Module Proforma

Approved, 2022.02

Summary Information

Module Code	6001PHASCI
Formal Module Title	Industrial Drug Development
Owning School	Pharmacy & Biomolecular Sciences
Career	Undergraduate
Credits	20
Academic level	FHEQ Level 6
Grading Schema	40

Module Contacts

Module Leader

Contact Name	Applies to all offerings	Offerings
Matthew Roberts	Yes	N/A

Module Team Member

Contact Name	Applies to all offerings	Offerings
Touraj Ehtezazi	Yes	N/A
Alice McCloskey	Yes	N/A
Iftikhar Khan	Yes	N/A

Partner Module Team

Contact Name	Applies to all offerings	Offerings

Teaching Responsibility

LJMU Schools involved in Delivery
Pharmacy & Biomolecular Sciences

Learning Methods

Learning Method Type	Hours
Lecture	30
Off Site	8
Workshop	12

Module Offering(s)

Offering Code	Location	Start Month	Duration
JAN-MTP	MTP	January	12 Weeks

Aims and Outcomes

Aims	To present information relating to pharmaceutical manufacturing processes and the associated regulatory controls to ensure consistency of patient safety.

Learning Outcomes

After completing the module the student should be able to:

Code	Description
MLO1	Evaluate the various processes involved in the industrial development and production of pharmaceutical and cosmetic products.
MLO2	Critically appraise the requirements for product registration and the role of regulatory bodies in the licensing process
MLO3	Synthesise a coherent proposal for the development of a theoretical product based on existing scientific data

Module Content

Outline Syllabus

Material will be delivered within 6 specified industrially relevant topics, which may be subject to change depending on current staff expertise and will focus on topical delivery systems of current interest. Potential topics include:

1. Formulation development and scale-up of pharmaceutical manufacturing processes
2. The structure of a pharmaceutical company
3. GMP, Quality Assurance and the role of the Qualified Person
4. Pharmaceutical product licensing
5. The role of regulatory authorities within the Pharmaceutical Industry
6. The International Conference on Harmonisation (ICH) process

Module Overview

Within this module, you will gain information relating to pharmaceutical manufacturing processes and the associated regulatory controls to ensure consistency of patient safety.

Additional Information

The Industrial Drug Development module will provide undergraduate students with information relating to manufacturing processes and associated regulatory controls within the Pharmaceutical Industry in order to ensure the consistency of patient safety. To achieve this a number of aspects will be considered including for example strategies associated with formulation development and material scale-up, organisational aspects within the Pharmaceutical Industry, the regulation of pharmaceutical manufacture and guidelines to ensure appropriate formulation development.

The requirement for professional behaviour within the Pharmaceutical Industry will be underscored throughout the module. A competency in this field will not be assessed.

Assessments

Assignment Category	Assessment Name	Weight	Exam/Test Length (hours)	Learning Outcome Mapping
Presentation	Presentation	40	0	MLO3
Centralised Exam	Exam	60	2	MLO1, MLO2