Liverpool John Moores University

Title:	PRODUCT DEVELOPMENT AND CONTROL
Status:	Definitive
Code:	**7007PHASCI** (120451)
Version Start Date:	01-08-2014

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

Team	emplid	Leader
Touraj Ehtezazi		Y
Matthew Roberts		

Academic Level:	FHEQ7	**Credit Value:**	30.00	**Total Delivered Hours:**	55.00
Total Learning Hours:	300	**Private Study:**	245		

Delivery Options
Course typically offered: Semester 2

Component	Contact Hours
Lecture	22.000
Practical	21.000
Workshop	9.000

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	Exam	Exam - long answer questions	60.0	3.00
Report	Report	Report	40.0	

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

References

Course Material	Book
Author	Michael Levin
Publishing Year	2011

Title	Pharmaceutical Process Scale-Up, Third Edition (Drugs and the Pharmaceutical Sciences)
Subtitle	
Edition	3rd
Publisher	CRC Press
ISBN	1616310014

Course Material	Book
Author	Stephen P. Denyer (Editor), Norman Hodges (Editor), Sean P. Gorman (Editor), Brendan F. Gilmore (Edi
Publishing Year	2011
Title	Hugo and Russell's Pharmaceutical Microbiology
Subtitle	
Edition	8th
Publisher	Wiley-Blackwell
ISBN	1444330632

Course Material	Book
Author	William Whyte
Publishing Year	2010
Title	Cleanroom Technology: Fundamentals of Design, Testing and Operation
Subtitle	
Edition	2nd
Publisher	Wiley-Blackwell
ISBN	0470748060

Course Material	Book
Author	Roop, k, Khar, SP Vyas, Farhad J. Ahmed, Gaurav K. Jain
Publishing Year	2013
Title	The Theory and Practice of Industrial Pharmacy
Subtitle	
Edition	1st
Publisher	CBS Publishers
ISBN	8123922892

Course Material	Journal / Article
Author	
Publishing Year	
Title	Drug Development and Industrial Pharmacy
Subtitle	
Edition	
Publisher	Informa Health
ISBN	

Course Material	Website
Author	

Publishing Year	
Title	ICH
Subtitle	
Edition	
Publisher	www.ich.org
ISBN	

Course Material	CD/DVD
Author	Micron Training
Publishing Year	
Title	Correct Behavior in the Cleanroom
Subtitle	
Edition	
Publisher	
ISBN	

Course Material	Book
Author	Anne Marie Dixon
Publishing Year	2006
Title	Environmental Monitoring for Cleanrooms and Controlled Environments (Drugs and the Pharmaceutical Sciences)
Subtitle	
Edition	1st
Publisher	CRC Press
ISBN	0824723597

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