Liverpool John Moores University

Title:	INDUSTRIAL DRUG DEVELOPMENT
Status:	Definitive
Code:	**6001PHASCI** (122601)
Version Start Date:	01-08-2020
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
Matthew Roberts	Y
Iftikhar Khan	
Touraj Ehtezazi	
Ismini Nakouti	

Academic Level:	FHEQ6	**Credit Value:**	20	**Total Delivered Hours:**	52
Total Learning Hours:	200	**Private Study:**	148		

Delivery Options
Course typically offered: Semester 2

Component	Contact Hours
Lecture	30
Off Site	8
Workshop	12

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	Exam	Examination: 2 hours	60	2
Presentation	Pres	Group presentation: 20 minutes	40	

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:

1	Demonstrate an understanding of the processes involved during formulation development and the industrial scale-up of pharmaceutical dosage forms.
2	Critically appraise key organisational aspects within a pharmaceutical company.
3	Constructively scrutinise how the Pharmaceutical Industry and product manufacture are regulated.
4	Summarise ICH guidelines and critically appraise their value within modern day pharmaceutical manufacture.

Learning Outcomes of Assessments

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

Exam	1	2	3
Presentation	4		

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

Learning Activities

Lectures covering each topic within the module (e.g. 6 topic groupings comprising 30 lectures).
A workshop to support the understanding of ICH guidelines and related implications.
Visits to pharmaceutical manufacturing sites in the locality to consolidate taught material.

Notes

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.