Bachelor of Science in Applied Bioscience	6	Elective
DK_SPHAR_7	Bachelor of Science in Pharmaceutical Science	6	Elective