APPROVED

BITC S7012: Pharmaceutical Biotechnology

Module Details

Module Code:	BITC S7012
Full Title:	Pharmaceutical Biotechnology APPROVED
Valid From::	Semester 1 - 2019/20 (June 2019)
Language of Instruction:	English
Duration:	1 Semester
Credits::	7.5
Module Owner::	Caroline Gilleran
Departments:	Unknown
Module Description:	The aims of this module are to explore how biological organisms (including genetically modified organisms) are involved in the production and manufacture of pharmaceuticals.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Explain the molecular methods used to create Genetically Modified Organisms and evaluate the merits of different expression systems for the production of recombinant proteins.
MLO2	Describe how Genetically Modified Organisms can be cultured on a large scale and are used in the production of recombinant proteins and pharmaceuticals.
MLO3	Examine and evaluate protein stability and the fundamental principles, operating criteria and design options for downstream processing operations.
MLO4	Interpret the regulatory and safety issues regarding application of recombinant biological systems in industry.
MLO5	Apply practical competence in selected molecular and biotechnological techniques.

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
Fundamentals of Pharmaceutical Biotechnology Molecular technologies to manipulate genomes and to express heterologous proteins.
Bioprocessing Modes of fermentation, bioreactor types, process control, scale-up.
Production of pharmaceutical products using recombinant systems Production of recombinant proteins using bacterial, yeast, insect cells, mammalian cells, plant and animal systems.
Protein purification Design and evaluation of protein purification strategies. Protein extraction techniques, protein concentration techniques, protein separation techniques and electrophoretic analysis.
Protein stability Protein denaturation and inactivation processes. Strategies to improve stability - fusion proteins, use of excipients, recombinant approaches.
Regulation Regulatory and safety issues associated with the use of recombinant microbes in industry
Sample practicals Yeast fermentation. Production of industrial biocatalysts using recombinant bacteria. GFP expression and purification. SDS-PAGE.

Module Assessment

Assessment Breakdown	%
Practical	50.00%
Final Examination	50.00%

Module Special Regulation

Assessments

Full Time On Campus

No Course Work

No Project

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	30
Marks Out Of	0	**Pass Mark**	0
Timing	Every Week	**Learning Outcome**	1,3,5
Duration in minutes	0		

Assessment Description
A 3-hour practical session each week will provide the student with the opportunity to back up the theory covered in formal lectures with practical experience. Students will be assessed weekly by a variety of methods including written reports, in-class quizzes and presentations.

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	5
Duration in minutes	0		

Assessment Description
Students will be assessed by a practical skills based exam.

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 On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	lecture	Every Week	3.00	3
Practical	Contact	Practical class	Every Week	3.00	3
Independent Study	Non Contact	Independent study	Every Week	5.00	5
Directed Reading	Non Contact	Supplementary reading material will be posted on moodle.	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

D.P. Clark and N.J. Pazdernik. (2012), Biotechnology, Update. Elsevier/Academic, Amsterdam.

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

G. Walsh. (2013), Biopharmaceuticals: Biochemistry and biotechnology, 2nd. Wiley-Blackwell.

G. Walsh. (2013), Pharmaceutical Biotechnology: Concepts and Applications, 1st. Wiley-Blackwell.

Supplementary Book Resources

Madigan et al.. (2011), Brock Biology of Microorganisms, 13th. Pearson education.

L.M. Prescott. (2005), Microbiology, McGraw-Hill.

Recommended Article/Paper Resources

N. Ferrer-Miralles, J. Domingo-Espin, J.L. Corchero, E. Vazquez, A. Villaverde. (2009), Microbial factories for recombinant pharmaceuticals, Microbial Cell Factories, 8 (17), p. 1-8.

Demain, A., Vaishnav, P.. (2009), Production of recombinant proteins by microbes and higher organisms, Biotechnology Advances, 27 (3), p.297.

Other Resources

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

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

Website, EU database,
http://europa.eu/index_en.htm

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

Journal search database, Science Direct,
http://www.sciencedirect.com

Journal search database, Entrez PubMed,,
http://www.ncbi.nlm.nih.gov/entrez