Module Definition Form (MDF)

Module code: MOD005038	**Version:** 3 **Date Amended:** 27/Feb/2020

1. Module Title
Drug, Development and Regulatory Affairs

2a. Module Leader
Irfan Bashir

2b. School
School of Allied Health and Social Care

2c. Faculty
Faculty of Health, Medicine and Social Care

3a. Level
6

3b. Module Type
Standard (fine graded)

4a. Credits
30

4b. Study Hours
300

5. Restrictions

Type	Module Code	Module Name	Condition
Pre-requisites:	None		
Co-requisites:	None		
Exclusions:	None		
Courses to which this module is restricted:	none		

LEARNING, TEACHING AND ASSESSMENT INFORMATION

6a. Module Description

Based on the previous knowledge/experience of pharmaceutics and medicinal chemistry, students will explore the processes involved in the development of a new drug, from discovery to marketing including a chronological account of the drug development process. The principles of quality assurance as applied to the processes involved in the development, manufacture and distribution of medicines will be addressed. This will include market assessment and evaluation of clinical need different stages of clinical trials, drug licensing procedures patents, approval and post-marketing surveillance. In addition, current topics about advanced drug delivery systems will be introduced. Student also will be involved in workshops and team work to critically discuss topical issues in the pharmaceutical industry and to develop their own prospective applications for new products. Drug Development and Regulatory Affairs module will be delivered using Face to face learning and students are expected to attend face to face sessions as well as participate in on-line study using our Canvas, internet resources and on line discussions as required. Student will have opportunities to develop their presentation and writing skills and to reflect their previous learning experience by writing their drug development reports.

6b. Outline Content

- Drugs are discovered by a variety of approaches – computer molecular modelling of structure-function relationships, combinatorial chemistry and high-throughput screening and identification of natural products. - Drug development is a very long and expensive process, taking in excess of ten years. Less than 1% of candidate drugs make it to market. The exhaustive procedures of Phase 1, 2 and 3 clinical trials are explained. - Chemical hazards and waste disposal. - GMP, GLP, Quality control and quality assurance - WHO and ICH regulations - Procedures for licensing of drugs varies in different countries, MHRA in the UK, EMA (Europe) and FDA (USA), is explained. - In the UK, the approval for prescribing a drug by NICE is decided largely on pharmaco-economic grounds. - There are extensive post-marketing surveillance arrangements to ensure the safety of medicines. - Current issues facing the pharmaceutical industry will also be considered e.g. problems of counterfeit medicines. - Current topics in drug delivery systems

6c. Key Texts/Literature

The reading list to support this module is available at: https://readinglists.aru.ac.uk/

6d. Specialist Learning Resources

Category two laboratory; Technical support; Computer laboratory; VLE

7. Learning Outcomes (threshold standards)		
No.	**Type**	**On successful completion of this module the student will be expected to be able to:**
1	Knowledge and Understanding	Describe methods and strategies of drug development.
2	Knowledge and Understanding	Critically analyse the regulatory issues surrounding the drug development process and the functions of the regulatory bodies involved.
3	Knowledge and Understanding	Explore current topics in drug delivery systems, pharmaceutical industry and drug developments
4	Intellectual, practical, affective and transferrable skills	Evaluate methods for controlling dosage form quality and determining drug effectiveness.
5	Intellectual, practical, affective and transferrable skills	Design and communicate a drug development strategy emphasizing the role of the regulatory bodies in the process.

8a. Module Occurrence to which this MDF Refers				
Year	**Occurrence**	**Period**	**Location**	**Mode of Delivery**
2026/7	ZZF	Template For Face To Face Learning Delivery		Face to Face

8b. Learning Activities for the above Module Occurrence			
Learning Activities	**Hours**	**Learning Outcomes**	**Details of Duration, frequency and other comments**
Lectures	20	1-5	2 h (10 weeks)
Other teacher managed learning	18	1-5	2 x 3 h Laboratory Sessions 4 x 2 h Workshops 4 x 1 h tutorials
Student managed learning	262	1-5	Self-directed study
TOTAL:	300		

9. Assessment for the above Module Occurrence

The assessment for some modules includes a presentation (see below for details on how this particular module is assessed). We recognise that presenting, especially to a large group, can cause significant anxiety or distress for some students. If this may affect you, please contact your Module Leader or the Disability and Neurodiversity Service as early as possible. We will work with you to consider appropriate reasonable adjustments. Depending on your individual needs, these might include, for example, presenting to a smaller group or presenting only to a member of academic staff.

Assessment No.	Assessment Method	Learning Outcomes	Weighting (%)	Fine Grade or Pass/Fail	Qualifying Mark (%)
010	Coursework	1-5	70 (%)	Fine Grade	30 (%)
Portfolio that compiles an essay and e-poster presentation (4000 words equivalent)					

Assessment No.	Assessment Method	Learning Outcomes	Weighting (%)	Fine Grade or Pass/Fail	Qualifying Mark (%)
011	Practical	1-4	30 (%)	Fine Grade	30 (%)
Practical: Video clip role-play covering topics on pharmaceutical regulations i.e. elements of GXP.					

In order to pass this module, students are required to achieve an overall mark of 40% (for modules at levels 3, 4, 5 and 6) or 50% (for modules at level 7*).

In addition, students are required to:
(a) achieve the qualifying mark for each element of fine graded assessment as specified above
(b) pass any pass/fail elements

[* the pass mark of 50% applies for all module occurrences from the academic year 2024/25 – see Section 3a of this MDF to check the level of the module and Section 8a of this MDF to check the academic year]