Liverpool John Moores University

Title:	Pharmaceutical Development and Manufacture
Status:	Definitive
Code:	**6007DFACAP** (117499)
Version Start Date:	01-08-2019
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
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Academic Level:	FHEQ6	**Credit Value:**	24	**Total Delivered Hours:**	51
Total Learning Hours:	240	**Private Study:**	189		

Delivery Options
Course typically offered: Standard Year Long

Component	Contact Hours
Lecture	30
Practical	15
Workshop	3

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	Exam	Closed Book Examination	70	3
Report	Report	Formulation Project	15	1
Test	MCQ	Coursework Test	15	1

Aims

To present the philosophy and procedures associated with the development and registration of pharmaceutical products, and to illustrate the techniques and processes used in sterile manufacture.

Learning Outcomes

After completing the module the student should be able to:

1	Demonstrate knowledge of the formulation development process and the steps required to bring a pharmaceutical product successfully to market.
2	Discuss the theory and concepts of Good Manufacturing Practice, Quality Assurance and the role of the Qualified Person.
3	Apply knowledge of aseptic techniques, sterilisation processes, controls and tests to the preparation and evaluation of sterile products.
4	Evaluate the formulation of sterile products (including ingredients and packaging) and suitable sterility procedure that may be used in their manufacture.
5	Demonstrate and understanding of the routine stability tests as applied to pharmaceutical products.
6	Discuss the role of regulatory authorities and the ICH process within the pharmaceutical industry.

Learning Outcomes of Assessments

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

Closed book examination	1	2	5	6
Formulation Project	3			
Coursework Test	4			

Outline Syllabus

• The structure of a pharmaceutical company, the role of regulatory authorities within the pharmaceutical industry and the International Conference on Harmonisation (ICH) process.
• Good Manufacturing Practice, Quality Assurance and the role of the Qualified Person.
• The manufacture of sterile pharmaceutical products - aseptic processes, clean rooms and isolation units, the use of sterilisation processes, controls, and sterility tests.
• Formulation development and scale-up of pharmaceutical manufacturing processes.
• Stability testing of pharmaceutical products.
• Pharmaceutical product licensing.

Learning Activities

Attending aseptic labs, formulation projects, lectures and workshops

Notes

This course is realted to manufacturing sterile products and understanding pharmaceutical industry