APPROVED

PHAR S8024: Validation and Instrumentation

Module Details

Module Code:	PHAR S8024
Full Title:	Validation and Instrumentation APPROVED
Valid From::	Semester 1 - 2020/21 (September 2020)
Language of Instruction:	English
Duration:	1 Semester
Credits::	5
Module Owner::	Arjan van Rossum
Departments:	Life and Health Sciences
Module Description:	This module introduces the learner to the principles of validation and risk management and the application of current Good Manufacturing Practices to the validation of equipment, plant, utilities, processes and procedures in the biopharmaceutical industry.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Illustrate the need for validation and explain how it complements good manufacturing practice.
MLO2	Examine the regulatory requirements of validation.
MLO3	Assess the principles of validation and a range of strategies used in its application.
MLO4	Evaluate the various process development considerations for the full scale manufacture of biopharmaceuticals.
MLO5	Develop suitable validation approaches to achieve process validation over the product lifecycle.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named DkIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).*
No recommendations listed

Module Indicative Content
Validation Principles, Regulations and Model EU and FDA regulations and guidelines. V-Model, introduction to the understanding-demonstration-monitoring approach, Quality by design, Industrial standard ASTM E2500-07. Risk management, industrially recognised risk management guidelines and tools, risk registers.
Process Validation Biopharmaceutical process unit operations, Process validation workflow, and process validation prerequisites, Process validation studies: viral clearance, impurity clearance, process consistency, process intermediate stability, process solution stability, drug substance fill/freeze/thaw/storage, mixing studies and chromatography resin and reusable membrane lifetime validation. Commissioning and qualification of processes and utilities. Process Performance Qualification, Continued Process Verification, Cleaning Validation/Verification. Prospective, concurrent and retrospective approaches in process validation. Revalidation. Review of the steps to prove that analytical methods are fit for purpose with reference to current guidelines.
Documentation Preparation and review of validation documents such as the User Requirement Specification, Validation Master Plan, Validation Protocol, Validation Report.
Instrumentation Overview of equipment and instrumentation for validation/biopharm manufacturing.

Module Assessment

Assessment Breakdown	%
Course Work	50.00%
Final Examination	50.00%

Module Special Regulation

Assessments

Part Time On Campus

Course Work

Assessment Type	Written Report	**% of Total Mark**	40
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	5
Duration in minutes	0		

Assessment Description
Prepare a validation document which sets out suitable validation approaches to achieve process validation over the product lifecycle.

Assessment Type	Continuous Assessment	**% of Total Mark**	10
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	1,2,3,4
Duration in minutes	0		

Assessment Description
In class assessment.

No Project

No Practical

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	50
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	1,2,3,4
Duration in minutes	0		

Assessment Description
n/a

Reassessment Requirement

A repeat examination
Reassessment of this module will consist of a repeat examination. It is possible that there will also be a requirement to be reassessed in a coursework element.

Module Workload

This module has no Full Time On Campus workload.

Workload: Part Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	Lecture / tutorial / discussion as appropriate	Every Week	2.00	2
Independent Study	Non Contact	Independent study	Every Week	3.00	3
Directed Reading	Non Contact	Directed reading	Every Week	3.00	3
				Total Weekly Learner Workload	8.00
				Total Weekly Contact Hours	2.00

Module Resources

Recommended Book Resources

Robert A. Nash,Alfred H. Wachter. (2003), Pharmaceutical Process Validation, Marcel Dekker, [ISBN: 0-8247-0838-5].

Anurag S. Rathore and Gail Sofer (Editors). (2012), Process Validation in Manufacturing of Biopharmaceuticals, CRC Press, [ISBN: 978-1-43-9850].

Walkiria S. Schlindwein,Mark Gibson. (2018), Pharmaceutical Quality by Design, John Wiley & Sons, [ISBN: 1118895207].

Feroz Jameel,Susan Hershenson,Mansoor A. Khan,Sheryl Martin-Moe. (2015), Quality by Design for Biopharmaceutical Drug Product Development, Springer, [ISBN: 1493923161].

This module does not have any article/paper resources

Other Resources

Website, Food and Drug Administration,
http://www.fda.gov

Website, Health Products Regulatory Authority,
http://www.hpra.ie/

Website, International Conference for Harmonization,
http://www.ich.org/

Website, EU GMP Guidelines,
https://ec.europa.eu/health/documents/eu dralex/vol-4_en

Website, Industrial Standard: ASTM 2007, E2500-07 Standard Guide for Specification, Design and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment , Philadelphia, US,
http://www.astm.org