

Liverpool John Moores University

Title: INDUSTRIAL PHARMACY
Status: Definitive
Code: **6002DFACAP** (113297)
Version Start Date: 01-08-2011

Owning School/Faculty: Pharmacy & Biomolecular Sciences
Teaching School/Faculty: Pharmacy & Biomolecular Sciences

Team	Leader
Matthew Roberts	Y
Sharon Moore	
Gerard Lee	
Alex Pleuvry	
Luigi Martini	
Touraj Ehtezazi	
Christopher Rostron	

Academic Level: FHEQ6 **Credit Value:** 24.00 **Total Delivered Hours:** 51.00
Total Learning Hours: 240 **Private Study:** 189

Delivery Options

Course typically offered: Standard Year Long

Component	Contact Hours
Lecture	40.000
Off Site	4.000
Workshop	4.000

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	AS1		75.0	3.00
Presentation	AS3		15.0	
Essay	AS2		10.0	

Aims

To provide a broad introduction to the pharmaceutical industry for students considering a career in that sector. The module will cover philosophy and procedures used in the discovery, development, registration and commercial production of pharmaceuticals. This will include a review of the regulatory framework governing the licensing of pharmaceuticals.

Learning Outcomes

After completing the module the student should be able to:

- 1 Discuss the steps required to bring a drug successfully to market
- 2 Discuss the theory and practice of pre-formulation, formulation and stability testing as applied during pharmaceutical R & D
- 3 Demonstrate an awareness of the various processes used in the development and production of pharmaceutical products
- 4 Demonstrate an understanding of the concept and design of pre-clinical studies and clinical trials in the pharmaceutical development process
- 5 Discuss the techniques involved in the routine Quality Control of marketed pharmaceutical products
- 6 Discuss the relevant national and international requirements for product registration and the role of national agencies such as the Medicines and Healthcare Regulatory Authority (MHRA)
- 7 Appreciate recent developments in the application of biotechnology in the pharmaceutical industry

Learning Outcomes of Assessments

The assessment item list is assessed via the learning outcomes listed:

Exam	1	2	3	4	5	6	7
Presentation	1	2	3	6			
Essay	5						

Outline Syllabus

Organisation: The structural organisation of a pharmaceutical company.

Clinical trials: The role of pre-clinical studies and clinical trials, CT protocols and supplies, Phase I, II and III studies, data evaluation.

Drug discovery: An overview of early-stage pharmaceutical R & D, approaches to drug design and lead generation, chemical and biological drugs, high throughput screening.

Formulation: Pre-formulation theory and practice, formulation development approaches, packaging.

Licensing: UK, EU & US legislation, regulatory submissions, the ICH process.

Pharmaceutical Biotechnology: Classification of modern biopharmaceuticals, production & formulation of biopharmaceutical proteins & oligonucleotides.

Quality Management Systems: Legal requirements and guidelines, QA, cGxP, QC and the QP. The role of the pharmacopoeia, pharmaceutical analysis techniques, specifications & data evaluation.

Stability: The theory of pharmaceutical stability, stability protocol design, assessment of stability data.

Learning Activities

Lectures by internal academic staff and external, industry-based practitioners. Workshops requiring information gathering followed by verbal and written presentation. Tutorials addressing case examples. Industrial visits.

References

Course Material	Book
Author	MHRA
Publishing Year	2007
Title	Rules and guidance for pharmaceutical manufacturers and distributors:
Subtitle	The Orange Guide
Edition	
Publisher	Pharmaceutical Press
ISBN	0853697191

Course Material	Book
Author	MHRA
Publishing Year	2009
Title	British Pharmacopoeia
Subtitle	
Edition	
Publisher	TSO
ISBN	01132279X

Course Material	Book
Author	Remington
Publishing Year	2006
Title	The Science and Practice of Pharmacy
Subtitle	

Edition	21st Edition
Publisher	Lippincott, Williams & Wilkins
ISBN	0781746736

Course Material	Book
Author	Gibson, M.
Publishing Year	2009
Title	Pharmaceutical Preformulation and Formulation
Subtitle	
Edition	2nd edition
Publisher	Informa Healthcare
ISBN	1420073176

Course Material	Book
Author	Evens, R.P. (Ed)
Publishing Year	2007
Title	Drug and Biological Development
Subtitle	
Edition	
Publisher	Springer
ISBN	9780387329789

Notes

This module introduces the student to the discovery, development, manufacture, control and marketing of pharmaceutical products.