GMIT
INSTITIÚID TEICNEOLAÍOCHTA NA GAILLIMHE-MAIGH EO
GALWAY-MAYO INSTITUTE OF TECHNOLOGY

SCIE07008
Clean Room Management

Full Title	Clean Room Management		
Status	Uploaded to Banner	**Start Term**	2015
NFQ Level	07	**ECTS Credits**	05
Module Code	SCIE07008	**Duration**	Stage - (26 Weeks)
Grading Mode		**Department**	Physical & Life Sciences
Module Author	Ita Kelly		

Module Description

This module aims to provide the student with the knowledge to understand and maintain clean room environments.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Identify the common sources of contaminants.
2.	Apply the fundamental steps of aseptic practice.
3.	Use a wide range of cleaning agents and know when to apply them.
4.	Define and apply the basis of cleaning validation.
5.	Work in a clean-room environment.
6.	Describe the basis of clean-room operation.
7.	Monitor the clean-room environment.
8.	Decontaminate the clean-room.

Indicative Syllabus

Clean-rooms

Clean-room classifications and standards. Types of clean-rooms, their location within buildings and their various applications in the pharmaceutical industry. Analysis of the fundamentals of air filtration: principles of HEPA filtration and design of HEPA systems and ventilators. Systems of air classification: Federal Standard 209. B.S. 5295. ISO standards etc.

Materials and Equipment for Clean-rooms

Selection of walls, ceilings, floor material 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 quality of materials entering the clean-room. Monitoring air and surface quality in clean-rooms. Monitoring decontamination procedures used in clean-rooms. Clean-room standards for designating normal, alert and alarm levels.

Cleaning, Decontamination and Segregation of Working Areas within Clean-rooms

Introduction to specialized methods of cleaning and decontaminating clean-rooms. Introduction to positive 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.

Contamination

The nature of contamination; physical, chemical and biological residues. Examination of sources of residues and how residues are transported within the work environment. Problems caused by the presences of contaminating residues in pharmaceutical processes. Materials/equipment compatibility and contamination of pharmaceuticals.

Cleaning equipment and Reagents

Selection of cleaning agents and items of equipment in use in the pharmaceutical manufacturing sector. Criteria used in the selection of appropriate cleaning agents and equipment.

Controlled Cleaning

Principles of effective cleaning. Understanding the chemistry of cleaning. Writing standard operating procedures describing controlled cleaning practices. Disinfectant effectiveness testing, testing the effectiveness of cleaning agents. Practical monitoring the effectiveness of cleaning regimes. And disinfectants. Cleaning validation made simple.

Housekeeping and Contamination Control

Review of good housekeeping practices, procedures and barrier technology used in the control of contamination in pharmaceutical manufacturing facilities. Analysis of facility design and its influence on the spread of contaminants.

Teaching and Learning Strategy

Delivery of this module will involve lectures, group work, in-class discussion and analysis.

Assessment Strategy

Examples of assessment include controlled documentation preparation, short in-class quiz/exam, report preparation on specialist topics.

Repeat Assessment Strategies

Repeat exams will be offered

Indicative Coursework and Continuous Assessment:		**50 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assignment	Assignments	35 %	OnGoing	1,2,3,4,5,6,7,8
Assignment	Mid Term Exam	15 %	OnGoing	1,2,3,4,5,6,7,8

End of Semester / Year Formal Exam:		**50 %**		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Closed Book Exam	Final Exam	50 %	End of Term	1,2,3,4,5,6,7,8

Full Time Delivery Mode Average Weekly Workload:			**1.50 Hours**		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Not Specified	1.5	Weekly	1.50

Recommended Reading Book List

(2006). *Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition*. CRC Press.
ISBN 0748406158 ISBN-13 9780748406159

Whyte, W., (2010). *Cleanroom Technology: Fundamentals of Design, Testing and Operation*. Wiley.
ISBN 0470748060 ISBN-13 9780470748060

Peine, C., *Quality Assurance Compliance: Procedures for Pharmaceutical and Biotechnology Manufacturers*. CRC Press.
ISBN 0935184511 ISBN-13 9780935184518

Ljungqvist, B., *Clean Room Design: Minimizing Contamination Through Proper Design*. CRC Press.
ISBN 1574910329 ISBN-13 9781574910322

Literary Resources

Denyer, SP & Baird, RM (2007). Guide to microbiological control in pharmaceuticals and medical devices. CRC Publishing

Whyte, W (2010) Cleanroom technology: fundamentals of design, testing and operation. Wiley.

Peine, I (2001) Quality Assurance Compliance: Procedures for Pharmaceutical and Biotechnology Manufacturers. Interpharm Press.

American Health Research Institute (1995). Medical Devices and Equipment – Design, Supplies, Failures, Control, Contamination and Alarms

Ljungqvist, B & Reinmuller, B (1997) Clean room design: minimizing contamination through proper design. Interpharm press

Other Resources

American Health Research Institute (1995). Medical Devices and Equipment - Design, Supplies, Failures, Control, Contamination and Alarms

Appropriate company procedures

Programme Membership

GA_SQRAG_S07 201500 Certificate in Science in Quality & Regulatory Affairs
GA_SQUAG_B07 201400 Bachelor of Science in Quality for Industry