MANU09003
Biopharmaceutical Manufacturing

Full Title	Biopharmaceutical Manufacturing		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	09	**ECTS Credits**	10
Module Code	MANU09003	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences
Module Author	Mary McMahon		
Co Authors	Orla Slattery		

Module Description

Manufacturing processes for biopharmaceuticals must be designed to produce products that have consistent quality attributes. This manufacturing process involves fermentation technologies, product recovery and the removal of impurities and contaminants that include endotoxins, viruses, cell membranes, nucleic acids, proteins, culture media components, process chemicals, and ligands leached from chromatography media, as well as product modifications, aggregates, and inactive forms. This module is designed to provide the student with a comprehensive understanding of the manufacturing process involved in the production of biopharmaceuticals.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Illustrate and implement an understanding of the key steps involved in the development of a biopharmaceutical drug.
2.	Evulate and critical appraise the technologies,processes and the technical parameters pertinent to the upstream and downdstream procceses in biopharmaceutical manufacturing.
3.	Analyse and apply knowledge of the key parameters in biopharmaceutical product formulation, lyophilization, fill, packaging and labelling.
4.	Corroborate an indepth knowledge of the key parameters in biopharmaceutical analysis.

Indicative Syllabus

1. The Drug Development Process

Discovery and delivery of biopharmaceuticals, patenting, preclinical studies and clinical trials, role and remit of regulatory authorities.

2. Biopharmaceutical Industry

A review of the major biopharmaceutical companies involved in the biopharmaceutical sector.

3. Upstream Processing

Sources of biopharmaceuticals (E.coli, animal cells, yeast, fungi, transgenic animals sand plants, insect based systems) and upstream processing (cell banking systems, microbial fermentation and mammalian cell culture systems).

4. Downstream Processing

Product recovery, cell disruption, product concentration, chromatographic purification, product formulation and fill, freeze drying, labelling and packaging.

5. Product Analysis

Product potency, protein concentration, immunological methods to detect target protein and protein based contaminants, amino acid analysis, peptide mapping, N-terminal sequencing, analysis of secondary and tertiary structure, endotoxin testing, DNA, microbial and viral contaminants and miscellaneous contaminants.

Teaching and Learning Strategy

Supporting theory, Industrial visits, Self-directed study. NIBRT practical to include a visit and or virtual tour of the bioprocessing plant.

Assessment Strategy

Written examination, reports on Industrial visits and written assignment.

Repeat Assessment Strategies
Written examination, reports on Industrial visits and written assignment.

Indicative Coursework and Continuous Assessment:		60 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assignment	Assessment	30 %	OnGoing	1,2,3,4
Practical Evaluation	NIBRT Practical/Visit/Virtual Tour	30 %	End of Semester	3,4

End of Semester / Year Formal Exam:		40 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Closed Book Exam	Final Exam	40 %	End of Semester	1,2,3,4

Blended Delivery Mode Average Weekly Workload:			6.62 Hours		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Independent Learning	Self directed learning	Not Specified	3	Weekly	3.00
Practical	Trip and or Virtual tour of NIBRT	Not Specified	8	Once Per Module	0.62
Lecture	Theory	Not Specified	6	Weekly	6.00

Required Reading Book List
Walsh, G., (2006). *Biopharmaceuticals*. Wiley-Blackwell. ISBN 9780470868393 ISBN-13 0470868392
Stefania, G., (2019). *Directory of Approved Biopharmaceutical Products*. CRC Press. ISBN 0367393964 ISBN-13 9780367393960
Walsh, G., (2009). *Post-translational Modification of Protein Biopharmaceuticals*. John Wiley & Sons. ISBN 9783527320745 ISBN-13 3527320741
Walsh, G., (2007). *Pharmaceutical Biotechnology*. John Wiley & Sons. ISBN 9780470012444 ISBN-13 0470012447
Gnter, E., (2017). *Biopharmaceutical Processing*. ISBN 0081006233 ISBN-13 9780081006238
Wu, L., (2020). *Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation*. CRC Press. ISBN 9781000122947 ISBN-13 1000122948
Khan, F., (2018). *Biotechnology Fundamentals*. CRC Press. ISBN 9781315362397 ISBN-13 1315362392

