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

BIOL08027
Microbial Quality Assurance

Full Title	Microbial Quality Assurance

Status	Uploaded to Banner	**Start Term**	2017
NFQ Level	08	**ECTS Credits**	05
Module Code	BIOL08027	**Duration**	Semester - (13 Weeks)
Grading Mode	Numeric	**Department**	Physical & Life Sciences

Module Author	Seamus Lennon
Co Authors	Una Quigley

Module Description

This module will provide learners with a sufficient knowledge to enable them to adopt responsible positions in the areas of industrial sterilization and cleanroom operations.

	Learning Outcomes ***On completion of this module the learner will/should be able to:***
1.	Explain the principles of the main industrial sterilization methodologies
2.	Design, validate and monitor industrial sterilization cycles
3.	Analyse the factors pertinent to the commissioning, validation and management of cleanrooms
4.	Advise on the selection and validation of appropriate cleanroom technology
5.	Critically appraise cleanroom monitoring results with a view to specifying appropriate corrective actions

Indicative Syllabus

Industrial sterilization with emphasis on Moist Heat, Ethylene Oxide, e-Beam, Gamma Irradiation, Filtration and Aseptic Processing.

Terms and definitions (SAL, D, Z and Fo values). Heat sterilization – autoclave cycles and validation. Gaseous sterilization – ETO – properties and control. Ionising radiation – UV, e-Beam and Gamma Irradiation. Filtration, flter validation. Aseptic processing.

Cleanroom technology:

Standards and Guidelines (EU GMP and ISO), FDA Guidance for industry. Microbiological monitoring of cleanrooms. Cleanroom validation and monitoring.

Quality tools as they apply to microbiological quality management

Teaching and Learning Strategy

Lectures will involve case studies from industrial clean room and serilization activities. A site visit(s) will be completed to local cleanroom operations, and guest lecturers will cover current topics in cleanroom management and industrial sterilization.

Assessment Strategy

CA and final exam. The CA will focus on creation of validation documents on processes and tests. Written reports on visits to clean rooms and management of cleanrooms will also feature as part of CA.

Repeat Assessment Strategies

Repeat examination available

Indicative Coursework and Continuous Assessment:		100 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assessment	Assessment	30 %	Week 13	1,2,3,4,5
Assignment	Case study - creation of relevant validation documents / CA-PA on specific case studies	40 %	Week 7	1,2,3
Assignment	Assignment on cleanroom visit and case study on cleanroom management	30 %	Week 12	1,2,3,4,5

Part Time Delivery Mode Average Weekly Workload:			2.00 Hours		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Not Specified	2	Weekly	2.00

Recommended Reading Book List

Sandle, T., (2015). *Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control*. Woodhead Publishing.
ISBN 0081000227 ISBN-13 9780081000229

Sandle, T., (2013). *Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals: Technology, Validation and Current Regulations (Woodhead Publishing Series in Biomedicine)*. Woodhead Publishing.
ISBN 1907568387 ISBN-13 9781907568381

Sterile Pharmaceutical Manufacturing: Applications for the 1990's. Interpharm Pr.
ISBN 0935184228 ISBN-13 9780935184228

Carlberg, M., (2004). *Cleanroom Microbiology for the Non-Microbiologist*. CRC Press.
ISBN 084931996X ISBN-13 9780849319969

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

Programme Membership

GA_SQUAG_H08 201700 Bachelor of Science (Honours) in Quality For Industry