Liverpool John Moores University

Title:	PRODUCT DEVELOPMENT AND CONTROL
Status:	Definitive
Code:	**7107PHASCI** (123669)
Version Start Date:	01-08-2021
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
Touraj Ehtezazi	Y
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Academic Level:	FHEQ7	**Credit Value:**	30	**Total Delivered Hours:**	55
Total Learning Hours:	300	**Private Study:**	245		

Delivery Options
Course typically offered: Semester 2

Component	Contact Hours
Lecture	22
Practical	21
Workshop	9

Grading Basis: 50 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	Exam	Exam - long answer questions	60	3
Report	Report	Report	40	

Aims

To understand and apply the principles of good manufacturing practice to the production and quality control of pharmaceutical products

Learning Outcomes

After completing the module the student should be able to:

1	Display mastery of applying the appropriate testing procedures to ensure the quality of sterile and non-sterile dosage forms and interpreting the data generated.
2	Demonstrate expertise in the understanding and application of the principles of good manufacturing practice in the production of sterile and non-sterile dosage forms

Learning Outcomes of Assessments

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

Examination	1
Report	2

Outline Syllabus

GMP, ICH & Quality by Design
Milling, mixing, granulation, drying
Spray-Drying
Freeze Drying
Process Scale-up
Process Analytical Technology (PAT)
Extrusion-spheronisation
Tableting, compaction simulation, coating
Quality Control Testing
Sterile product manufacture
Steriolisation process
Sterile Product Testing
Sterilisation Validation
Bacterial Endotoxin Levels

Learning Activities

Lectures covering each topic within the module
Practical sessions giving students first-hand experience of relevant manufacturing techniques
Performing laboratory based activitoes plus writing reports, which inlcudes data analysis
Workshops on ICH guidelines and their application in practice and to support analysis of data generated during practical sessions

Notes

Practical sessions will involve students developing hands-on experience of the manufacturing procedures in the production of sterile (injectable ampoules, eye-

drops) and non-sterile (tablets) pharmaceutical dosage forms as well as the pharmacopoeial standard QC testing procedures used.
Exam will assess students understanding of the principles through data interpretation/problem solving questions