Online Resources
https://www.idaireland.com/newsroom/publications/ida_pharma
https://www.idaireland.com/doing-business-here/explore?categories=bio-pharmaceuticals&type=casestudy
http://www.biopharma.com/whatsabiogeneric_pt1.pdf
http://www.biopharma.com/biopharmacopeia/whatsabiogeneric_pt2.pdf
http://www.biopharma.com/biopharmacopeia/Redefining.pdf
http://www.biopharma.com

Other Resources
Non ISBN Literary Resources
1. Pharmaceutical Biotechnology - Concepts and Applications (2007) G. Walsh, published by Wiley.

2. Biopharmaceuticals - Biochemistry and Biotechnology (2003) G. Walsh, published by Wiley.

3. Protein Purification: Principles and Practice. R. K. Scopes. Springer-Verlag, New York. (1982).

4. Protein Purification Methods. Eds. E. L. V. Harris and S. Angal. IRL Press, Oxford. (1989).

5. Protein Purification Applications. Eds. E.L.V. Harris and S. Angal. IRL Press, Oxford. (1990).

6. Chromatographic Methods. A. Braithwaite and F. S. Smith. Chapman and Hall. (1985).

7. Affinity Chromatography: A Practical Approach. Eds. P. D. G. Dean, W. S. Johnson and F. A. Middle. IRL Press, Oxford. (1985).

8. HPLC of Small Molecules: A Practical Approach. Ed. C. K. Lim. IRL Press, Oxford. (1986).

9. High Pressure Liquid Chromatography. S. Lindsay and J. Barnes. Wiley, London. (1992).

10. Gas Chromatography: A Practical Approach. Ed. P. J. Baugh. IRL Press, Oxford. (1994).

11. Modern NMR Spectroscopy. J. K. M. Sanders and B. K. Hunter. Oxford University Press. (1993).

12. Modern Experimental Biochemistry. R. Boyer. Benjamin / Cummings, California. (1993).

13. Experimental Biochemistry. R. L. Dryer and G. F. Lata. Oxford University Press. (1989).

14. Analytical Biochemistry. D. J. Holme and H. Peck. Longman, Harlow. (1993).

15. Assessment and Control of Biochemical Methods. T. Hector and A. M. James. Wiley. (1996).

16. Principles of Fermentation Technology. 2nd Edition. F. F. Stanbury, A. Whitaker and S. J. Hall. Pergamon Press. (1995).

17. Biotechnology: a Textbook of Industrial Microbiology. 2nd Edition. W. Crueger, A. Crueger and T. Brock. Sinauer Associates. (1990).

18. In Vitro Cultivation of Microorganisms. Butterworth - Heinmann. (1992).

19. Downstream Processing of Natural Products. Ed. M. Verrall. John Wiley. (1996).

20. Fermenter Manuals for Laboratory Fermenters and other Equipment and Kit Manuals.

21. Basic Cell Culture - a practical approach. J. M. Cavis. Irl. Press, at Oxford University Press. (1994).

22. Culture of Animal Cells: a Manual of Basic Technique. Freshney, R.I. Wiley-Liss, New York. (2005).

23. Cell Culture for Biochemists. Laboratory Techniques in Biochemistry and Molecular Biology. Adams, R. L. P. Elsevier, Amsterdam. (1980).

24. Biotechnology, Theory and Technique. Vol. I. Plant Biotechnology, Animal Cell Culture, Immunobiotechnology. J. G. Chirikyian. Jones and Bartlett, Boston, USA. (1995).

25. Parenteral Quality Control. 2nd Edition. M. J. Akers. Marcel Dekker. (1994). Microbiology. 6th Ed. Prescott, L.M., Harley, J.P. and Klein, D.A. McGraw Hill. (2005).

26. Pharmaceutics: The Science of Dosgae Form Design ed. (2005) by M.E. Aulton, published by Churchill Livingstone.

27. Biotechnology and Biopharmaceuticals (2003) R. Ho and M. Gibaldi, published by Wiley.

Programme Membership
GA_SADVG_O09 202000 Postgraduate Diploma in Science in Advanced Biopharmaceutical Science