Liverpool John Moores University

Title:	TOPICS IN INDUSTRIAL PHARMACY
Status:	Definitive
Code:	**6005DFPHAR** (113302)
Version Start Date:	01-08-2011
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
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Academic Level:	FHEQ6	**Credit Value:**	12.00	**Total Delivered Hours:**	22.00
Total Learning Hours:	120	**Private Study:**	98		

Delivery Options
Course typically offered: Semester 2

Component	Contact Hours
Lecture	17.000
Workshop	3.000

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	AS1	Examination	80.0	2.00
Essay	AS2	Assignment	10.0	

Aims

To provide a broad introduction to the pharmaceutical industry for pharmacy students considering a career in that sector or those wanting a better understanding of how the products they will dispense (as hospital or community pharmacists) are developed and brought to market. The module will cover the philosophy and procedures used in the development, registration and commercial production of

pharmaceuticals.

Learning Outcomes

After completing the module the student should be able to:

1	Discuss the steps required to bring a pharmaceutical product succesfully to market.
2	Discuss the theory and practice of formulation and process scale-up as applied during pharmaceutical R & D.
3	Demonstrate 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 relevant national and international requirements for product registration and the role of national agencies such as the Medicines and Healthcare Products Regulator Agency (MHRA)
6	Demonstrate an awareness of the 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
Essay	3					

Outline Syllabus

The structural organisation of a pharmaceutical company.
Pre-clinical studies and clinical trials, CT protocols and supplies, Phase I, II and III studies, data evaluation.
Formulation development and scale-up approaches.
Licensing, UK, EU & US legislation, regulatroy submissions, the ICH process.
Classification of modern biopharmaceuticals, production & formulation of biopharmaceutical proteins and oligonucleotides.

Learning Activities

Lectures by internal academic staff and external, industry-based practioners. Group workshops requiring information gathering followed by oral and/or written presentation.

References

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	From Molecule to Product and Beyond
Edition	
Publisher	Springer
ISBN	9780387329789

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	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	011322799X

Notes

This module is an option module for MPharm students