APPROVED

PHAR S8022: Bioprocessing

Module Details

Module Code:	PHAR S8022
Full Title:	Bioprocessing APPROVED
Valid From::	Semester 1 - 2020/21 (September 2020)
Language of Instruction:	English
Duration:	1 Semester
Credits::	10
Module Owner::	annamarie rogers
Departments:	Life and Health Sciences
Module Description:	The aim of the module is to provide students with an in-depth knowledge of the upstream and downstream processing of biopharmaceuticals (both theoretical pertained to the development, production and purification of biopharmaceuticals).

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Critique the choice of expression systems used for the production of recombinant proteins.
MLO2	Evaluate how plasmid vectors can be modified and utilised to produce high, and sustainable, production levels of recombinant biopharmaceuticals.
MLO3	Critique how Genetically Modified Organisms can be cultured on a large scale in a bioreactor to maximize their growth and formation of product.
MLO4	Evaluate different chromatography and electrophoretic techniques in downstream processing for optimal purification for recombinant proteins.
MLO5	Appraise filtration systems for recovery, purification, concentration and final polishing of biopharmaceuticals and viral clearance.
MLO6	Characterise finished biopharmaceutical products.

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
COURSE CONTENT Upstream Processing n/a
Expression Systems Evaluation of different expression systems (bacteria, yeast, insect, plant, mammalian). Selecting a gene and designing a vector for recombinant protein production. Experimental approaches for expression system transfection (viral vectors, plasmids, calcium phosphate transfection, heat shock, electroporation).
Cell culture and aseptic technique Nutritional requirements of mammalian cells: growth media preparation, sterilisation and quality control. Adherent vs suspension cells. Generation of cell banks. Sub-culturing and cryopreservation techniques. Methods for monitoring the growth and viability of mammalian cells. Aseptic requirements for cell culture: sources of contamination, processes and techniques involved in maintaining culture sterility.
Cell culture control Monitoring / optimisation of expression system growth and product formation (pH, temperature, dissolved O2, nutrients, agitation, biomass, contamination, protein stability).
Cell growth equipment (small & large scale) Selection of appropriate bioreactor configuration (bioreactor, continuous stirred tank reactor, airlift reactor, bubble reactor, trickle bed reactor). Evaluation of cell culture configuration for specific biopharmaceutical products (batch culture, fed-batch, continuous culture, perfusion culture, cell immobilisation strategies).
COURSE CONTENT Downstream Processing n/a
Capture & Harvest Compare and contrast methods for intracellular and extracellular biopharmaceutical recovery - cell disruption (physico-mechanical and chemical), centrifugation (disk stack centrifuge), filtration (normal flow filtration (NFF), tangential flow filtration (TFF), single path TFF).
Chromatography Evaluate chromatographic techniques for recombinant protein separation and purification (Protein A affinity, ion exchange, hydrophobic interaction and size exclusion).
Filtration Compare and contrast filtration systems for product concentration & buffer exchange (Ultra/Diafiltration). Integrity testing of filters. Evaluate filtration systems for viral inactivation & final polishing - NF versus TFF. Viral inactivation and removal.
Fill finish Methods for aqueous and freeze dried products. Vial filling, stoppering, capping, labelling & packaging. Depyrogenation.
Protein characterisation Characterisation of finished biopharmaceutical products - in-process and final product testing. Detection and determination of yield, purity, concentration and biological activity. Electrophoretic methods (SDS-PAGE, UV spectroscopy, protein assays).
NIBRT Training Students will gain theoretical knowledge and practical experience in a range of upstream and downstream biopharmaceutical techniques (eg cell culture, filtration, chromatography) in an Industrial setting.

Module Assessment

Assessment Breakdown	%
Course Work	10.00%
Practical	40.00%
Final Examination	50.00%

Module Special Regulation

Assessments

Part Time On Campus

Course Work

Assessment Type	Class Test	**% of Total Mark**	10
Marks Out Of	0	**Pass Mark**	0
Timing	S1 Week 6	**Learning Outcome**	1,2,3
Duration in minutes	0		

Assessment Description
n/a

No Project

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	3,4,5
Duration in minutes	0		

Assessment Description
Students will attend a specialised workshop in the National Institute for Bioprocessing Research and Training (NIBRT) in UCD. During the workshop, students will compare biopharmaceutical up- and down-stream processes from laboratory to industrial scale eg bioreactors, chromatography, filtration. Students will be assessed on their understanding and analysis of the techniques practiced.

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	4,5,6
Duration in minutes	0		

Assessment Description
Students will participate in a laboratory-based practical session in which formative assessments will be performed in interactive group settings (e.g. problem based learning, competency skill-set tests, quizzes, protocol review exercises, worksheet completion etc.).

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	50
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	1,3,4,5
Duration in minutes	0		

Assessment Description
End-of-Semester 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

This module has no Full Time On Campus workload.

Workload: Part Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	2 x 1 hour lectures	Every Week	2.00	2
Practical	Contact	2 x 4 hour practical at end of semester	Once per semester	0.53	8
Practical	Contact	1 day training in NIBRT	Once per semester	0.53	8
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	10.07
				Total Weekly Contact Hours	3.07

Module Resources

Recommended Book Resources

Michael Butler. (2007), Cell Culture and Upstream Processing, Taylor and Francis Group, Available on the DkIT NetLibrary collection.

William Whyte. (2010), Cleanroom Technology: Fundamentals of Design, Testing and Operation, 2nd. Wiley.

John M. Davis. (2011), Animal Cell Culture: Essential Methods, 1. Wiley.

Walls and Loughran. (2011), Protein Chromatography "Methods and Protocols", Humana Press, [ISBN: ISBN:9781607].

Pauline M. Doran. (2012), Bioprocess Engineering Principles, 2. Academic Press.

Walsh, G.. (2013), Biopharmaceuticals: Biochemistry and biotechnology, 2nd. J. Wiley and Sons.

Shijie Liu. (2016), Bioprocess Engineering : Kinetics, Biosystems, Sustainability, and Reactor Design, 2. Elsevier.

Gunter Jagschies, Eva Lindskog, et al. (2017), Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes., Elsevier, [ISBN: 978-008100623].

Damian J. Houde. (2019), Biophysical Characterization of Proteins in Developing Biopharmaceuticals, Elsevier, [ISBN: 978-044464173].

Supplementary Book Resources

R. Ian Freshney. (2011), Culture of Animal Cells: A Manual of Basic Technique and Specialized Applications, 6. Wiley-Blackwell.

Ganapathy Subramanian. (2012), Biopharmaceutical Production Technology, Wiley.

This module does not have any article/paper resources

Other Resources

Textbook collection online with DkIT, 'Access online textbooks through DkIT's eBook collection (go to DkiT library site to begin)'.

website, Biopharm International, http://www.biopharminternational.com/

website, Science Break-throughs: www.breebio.com.

website, American tissue culture collection http://www.atcc.com.

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

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

website, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) http://www.ich.org/.

website, HPRA http://www.hpra.ie/.

website, 'U.S. Food and Drug Administration http://www.fda.gov'.

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

website, Bioconnect Ireland: www.biotechnologyireland.com.