APPROVED

PHAR S8023: Regulatory Affairs and (Bio) Pharmaceutical Data Integrity

Module Details

Module Code:	PHAR S8023
Full Title:	Regulatory Affairs and (Bio)Pharmaceutical Data Integrity APPROVED
Valid From::	Semester 1 - 2020/21 (September 2020)
Language of Instruction:	English
Duration:	1 Semester
Credits::	5
Module Owner::	Matthew Molloy
Departments:	Life and Health Sciences
Module Description:	The development and production of pharmaceuticals occurs under the strictest of legislative and scientific frameworks. As such, procedures, systems and methodologies must be utilised and understood to ensure the highest of data integrity standards. Students will gain in-depth knowledge of the important role that Good Manufacturing Practice (GMP),Quality systems and regulations plays in the lifecycle of a new drug candidate. This module will enable candidates to objectively and rigorously assess dataset quality and integrity and see data as a valuable asset.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Evaluate the use of current Good Manufacturing Practice (cGMP), Quality Control (incl. quality management software) and Quality Assurance and evaluate their importance in the (bio)pharmaceutical industry
MLO2	Compare and contrast international legislation and the role of regulatory authorities in evaluating and approving (bio)pharmaceutical drug candidates.
MLO3	Evaluate and interpret pharmacovigilance, GVP (Good PharmacoVigilance Practices) and risk management plans for new (bio)pharmaceutical drug products
MLO4	Use descriptive statistics to characterise and validate datasets. Identify outliers in a dataset and set up warnings/flags when data breaches predefined working parameters.
MLO5	Protect and organise data by understanding filesystems, encryption and good data governance.

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
cGMP and Quality systems GMP and Quality management, Quality systems to include Complaints, Recalls, Self Inspections and Auditing, pharmacovigilance, GVP and Risk management plans. The role of GMP and QA in the discovery, testing, marketing and postmarketing of new (bio) pharmaceutical drugs / drug candidates.
Overview of the role and remit of Regulatory Authorities Review of the FDA (USA), EMA (EU) and HPRA(Ire): Structure and mission, role in the pharmaceutical drug development and approval process. Drug distribution and drug marketing authorisations (incl. IND & NDA applications)
Fundamental Analytics Skills Understand statistical terms and concepts, data types & importing, Data & Tables, Visualising data (Graphing, Line & Scatter Plots, Histograms, Analysing & Interpreting), Descriptive & predictive statistics, Outlier identification & Flags/Warnings

Module Assessment

Assessment Breakdown	%
Course Work	50.00%
Final Examination	50.00%

Module Special Regulation

Assessments

Part Time On Campus

Course Work

Assessment Type	Other	**% of Total Mark**	30
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	4,5
Duration in minutes	0		

Assessment Description
Data Analytics/Integrity assessment: This assessment will involve Case Study analysis & reporting. Learners will validate and analyse an encrypted dataset using appropriate graphs & descriptive statistics. Learners will analyse datasets in order to identify deviations from predefined working parameters.

Assessment Type	Continuous Assessment	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	1,2,3
Duration in minutes	0		

Assessment Description
Students will be asked to complete an assignment / report on a relevant aspect of GMP or related (bio)pharmaceutical regulatory component.

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
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	No Description	Every Week	2.00	2
Lecturer Supervised Learning	Contact	Practical data analysis workshop.	Once per semester	0.27	4
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	8.27
				Total Weekly Contact Hours	2.27

Module Resources

Recommended Book Resources

(2018), Calculations (GM5307), 8th. Teagasc Modular Training Programmes.

Croft, A. & Davison, R.. (2006), Foundation Mathematics, 4th.

Supplementary Book Resources

Wayne Winston. (2016), Microsoft Excel Data Analysis and Business Modeling, Microsoft Press, p.984, [ISBN: 9781509304219].

Shazia Sadiq. (2013), Handbook of Data Quality, Springer Science & Business Media, p.438, [ISBN: 978-3-642-36257-6].

This module does not have any article/paper resources

Other Resources

Website, Food and Drug Administration (USA). Food and Drug Administration (USA),
https://www.fda.gov/home

Website, European Medicines Agency,
https://www.ema.europa.eu/en

Website, Health Products Regulatory Authority (HPRA),
https://www.hpra.ie/

Website, European Directorate for the Quality of Medicines and Healthcare,
https://www.edqm.eu/en

Website, International Conference on Harmonisation (ICH),
https://www.ich.org/

Website, British Pharmacopoeia,
https://www.pharmacopoeia.com/

Website, 'Eudralex - EU legislation'. Eudralex - EU legislation,
https://ec.europa.eu/