UNIVERSITY of BRADFORD

Module Descriptor

Module Details	
Module Title	Quality Assurance and Medicine Safety
Module Code	PHA7051-B
Academic Year	2020/1
Credits	20
School	School of Pharmacy and Medical Sciences
Subject Area	Pharmacy
FHEQ Level	FHEQ Level 7
Pre-requisites	N/A
Co-requisites	N/A

Contact Hours	
Type	Hours
Tutorials	8
Independent Study	14
Lectures	34
Directed Study	144

Availability	
Occurrence	Location / Period
BDA	University of Bradford / Semester 1

Module Aims

To provide the students with the opportunity to develop their knowledge & understanding of the principles of Quality Assurance (QA), Quality Control (QC) & Good Manufacturing Practice (GMP) necessary for assuring & managing product quality in the manufacture of medicines.To provide the students with the opportunity to develop their knowledge & understanding of current regulatory procedures in the licensing of medicines, WHO guidelines for emergency medicine donation &medicines donated to resource-limited countries, the concepts of modern instrumental analysis & the monitoring of the cont O/S

Outline Syllabus

(a) Introduction to QA systems; principles of global QA and QC, Good Pharmaceutical Manufacturing Practice; the ICH guidelines and key managerial issues for the pharmaceutical industry. (b)Sterilisation processes for pharmaceuticals. (c) The role of International pharmacopoeia standards and monographs in medicine control and protecting public health; ICH guidelines for using analytical method validation in QC. (d) Systems for regulatory control of drugs: the Licensing authorities, ICH requirements, centralised and decentralised procedures. (e) Requirements for Pharmaceutical Products Licence approval: development of a drug registration dossier. (f) Regulatory issues associated with off-license, paediatric and orphan drugs, counterfeiting, natural products and homeopathic medicines and links with 'NICE'. (g) Quality assurance of donated medicines: shelf-life, presentation, packaging and labelling (h) Advanced topics in pharmaceutical analysis, focusing on modern analytical techniques.

Learning Outcomes

Outcome Number	Description
1	Assess, evaluate and describe with critical awareness the principles of the QA, QC and GMP systems necessary for assuring product quality in the manufacture of medicines.
2	Critically evaluate current regulatory procedures in the licensing of medicines and the development of International Harmonisation, and how they affect a developing country.
3	Analyse with critical awareness complex, incomplete or contradictory QA or regulatory data and formulate appropriate solutions.
4	Critically assess and evaluate the uses of modern analytical techniques in determining the quality of medicines both during processing and at the final product stage.
5	Devise a protocol for the assay of a compound in view of its chemical structure.
6	Analyse with critical awareness scientific research methods and develop capabilities to conduct research into QA and regulatory issues.
7	Employ verbal and written communication skills.
8	Employ team-working skills and the ability to evaluate individual contributions to group processes.

Learning, Teaching and Assessment Strategy

Learning outcomes 1 and 2 will be developed through a series of lead lectures supported by tutorial and discussion sessions. The students will be encouraged to examine the current guidelines and regulations in their home country and discuss how these will link with international harmonisation guidelines. Learning outcome 3 will be developed through small case studies of typical problem areas in QA (illustrated by film). Learning outcomes 3 and 4 will be developed through discussion sessions and syndicate workshops, followed by a short report and group presentations on key QA issues. Learning outcomes 5-8 will be developed through tutorials, independent studies and small group-learning opportunities; by conducting a small project on a drug profile, followed by group discussions and presentations.

Learning outcomes 1-2 will be assessed via summative examination. Learning outcomes 1-8 will be assessed via coursework: the presentation and a case study report.

Mode of Assessment				
Type	Method	Description	Length	Weighting
Summative	Examination - Closed Book	Written examination	2 hour	50%
Summative	Coursework	Oral presentation	N/A	25%
Summative	Coursework	Case study report 0-1500 words	N/A	25%

Reading List
To access the reading list for this module, please visit https://bradford.rl.talis.com/index.html

Please note:
This module descriptor has been published in advance of the academic year to which it applies. Every effort has been made to ensure that the information is accurate at the time of publication, but minor changes may occur given the interval between publishing and commencement of teaching. Upon commencement of the module, students will receive a handbook with further detail about the module and any changes will be discussed and/or communicated at this point.

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