BIOL09045
Quality Management Systems and Regulatory Affairs

Full Title	Quality Management Systems and Regulatory Affairs		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	09	**ECTS Credits**	05
Module Code	BIOL09045	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences
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Module Description

This module reviews the key regulatory requirements for (bio)pharmaceutical product development, production and marketing. It addresses the role of quality management in determining key factors such efficacy, purity and safety. It describes the ISO 9000 quality standard requirements of biopharmaceutical manufacturing and addresses the role of ISO 9000 certification in achieving these standards. It describes the difference between quality standards and international regulatory requirements and how quality management is associated with regulatory compliance. It addresses the regulatory requirements of various international regulatory authorities such as the FDA and EMA, National Authorities (i.e..HPRA) and describes the role of the more general ICH guidelines in meeting regulatory requirements.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Demonstrate a clear understanding of the role of quality assurance throughout the lifecycle of a biopharmaceutical product and identify key elements monitored by the quality control system in the manufacture of a biopharmaceutical drug.
2.	Evaluate the regulatory demands of agencies such as the European Medicines Evaluation Agency (EMA) and Food & Drug Administration (FDA) in terms of the development, production, characterisation and evaluation of biopharmaceutical products
3.	Evaluate Critical Quality Attributes (CQA) for biopharmaceutical manufacturing and critically analyse CQAs that demonstrate compliance with regulatiions for different types of biopharmaceuticals.
4.	Analyse the role of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in regulating biopharmaceutical drugs and apply QbD principles to the step-by-step development of a purification process for a biopharmaceutical drug

Indicative Syllabus

Overview of biopharmaceuticals and the manufacturing process

- Nature of biopharmaceutuocal drugs compared with pharmaceutical products and associated challenges in regulating biopharmaceutical development and manufacture.
- Upstream process operations such as cell culture and harvest steps, and the downstream processes including purification with multiple steps of chromatography and filtration.

The International Organisation for Standardisation (ISO)

- History of ISO Structure of ISO The ISO 9000 quality standard.
- Key quality principles that apply to biopharmaceutical manufacturing.
- Quality management model.
- Quality aspects asssociated with the development, validation and manufacture of biopharmaceuticals

Regulatory Agencies

- Overview and history of the FDA
- The Code of Federal Regulations
- Structure of the EMA and European regulations and directives
- European Directorate for the Quality of Medicines (EQDM)
- National Authorities - Health Products Regulatory Authority (HPRA)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

- Brief history of the ICH
- Key Achievements
- Quality systems and regulatory requirements used to monitor biopharmaceutical product consistency and maintain clinical performance.

Regulation of Biopharmaceuticals

- Process control and validation in biopharmaceutical manufacturing
- CMC regulatory compliance
- Quality by Design

Teaching and Learning Strategy

Online lectures, tutorials and provision of addition notes and reading material. Students will also engage in active and independent learning where they carry out further study and investigations of topics introduced during delivery of the module.

Assessment Strategy

Assessment consists of continuous assessment (CA). The CA component will involve group work and individual independent learning and the students are assessed using various methods.

Repeat Assessment Strategies

Students who fail the CA component must repeat the module.

Indicative Coursework and Continuous Assessment:		**100 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Multiple Choice	MCQ	20 %	Week 2	1
Multiple Choice	MCQ	20 %	Week 5	2
Assignment	Assignment	30 %	Week 8	3
Group Project	Project	30 %	Week 14	4

Blended Delivery Mode Average Weekly Workload:			**2.00 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture (Online)	Online	1	Weekly	1.00
Tutorial	Discussion group (Online)	Not Specified	1	Weekly	1.00

Recommended Reading Book List

Feroz, S., (2015). *Quality by Design for Biopharmaceutical Drug Product Development*. 2nd edition. Springer.
ISBN 9781493923168 ISBN-13 1493923161

Geigert, J., (2019). *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals*. 3rd Edition. Springer.
ISBN 9783030137540 ISBN-13 3030137546

Online Resources

European Medicinces Agency https://www.ema.europa.eu/en

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use https://www.ich.org/

US Food & Drug Administration https://www.fda.gov/

Other Resources

Other notes as provided during delivery of the module

Programme Membership

GA_SADVG_O09 202000 Postgraduate Diploma in Science in Advanced Biopharmaceutical Science