Module Definition Form (MDF)

Module code: MOD005389	**Version:** 1 **Date Amended:** 21/Apr/2016

1. Module Title
Pharmaceutical Manufacturing and Quality Principles

2a. Module Leader
Basel Arafat

2b. School
School of Allied Health and Social Care

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

3a. Level
7

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:			

LEARNING, TEACHING AND ASSESSMENT INFORMATION

6a. Module Description

In this module, students will develop wider knowledge of the integral parts of the pharmaceutical industry including research, development, manufacturing, distribution, marketing and sales. The general considerations to plan, design, construct, validate, and operate complex manufacturing facilities that meet world-class pharmaceutical standards will be covered. Students will study and debate the practical applications of Good Design Practices (GDPs) including compliance with applicable safety, health, environmental regulations and current Good Manufacturing Practice (cGMP).

Students will critically evaluate the processes of manufacturing large-scale productions in compliance with cGMP, and establish the principles of quality assurance as applied to the processes according to EU Regulations or International Conference on Harmonization (ICH) guidelines. Workshops are designed to critically appraise the process of scale-up a product to ensure that manufactured medicine is safe and effective.

In addition, pharmaceutical industry practitioners will deliver seminars in how a quality system has to be set up such that the drug is manufactured in accordance with approved procedures. This will include the principles of quality assurance (QA) as of the development, manufacture and distribution of medicines. Quality control tests (QC) and documentation will be comprehensively covered,

students will be required to critically assess audit trails (i.e., traceability of materials and processes) as well as tests to be conducted on the raw materials, intermediates, and finished products. The role of the QA/QC team within the industry framework will be detailed, including product manufacture and registration. Furthermore, this module equips graduates with the relevant knowledge and skills to apply Pharmaceutical Quality by Design (QbD) bases on the application of product and process sciences, from early to late stages of the product development cycle, to provide accelerated regulatory submission pathways for new applications.

This module adopts both approaches face-to-face learning and independent approach to learning. Thus, students expected to attend lectures, seminars and workshop sessions as well as conduct a reflective and analytical evaluation of current scientific literature relevant to particular pharmaceutical challenges.

6b. Outline Content

cGMP

Industrial facilities and premises

Contamination and contamination control

Manufacturing processes of scale-up

QC/QA

Applied biopharmaceutical tests

Stability testing of dosage forms

Pharmacoeconomics and outcomes research

Sales and Marketing

Legal and Intellectual Property, and Regulatory Affairs

6c. Key Texts/Literature
The reading list to support this module is available at: https://readinglists.aru.ac.uk/

6d. Specialist Learning Resources
None

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	Critically validate the processes of manufacturing large-scale productions in compliance with cGMP
2	Knowledge and Understanding	Critically appraise quality standards, regulatory requirements and commercial bases surrounding the production of pharmaceuticals
3	Knowledge and Understanding	Critically assess audit trails, QC testing and QbD principles applied on manufacturing processes and R&D laboratories
4	Intellectual, practical, affective and transferrable skills	Critically discuss topical issues in the pharmaceutical industry, specifically, in the development, manufacture and distribution of medicines
5	Intellectual, practical, affective and transferrable skills	Propose strategies to improve and optimise methods of formulation and production to apply appropriate decisions on a development project

8a. Module Occurrence to which this MDF Refers				
Year	**Occurrence**	**Period**	**Location**	**Mode of Delivery**
2025/6	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	24	1-5	2 hours per week (12 weeks) combining lectures and seminars
Other teacher managed learning	32	1-5	8 x 4 hours workshops. Opportunity for formative assessment during course delivery
Student managed learning	244	1-5	Guided study engaging in collaborative online learning activities (VLE) which is student managed and resource-based
TOTAL:	300		

9. Assessment for the above Module Occurrence					
Assessment No.	**Assessment Method**	**Learning Outcomes**	**Weighting (%)**	**Fine Grade or Pass/Fail**	**Qualifying Mark (%)**
010	Coursework	1-3	60 (%)	Fine Grade	40 (%)
Equivalent to 3000 words					
Assessment No.	**Assessment Method**	**Learning Outcomes**	**Weighting (%)**	**Fine Grade or Pass/Fail**	**Qualifying Mark (%)**
011	Practical	4-5	40 (%)	Fine Grade	40 (%)
10 min video of role-play (in pairs) as an interview covering topical issues and debating development strategies					

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]