APPROVED

PHAR S8019: (Bio)Pharmaceutical Manufacturing and Supply Chain Management

Module Details

Module Code:	PHAR S8019
Full Title:	(Bio)Pharmaceutical Manufacturing and Supply Chain Management APPROVED
Valid From::	Semester 1 - 2020/21 (September 2020)
Language of Instruction:	English
Duration:	1 Semester
Credits::	7.5
Module Owner::	Richard Crowley
Departments:	Life and Health Sciences
Module Description:	Provide the student with the necessary knowledge and understanding of the manufacturing processes, equipment, tools, control systems and understanding of supply chain management requirements needed to function effectively in a highly regulated and controlled pharmaceutical manufacturing environment.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Categorise the manufacturing activities, inputs, outputs etc. using a Generic Process Approach model.
MLO2	Examine the key principles and methodologies used in a implementing a Lean/Six Sigma approach to manufacturing.
MLO3	Formulate the basic concepts associated with the design, layout, operation and control of clean rooms, how they are applied and used to maintain regulatory conformance.
MLO4	Interpret and explain the principles of tablet /capsule production systems and the associated control/measurement systems i.e. Manual, CLAS and CMMS.
MLO5	Explain how the principles of Cleaning, Decontamination and Sanitation (CDS), Cleaning In Place (CIP), Fogging are applied and how to provide and distribute Purified Water, Water for Injection and Clean Steam.
MLO6	Evaluate the importance of good Supply Chain Management regarding risk mitigation and continuous production.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named DkIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).*
No recommendations listed

Module Indicative Content
Manufacturing Process Approach - Definitions, transformation process diagrams i.e.inputs, outputs, activities, deliverables etc. Flow Charts and Process Flow Diagrams
Site Selection and Premises Design Criterion, decision and ranking matrix. Material, process and people flow. Weighing & Dispensing area design and environmental control
Premise and Regulatory GMP Impact on and design of Ancillary, Storage, Production and Quality Assurance areas
Manufacturing GMP and regulatory requirements How regulatory requirements impact personnel , premise and equipment,
Clean Rooms Definitions and standards. Turbulent and Laminar flows. Layouts and design, including air locks, air showers and stepover benchs. Factors affecting effectiveness i.e. rest and occupancy. Air supply, distribution and filtration. Zone control and clean room clothing.
Water purification and distribution Classification types and uses of water. Multistep purification process, Distillation and Reverse Osmosis, Distribution systems for WFI and PW.
Principles of steam generation – steam equipment, boilers. Utility and Cleam steam. Generation and distribution of Clean Steam
CDS – Cleaning, Decontamination and sanitation Cleaning, Decontamination and Sanitation (CDS). Clean In Place (CIP) and Fogging
Tablet Production Systems Tablet forms and formulations, Physical propertie i.e. shape, size and strength. Granual an Dry compression mixes. Wet and Dry cranulation. Eccentric and Rotary presses. powder and granual delivery systems. Weight control systems i.e. Manual, CLAS and CMMS. Correlation betwen compaction force and weight.
Tablet Coating systems Acid resistant v non resistant coatings. Types of coating processes
Capsule Filling Systems Generic Filling steps. Filling methodologies, Plate, Auger, Tamping, Compression and Drug-pack
Supply Chain Management Basic economics (incl. market conditions), Basic contract law, Corporate social responsibilities, code of ethics and anti-corruption, Strategy and planning, Distribution Channels, INCO Terms, Incoming inspection and warehouse controls, Stock Control, Risk management, Procurement and Vendors

Module Assessment

Assessment Breakdown	%
Course Work	20.00%
Practical	20.00%
Final Examination	60.00%

Module Special Regulation

Assessments

Part Time On Campus

Course Work

Assessment Type	Class Test	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	1,2
Duration in minutes	0		

Assessment Description
The test will evaluate knowledge, understanding and application of the subject matter covered in lectures and tutorials

No Project

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	4,5
Duration in minutes	0		

Assessment Description
Laboratory practical workshop on practical situations applicable to the manufacture of biopharmaceutical products e.g. • How to generate a signal: The science behind a pH and/or dO2 probe. • Batch ultrafiltration of milk powder solutions. • Dynamics of heat transfer in a stirred tank reactor. • Dynamics of oxygen transfer in a stirred tank reactor. • Evaporation of sugar solutions. • Filtration in a bench top filter cell. • Sedimentation of calcium carbonate suspensions.

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	60
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	1,2,3,4,5
Duration in minutes	0		

Assessment Description
End-of-Semester Final Examination

Module Workload

This module has no Full Time On Campus workload.

Workload: Part Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	No Description	Every Week	2.00	2
Independent Study	Non Contact	No Description	Every Week	5.00	5
Directed Reading	Non Contact	No Description	Every Week	3.00	3
Independent Study	Non Contact	Preparation for practical's and reporting results	Once per semester	0.67	10
Practical	Contact	2 Hrs x 4 Labs	Once per semester	0.53	8
				Total Weekly Learner Workload	11.20
				Total Weekly Contact Hours	2.53

Module Resources

Recommended Book Resources

Augsburger L. Larry, Hoag W, Stephen. (2008), Pharmaceutical Dosage Forms- Tablets: Manufacturing and Process Control, 3. Informa healthcare, [ISBN: 978-0849390166].

Haider, Imtiaz Syed. (2006), Validation Standard Operating Procedures: Achieving Compliance in Pharmaceutical, Medical Devices and Biotech Industries, 2nd. Informa Healthcare, [ISBN: 978-0849395291].

Buckbee George, Alford Joseph. Automation Applications in Bio Pharmaceuticals, 2008. ISA, [ISBN: 978-1934394250].

LeBlanc L. Destin. (2000), Validated Cleaning Technologies for Pharmaceutical Manufacturing, Informa Healthcare, [ISBN: 978-1574911169].

Paikh, D.M.. (1997), Handbook of pharmaceutical granulation technology, Marcel Dekker Inc, [ISBN: 978-0824798826].

Allport-Settle J. Mindy. (2009), Current GMP Practices, Create Space Indep Publishing Platform., [ISBN: 978-144955236].

Whyte William. (2010), Cleanroom Technology: Fundsmentals nof Design, Testing and Operation, 2nd. Wiley, [ISBN: 978-0470748060].

Collentro V. William. (2010), Pharmaceutical Water: System: Design, Operation, and Validation, 2nd. CRC Press, [ISBN: 1420077821].

Lachman Leon. (2010), The theory an practice of industrial pharmacy, CBS Publishing and Distributors P Ltd, [ISBN: 978-8123916798].

Walsh, G. (2003), Biopharmaceuticals: Biochemistry and Biotechnology, Wiley.

Lachman Leon, Lieberman A. Herbert, Kanig L. Joseph. (1986), The Theory and Practice of Industrial Pharmacy, 3rd. Lea & Febiger, [ISBN: 978-0812109771].

This module does not have any article/paper resources

Other Resources

Link, Library Catalogue,
http://tinyurl.com/o3adncv

Link, Library Catalogue,
http://tinyurl.com/ke55lv2

Link, Library Catalogue,
http://tinyurl.com/lvl4bqg