BIOL09046
Validation for Biopharmaceuticals

Full Title	Validation for Biopharmaceuticals		
Status	Uploaded to Banner	**Start Term**	2020
NFQ Level	09	**ECTS Credits**	05
Module Code	BIOL09046	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences
Module Author	Rita Woodings		
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Module Description

This module aims to provide learners with a broad understanding of Validation in the Biopharmacuetical manufacturing context, including Process, Equipment, Cleaning, Automated System and Test Method Validation.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Understand the regulatory basis for Validation and the related requirements of the (Bio)pharmaceutical sector from regulatory bodies.
2.	Communicate the key steps required for any Validation and fully comprehend the underpinning concepts of specification and verification.
3.	Participate and add value as a team member in industry on multiple types of Validation projects, e.g. Process, Equipment, Cleaning, Automated System or Test Method Validation.
4.	Implement the principles of Validation to design and develop Validation documents.
5.	Apply risk management and change control to Validation activities and Validated entities, e.g. Process, Equipment, Test Methods.
6.	Appreciate the key validation characteristics of a test method and factors that influence test method variability.

Indicative Syllabus

Regulatory perspective: ICH/FDA/EMA

Fundamental principles of Validation in the context of GMP

Building Validation documents, including specifications, protocols and reports.

Biopharmaceutical process and equipment qualification (DQ, IQ, OQ, PQ)

Introduction to the GAMP guidance for validating automated / computerized systems

Fundamental principles of analytical method validation

Typical validation characteristics for test method validation, e.g. accuracy, precision, specificity

Key validation support processes like risk management and change control

Teaching and Learning Strategy

Teaching is carried out using synchronous and asynchronous online lectures as well as online discussion and problem-solving tutorial sessions. There will also be some workshop type sessions where students will work as part of a team to achieve specific outputs, e.g. risk assessment, protocol generation. 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) throughout the semester. This will be broken into a question-based assessment, an essay and a group project write-up. In addition to nurturing individual independent learning, a key focus of this module is to develop team and

project management skills. This will be achieved through an assigned validation project with students required to work constructively together to design a validation protocol.

Repeat Assessment Strategies
Written assignment.

Indicative Coursework and Continuous Assessment:		**100 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Group Project	Protocol project	50 %	Week 8	3,4,5
Assessment	Theory questions	50 %	Week 12	1,2,5,6

Blended Delivery Mode Average Weekly Workload:			**3.00 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Online	2	Weekly	2.00
Tutorial	Tutorial	Online	1	Weekly	1.00

Required Reading Book List
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
Wingate, B., (2008). *GAMP 5 A Risk-Based Approach to Compliant GxP Computerized systems* Version 5 Edition. International Society of Pharmaceutical Engineering.

Online Resources
www.ICH.org
www.fda.gov
www.ema.europa.eu
https://www.intechopen.com/books/analytical-chemistry/analytical-method-validation-for-biopharmaceuticals

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