BIOL09043
Research Project

Full Title	Research Project		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	09	**ECTS Credits**	10
Module Code	BIOL09043	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences
Module Author	Orla Slattery		
Co Authors	Mary McMahon		

Module Description

The research project is the culmination of the Biopharmaceutical Higher Diploma. The project should take the form of a proposal for design and development of a biopharmaceutical product to prevent treat or diagnose a specific medical condition. The student will undertake a literature review to source information on the target condition and current gold-standard therapies. Based on this information and the student's knowledge gained through the programme, the student should propose an alternative biopharmaceutial product, for prevention, treatment or diagnosis of said medical condition. Thereafter, students should include a detailed overview of the design, function, clinical trials, manufacturing, validation and quality control testing prior to release of their proposed product. The students will apply their knowledge of quality standards and regulations pertaining to the manufacturing of biopharmaceutical products throughout this work.

Learning Outcomes

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

1.	Lead the development of a proposal for the design and manufacture of a biopharmaceutical product.
2.	Critically evaluate and review literature (and other relevant, reliable sources) using appropriate keywords and databases.
3.	Synthesize and collate relevant information from the programme modules to apply their knowledge to a current medical concern and the proposed design, manufacture, release and control of a biopharmaceutical.
4.	Communicate results of the review in written and oral forms, demonstrating critical analysis, synthesis and organisation of knowledge.

Indicative Syllabus

Completion of a major literature survey relating to a chosen medical condition and current gold-standard therapeutics (to be assigned by the project co-ordinator).

Completion of a proposal for the design and development of a novel biopharmaceutical product for the prevention, treatment or diagnosis of a specifc medical condition which should include details of production function, manufacturing, validation, quality control testing and regulation.

Students should draw on their breadth of knowlege from all modules of the Biopharmaceutical Science Higher Diploma to complete the proposal.

Teaching and Learning Strategy

Learners will be assigned an academic supervisor.

The preparation of the thesis is largely self-directed with guidance from the assigned academic supervisor.

The word count for the thesis is 10,000 +/- 5% which excludes prelimilary pages, bibliography and appendices.

Students who are not in a relevant industrial setting will be supported by all programme board staff who have have expertise in various aspects of the Biopharm Industry.

Assessment Strategy

Thesis (biopharmaceutical product comprehensive review) 60% - failed element

Oral presentation / viva 40% - failed element

Repeat Assessment Strategies
Arranged on an individual basis and at the discretion of the Programme Board.

Indicative Coursework and Continuous Assessment:		100 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Thesis	Thesis	60 %	End of Semester	1,2,3,4
Oral Exam	Oral presentation / viva	40 %	End of Semester	4

Blended Delivery Mode Average Weekly Workload:			0.50 Hours		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Supervision	Consultation with Academic Supervisor	Not Specified	0.5	Weekly	0.50

Required Reading Book List
Sindelar, D., (2019). *Pharmaceutical Biotechnology*. Edition. Springer. ISBN 303000709X ISBN-13 9783030007096
Walsh, G., (2013). *Biopharmaceuticals*. John Wiley & Sons. ISBN 9781118687383 ISBN-13 1118687388
Stefania, G., (2004). *Directory of Approved Biopharmaceutical Products*. CRC Press. ISBN 0415263689 ISBN-13 9780415263689
Walsh, G., (2007). *Pharmaceutical Biotechnology*. John Wiley & Sons. ISBN 9780470012444 ISBN-13 0470012447
Patten, L., (2017). *Molecular Biotechnology*. ASM Press. ISBN 1555819362 ISBN-13 9781555819361
Montgomery, C., (2012). *Design and Analysis of Experiments*. John Wiley & Sons. ISBN 1118097939 ISBN-13 9781118097939
Anurag, G., (2012). *Process Validation in Manufacturing of Biopharmaceuticals, Third Edition*. CRC Press. ISBN 9781439850930 ISBN-13 1439850933
McB, H., (2006). *Method Validation in Pharmaceutical Analysis*. John Wiley & Sons. ISBN 9783527604470 ISBN-13 3527604472
Buckingham, L., (2019). *Molecular Diagnostics*. ISBN 0803668295 ISBN-13 9780803668294
Feroz, S., (2015). *Quality by Design for Biopharmaceutical Drug Product Development*. Springer. ISBN 9781493923168 ISBN-13 1493923161

Online Resources
http://www.biopharma.com

Other Resources
GMIT Harvard Referencing Guide

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