APPROVED

PHAR S8009: Recombinant Drug Manufacturing & Engineering

Module Details

Module Code:	PHAR S8009
Full Title:	Recombinant Drug Manufacturing & Engineering APPROVED
Valid From::	Semester 1 - 2013/14 (September 2013)
Language of Instruction:	
Duration:	1 Semester
Credits::	5
Module Owner::	Richard Crowley
Departments:	Unknown
Module Description:	The aim of this module is to provide the students with an in-depth knowledge of the fundamental engineering principles and tools required to work effectively in a highly regulated and controlled biopharmaceutical process plant environment.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Interpret P&ID's and select appropiate instrumentation to measure/control bio processes.
MLO2	Explain the characteristics of fluid distribution systems including pump/valve control technologies and safety systems.
MLO3	Examine and compare how purified water, clean steam, clean air etc. are processed, distributed and stored.
MLO4	Explain the principles and dynamics of heat transfer, fluid flow, mixing and aeration and solve associated technical problems.
MLO5	Discuss and analyse the major legislative and regulatory instruments in relation to waste and biohazard management.

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
The Process Approach . Process definitions and diagrams. How to document processes i.e. Flow charts, Block Diagrams (BD), Process Flow Diagrams (PFD) and Piping & Instrumentation Diagrams (P&ID).
Pipe & Instrument Drawings (P&ID) P&ID definitions, symbols, TAG ID etc. as per ISA-5.1-1984 (R1992).
Instrumentation: Function, Types and Construction Instrumentation function i.e. Indicators, Sensors, Transmitters and Controllers. Instrumentation types and construction i.e. measuring gauges, probes, thermocouples etc.
Process Control & Safety Closed and Open loop control systems. Manual, semi-automatic and automatic control systems. Safety systems, i.e. pressure relief etc. Fail Open and Fail Closed systems
Fluid Flow Force, Pressure, Friction and Flow Rates. How fluid distribution systems can negatively affect fluid flow and damage product and instrumentation
Pumping Technology Pump Classification i.e. centrifugal and positive displacement pumps. The advantages and disadvantages of pumps as Constant Flow Machines. Linear and Rotary classifcation. Pump types i. e. Diaphragm, Lobe, Peristalic, Gear, Vane etc. Selecting pumps with Characteristics suitable to bio processing. The effect of cavitation and water hammer on hardware and instrumentation.
Valve Technology Definition and function of valves. Valve types i.e. Diaphragm, Ball, Globe, Gate,Piston etc. Function and uses of Check valve technology. Types of Check valve i.e. Disc, Tilting Disc, Swing etc. The need for Safety Valves to protect equipment, product and instrumentation.
Plant & Utilities & HEVAC Water i.e. grades (PW, HPW and WFI), uses, purification process and distribition. Water standards and specifications. Steam i.e. plant amd clean steam, uses for clean steam, purity and specifications. How to sample clean steam. Design of a typical Clean Steam System (CSS). Rouging and De-rouging. How to generate Clean Steam. Fundamentals of distributing Clean Steam. Validation of CSS. Heating, ventilation and air conditioning (HEVAC) systems.
Aseptic Operation Aseptic operation and sterilistaion of process hardware. Cleaning in place (CIP) and steaming in place (SIP) principles.
Aeration: Oxygen requirement of industrial fermentations, oxygen supply, sparger design, oxygen transfer from gas bubble to cell.
Waste management: Biohazardous waste, effluent disposal and associated legislation. Environmental Standard ISO 14001.
Experimental Work The following list is designed to serve as an illustration of possible practical exercises which would illustrate key concepts and techniques. Many of the practical situations are applicable to a range of biopharmaceutical products and so have a broad spectrum of merit. • 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.

Module Assessment

Assessment Breakdown	%
Course Work	40.00%
Final Examination	60.00%

Module Special Regulation

Assessments

Full Time On Campus

Course Work			
Assessment Type	Class Test	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	Week 25	**Learning Outcome**	1,2,4
Duration in minutes	0		
Assessment Description Evaluate understanding and application of knowledge gained in lectures and tutorials			
Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	Every Second Week	**Learning Outcome**	2,4
Duration in minutes	0		
Assessment Description To support theoretical knowledge			

No Project

No Practical

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			

Reassessment Requirement
A repeat examination *Reassessment of this module will consist of a repeat examination. It is possible that there will also be a requirement to be reassessed in a coursework element.*

Module Workload

Workload: Full Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	No Description	Every Week	3.00	3
Tutorial	Contact	No Description	Every Week	1.00	1
Practical	Contact	2hrs x 4 practicals	Every Second Week	1.00	2
Independent Study	Non Contact	No Description	Every Week	2.00	2
Directed Reading	Non Contact	No Description	Every Week	2.00	2
				Total Weekly Learner Workload	9.00
				Total Weekly Contact Hours	5.00

This module has no Part Time On Campus workload.

Module Resources

Recommended Book Resources

Doran, P.M.. (2013), Bioprocess engineering principles, 2nd. Elsevier Ltd..

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

Morris, A.S. and Langari, R.. (2012), Measurement and instrumentation: Theory and application, Elsevier.

Seiberling A. Dale. (2007), Clean -In-Place for Biopharmaceutical Processes., 1st. CRC Press, [ISBN: 978-089340697].

Charles E. Thomas. (2009), Introduction to Process Technology, 3rd. Delmar Cengage Learning, [ISBN: 978-1435454255].

Thomas E. Charles. (2010), Process Technology Equipment and Systems, 3rdge Learning. Delmar cenga, [ISBN: 978-1435499123].

Centre for the Advancement of Process Tech. (CAPT). (2009), Instrumentation, 1st. Prentice Hall, [ISBN: 978-0137004133].

Pandiyan Jaqadeesh. (2010), Introduction to SmartPLant P&ID: The Piping & Instrumentation Diagrams (P&ID) Handbook, 1st. APJ Books, [ISBN: 978-0615339212].

Smith, J.M., Van Ness, H.C. and Abbott, M.M.. (2005), Introduction to chemical engineering thermodynamics., McGraw-Hill.

Bunn, G.. (2006), Good manufacturing practice for pharmaceuticals, 6th. Taylor & Francis.

Walsh, G.. (2003), Biopharmaceuticals: Biochemistry and biotechnology, J. Wiley and Sons.

Shuler, M.L.L. and Kargi, F.. (2002), Bioprocess engineering basic concepts, 2nd. Prentice Hall.

Harrison, R.G., Todd P.W., Rudge, S.R. and Petrides, D.. (2003), Bioseparations science and engineering, Oxford University Press.

Stanbury, P.F., Whitaker, A. and Hall, S.J.. (1995), Principles of fermentation technology, 2nd. Irwin.

This module does not have any article/paper resources

Other Resources

Website, British pharmacopoeia,
http://www.pharmacopoeia.co.uk

Website, European Directorate for the Quality of Medicines and Healthcare,
http://www.edqm.eu

Website, European Medicines Agency,
http://www.ema.europa.eu/ema/

Website, International Biopharmaceutical Association,
http://ibpaalliance.org/

Website, International Organisation for Standardisation,
http://www.iso.org/iso/home.htm

Website, Irish Medical Board,
http://www.imb.ie

Website, National Standards Authority of Ireland,
http:///www.nsai.ie

Website, U.S. Food and Drug Administration,
http://www.fda.gov

Website, United States Pharmacopoeial Convention,
http://www.usp.org

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