

## Liverpool John Moores University

Title: INDUSTRIAL PHARMACEUTICAL SCIENCE  
Status: Definitive  
Code: **7000DFPHAR** (113102)  
Version Start Date: 01-08-2013

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

Team	Leader
Matthew Roberts	Y
Andrew Leach	

**Academic Level:** FHEQ7      **Credit Value:** 10.00      **Total Delivered Hours:** 22.00  
**Total Learning Hours:** 100      **Private Study:** 78

### Delivery Options

Course typically offered: Semester 1

Component	Contact Hours
Lecture	15.000
Tutorial	2.000
Workshop	3.000

**Grading Basis:** 40 %

### Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	AS1	Examination	80.0	2.00
Presentation	AS2	Workshop assignment	20.0	

### 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 Critically review the steps required to bring a pharmaceutical product successfully to market.
- 2 Demonstrate expertise in the theory and practice of formulation and process scale-up as applied during pharmaceutical R & D.
- 3 Critically review the various processes used in the development and production of pharmaceutical products.
- 4 Display mastery of the concept and design of pre-clinical studies and clinical trials in the pharmaceutical development process.
- 5 Critically evaluate 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 Critically review the recent developments in the application of drug discovery techniques & 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
Workshop presentation	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.*

*Drug discovery, formulation development and scale-up approaches.*

*Licensing, UK, EU & US legislation, regulatory submissions, the ICH process and the role of the Qualified Person.*

*Classification of modern biopharmaceuticals, production & formulation of biopharmaceutical proteins and oligonucleotides.*

## Learning Activities

Lectures by internal academic staff and external, industry-based practitioners. Tutorials addressing case examples. Group workshops requiring information gathering followed by oral and/or written presentation.

## References

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

<b>Course Material</b>	Book
<b>Author</b>	Evens, R.P. (Ed)
<b>Publishing Year</b>	2007
<b>Title</b>	Drug and Biological Development
<b>Subtitle</b>	From Molecule to Product and Beyond
<b>Edition</b>	
<b>Publisher</b>	Springer
<b>ISBN</b>	9780387329789

<b>Course Material</b>	Book
<b>Author</b>	Remington
<b>Publishing Year</b>	2012
<b>Title</b>	The Science and Practice of Pharmacy
<b>Subtitle</b>	
<b>Edition</b>	22nd edition
<b>Publisher</b>	Lippincott, Williams & Wilkins
<b>ISBN</b>	0857110624

<b>Course Material</b>	Book
<b>Author</b>	MHRA
<b>Publishing Year</b>	2013
<b>Title</b>	Rules and Guidance for Pharmaceutical Manufacturers and Distributors
<b>Subtitle</b>	The Orange Guide
<b>Edition</b>	
<b>Publisher</b>	Pharmaceutical Press
<b>ISBN</b>	0857111027

<b>Course Material</b>	Book
<b>Author</b>	MHRA
<b>Publishing Year</b>	2013
<b>Title</b>	British Pharmacopoeia
<b>Subtitle</b>	
<b>Edition</b>	
<b>Publisher</b>	TSO
<b>ISBN</b>	0113229321

## **Notes**

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.