

BIOL09040 Biopharmaceutical Science

Full Title	Biopharmaceutical Science		
Status	Uploaded to Banner	Start Term	2020
NFQ Level	09	ECTS Credits	05
Module Code	BIOL09040	Duration	Semester - (13 Weeks)
Grading Mode	Numeric	Department	Physical & Life Sciences
Module Author	Orla Slattery		
Co Authors	Karen Finn		

Module Description

A comprehensive overview of the development and clinical applications of protein, nucleic acid and cell-based therapeutics in the biopharmaceutical sector.

Learning Outcomes

On completion of this module the learner will/should be able to:

1. Evaluate protein and nucleic acid structure and recognise how structure dictates function and therapeutic effect.
2. Demonstrate key techniques fundamental to recombinant DNA technology and their application in the development and production of protein-based therapeutics.
3. Critically appraise the clinical applications of nucleic acid and whole-cell based therapeutics.
4. Evaluate and assess protein-based therapeutics, their development, production and mode of action.
5. Lead research on the activities of key players in the biopharmaceutical industry - with focus on the company, products and targeted diseases.
6. Design and perform experiments based on advanced molecular techniques. Present and interpret scientific results.

Indicative Syllabus

1. Overview of Protein Structure

Protein Structure (primary, secondary, tertiary and quaternary levels of organisation), protein stability and folding, post-translational modifications.

2. Gene manipulation and recombinant DNA technology

Function and structure of nucleic acids, isolation and cloning of DNA, bioinformatics and computer-based tools for vector construction and mapping, modulation of protein expression and analysis of gene expression and function. Applications of CRISPR-Cas9 technology.

3. Protein Therapeutics

Production of first-generation recombinant protein biopharmaceuticals, using *E. coli*, yeasts, fungi, animal and plant cell lines, transgenic animals and plants. Design of second and third generation protein biopharmaceuticals. Comprehensive overview of the biopharmaceutical industry and key their associated protein-based therapeutics including:

Therapeutic Hormones (Insulin, Glucagon, Human Growth Hormone, Gonadotrophins etc).

Cytokines (Interferons Interleukins Tumour Necrosis Factors etc).

Therapeutic Enzymes (Asparaginase, DNase, Galactosidase, Superoxide Dimutase, digestive aids etc).

Recombinant Blood Products (Factor VIII and IX, Anticoagulants, Thrombolytic agents etc)

4. Nucleic Acid and Cell-based Therapeutics

Clinical conditions targeted by nucleic acid and cell-based therapeutics.

Gene therapy (Genticine, Glybera, Luxtuma, Zolgensma, Kymriah, Patisiran etc).

Antisense and Aptamer Technology (Vitravene and Maucagen etc).

Stem-cell therapeutics.

Teaching and Learning Strategy

Teaching and learning strategies include lectures, tutorials and laboratory workshops and an industrial site-visit. Tutorials will involve active learning where students work in small groups to solve problems and discuss module topics under the supervision of the lecturer. Delivery will be based on student pre-reading of chosen topics from the designated textbook, ebrary sources, and from Moodle-based resources. Lectures will be supported by PowerPoint slides and Technology-enhanced learning tools that will be made available to the students *via* Moodle. The laboratory workshop comprises laboratory-based activities and an industrial site-visit. which take place over a three day period. These activities involve students working individually, and in groups, to gain experience and competence in a range of advanced molecular biology techniques.

Assessment Strategy

Continuous assessment (CA), laboratory workshops, and a final written examination are used to mark student performance. CA (30% of total grade) will consist of a Moodle-based examination that assesses student knowledge of theory and practical content. Practical evaluation (30% of total grade) will consist of scientific report writing and data handling exercises that encourage student exploration/discovery of more in-depth knowledge of practical protocols and the underlying theory. The end of year formal examination (40% of total grade) will examine the theoretical aspects of the module, in addition to the experimental techniques conducted by the students.

Repeat Assessment Strategies

Repeat module components as dictated based on student performance and at the discretion of the programme board.

Indicative Coursework and Continuous Assessment:		60 %		
Form	Title	Percent	Week (Indicative)	Learning Outcomes
Assessment	Assessment	30 %	OnGoing	1,2,3,4,5
Assessment	Practical	30 %	End of Semester	6

End of Semester / Year Formal Exam:		40 %		
Form	Title	Percent	Week (Indicative)	Learning Outcomes
Closed Book Exam	Final Exam	40 %	End of Semester	1,2,3,4,5,6

Blended Delivery Mode Average Weekly Workload:			4.85 Hours		
Type	Description	Location	Hours	Frequency	Weekly Avg
Lecture	Lecture	Not Specified	3	Weekly	3.00
Practical	Practical	Not Specified	24	Once Per Module	1.85

Required Reading Book List

Sindelar, D., (2019). *Pharmaceutical Biotechnology*. Edition. Springer.
ISBN 303000709X ISBN-13 9783030007096

Pazdernik, J., (2018). *Molecular Biology*. Academic Cell.
ISBN 0128132884 ISBN-13 9780128132883

Patten, L., (2017). *Molecular Biotechnology*. ASM Press.
ISBN 1555819362 ISBN-13 9781555819361

Walsh, G., (2013). *Biopharmaceuticals*. John Wiley & Sons.
ISBN 9781118687383 ISBN-13 1118687388

Walsh, G., (2007). *Pharmaceutical Biotechnology*. John Wiley & Sons.
ISBN 9780470012444 ISBN-13 0470012447

Ho, R., (2013). *Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs*. 2nd Edition. Wiley-Blackwell.

Online Resources

BIOPHARMA: Biopharmaceutical Products in the U.S. and European Markets - Recent U.S. Approvals

<https://www.ncbi.nlm.nih.gov>

<https://www.ensembl.org/index.html>

<https://www.uniprot.org>

<https://www.rcsb.org/>

Other Resources

British/European/US Pharmacopoeia

Programme Membership

GA_SADVG_O09 202000 Postgraduate Diploma in Science in Advanced Biopharmaceutical Science

GA_SBIOG_V09 202100 Master of Science in Biopharmaceutical Manufacturing

GA_SBIOG_N09 202100 Certificate in Biopharmaceutical Manufacturing