Title:	Cleanroom Management APPROVED
Long Title:	Cleanroom Management

Module Code:	BIOM6003	**Duration:**	1 Semester

Credits:	5
NFQ Level:	Fundamental
Field of Study:	Microbiology
Valid From:	Semester 2 - 2017/18 (January 2018)
Module Delivered in	**4 programme(s)**
Module Coordinator:	NIALL MORRIS
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Module Description:	This module introduces the student to the use of cleanroom technology in the medical technologies industries. It covers cleanroom classification, standards and design materials, HEPA systems and filtration, cleanroom practices, control and monitoring.

Learning Outcomes	
On successful completion of this module the learner will be able to:	
LO1	Classify a cleanroom to ISO 14644-1, EU GMP and FDA standards.
LO2	Identify the principles of cleanroom design and construction for various types of manufacturing operations.
LO3	Describe policies for cleanroom behaviour and define what materials and clothing are cleanroom compatible.
LO4	Explain the validation requirements for cleanrooms and describe how a monitoring program is established.
LO5	Specify the mechanisms for the removal of particulate contamination from cleanroom air.

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 CIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).*
None
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module. You may not earn additional credit for the same learning and therefore you may not enrol in this module if you have successfully completed any modules in the incompatible list.*
No incompatible modules listed
Co-requisite Modules
No Co-requisite modules listed
Requirements *This is prior learning (or a practical skill) that is mandatory before enrolment in this module is allowed. You may not enrol on this module if you have not acquired the learning specified in this section.*
None

Module Content & Assessment

Indicative Content
Cleanrooms Clean room classification and standards. Types of clean rooms, and their various applications in the pharmaceutical and medical device industry. Fundamentals of air filtration: principles of HEPA filtration and design of cleanrooms to include HVAC systems. Systems of air classification: ISO 14644 standard, EU GMP and FDA standards and Federal Standard 209. Alarm levels
Materials and Equipment for clean rooms Selection of walls, ceilings, floor materials and equipment. Barrier/Isolator technology. Air showers, weighing cabinets and material pass-through corridors.
Clean room practices Clothing and housekeeping practices for the clean room staff and maintenance contractors. Critical control of clean room entrance practices. Standard Operating Procedures for clean room work.
Clean room test equipment and monitoring Monitoring the viable and non-viable particle counts, environmental monitoring, air flow rates and air flow patterns, pressure differentials, filter leak and seal testing, testing gloves in Isolator units and RABs.
Cleaning, Decontamination & Segregation Introduction to positive/negative air pressure environments and their use in segregating working areas within clean rooms. Review of personal behaviour in clean rooms and how this influences clean room contamination. Cleaning strategies and sterilization and decontamination of isolator units.
Indicative Practical Programme Entry and Exits procedure and garbing, Environmental Monitoring, Characterisation of a HVAC system, particle counting in RABs.

Assessment Breakdown	%
Course Work	100.00%

Course Work

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Written Report	Evolution of cleanrooms and related standards	1,2,3	10.0	Week 5
Presentation	Monitoring a cleanroom aspect/parameter to establish/maintain control	4	20.0	Week 9
Practical/Skills Evaluation	Laboratory practicals and reports	4,5	30.0	Every Second Week
Short Answer Questions	1 hour closed book exam	1,2,4,5	40.0	Week 12

No End of Module Formal Examination

Reassessment Requirement
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.*

The institute reserves the right to alter the nature and timings of assessment

Module Workload

Workload: Full Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Classroom Instruction	2.0	Every Week	2.00
Lab	Practicals	2.0	Every Second Week	1.00
Independent & Directed Learning (Non-contact)	Student Study	4.0	Every Week	4.00
			Total Hours	8.00
			Total Weekly Learner Workload	7.00
			Total Weekly Contact Hours	3.00

Workload: Part Time				
Workload Type	*Workload Description*	*Hours*	*Frequency*	*Average Weekly Learner Workload*
Lecture	Classroom Instruction	2.0	Every Week	2.00
Lab	Practicals	2.0	Every Second Week	1.00
Independent & Directed Learning (Non-contact)	Student Study	4.0	Every Week	4.00
			Total Hours	8.00
			Total Weekly Learner Workload	7.00
			Total Weekly Contact Hours	3.00

Module Resources

Recommended Book Resources

- **W. Whyte 2010, *Cleanroom technology*, John Wiley & Sons Chichester, West Sussex, U.K. [ISBN: 9780470748060]**
- **Sandle, T.; Saghee, M. R. 2013, *Cleanroom management in pharmaceuticals and healthcare*, Euromed Communications Ltd [ISBN: 1899015833]**

Supplementary Book Resources

- **Denyer, S.P. & Baird, R.M. 2007, *Guide to Microbiological Control in Pharmaceuticals and Medical Devices*, 2nd Ed. Ed., CRC Press [ISBN: 978-0748406159]**
- **Whyte, W. 2000, *Cleanroom Design*, 2nd Ed. Ed., Wiley [ISBN: 978-0471942047]**

This module does not have any article/paper resources

Other Resources

- **Hard or Soft Copy: *Course Notes***

Module Delivered in

Programme Code	Programme	Semester	Delivery
CR_ECBPO_6	Certificate in Chemical and Biopharmaceutical Process Operations	1	Elective
CR_ECLMP_6	Certificate in Cleanroom Manufacturing Practices	2	Mandatory
CR_SGMPP_6	Certificate in GMP and Process Operations	2	Elective
CR_SGMPR_6	Higher Certificate in Science in Good Manufacturing Practice and Technology	3	Mandatory