ZPHA C3108: Microbiology for Pharmaceutics

Module Title:	Microbiology for Pharmaceutics
Language of Instruction:	English

Credits:	5

NFQ Level:	7

Module Delivered In	2 programme(s)

Teaching & Learning Strategies:	This module will be taught over 12 hours as a one hour theory classes plus 36 hours practical laboratory class, integrating a flipped classroom approach for both theory and practical, with theory and practical module content synchronised. Material presented will be relevant to current issues in pharmaceutical microbiology. This module has been designed so that learning outcomes, learning strategies and assessment are constructively aligned, the topics in the module being related to each assessable learning outcome. A constructivist learning strategy will be used. A range of active learning activities will be used to develop important enquiry and research skills that will enhance knowledge acquisition, evaluation and communication. While learning will be scaffolded, the participants will be expected contribute to their own and the learning of others via autonomous and peer learning activities. Lectures will be given to identify key topics, however on occasion learners will be expected prepare in advance so that class time can be used for discussion of case studies/scenarios, problem solving and critical thinking etc. Scaffolded reading the primary literature and other sources in this area will allow the complexity of situations and emerging issues to be explored. Practicals will allow the development of key technical competencies, data interpretation and understanding the limitations of methodologies. Students will have opportunities throughout the practical and theoretical parts of the module, to develop and practice effective written and oral and other communication skills and to develop digital competencies. Students will submit timely, concise reports in an industrial appropriate manner; write and present assignments based on their research into relevant topics from a range of credible sources. Appropriate conventions of format, citing and referencing will be used. The virtual learning environment Blackboard® will facilitate scaffolded, independent and group learning. It will act not only as a repository of a range of different resources but will allow easy communication of feedback and the sharing of new knowledge and ideas.

Module Aim:	The aim of this module is to impart knowledge, skills and of key practical and theoretical aspects of pharmaceutical microbiology within the current regulatory framework to learners who may not have previous microbiological experience.

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Provide evidence of the importance of pharmaceutical microbiology in maintaining product quality and safety in the current national and international legislative and regulatory context.
LO2	Examine and differentiate the key concepts of pharmaceutical microbiology including: isolation, identification and classification of contaminants; factors affecting microbial growth and its control, disinfection/sterilisation.
LO3	Identification and demonstration of the limitations of the data and its use in problem solving in an industrial setting. Be competent in the execution, interpretation and communication of pharmaceutically relevant microbial detection, enumeration and identification protocols.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is recommended before enrolment in this module.*
No recommendations listed
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module.*
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.*
No requirements listed

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Module Content & Assessment

Indicative Content
Indicative content LO1 Appreciate the importance of pharmaceutical microbiology in the current national and international legislative and regulatory context. • Principles of sterile and non sterile processing and manufacture. Hazards and risks posed by microorganisms to the health of the end user of the manufacturing process. Sources of microbial contamination. The importance of cGMP. • Regulatory frame work, e.g. Pharmacuetical compendia, FDA Eudralex. Regulations. Principles of risk assessment. Validation and verification of methods.. Sterility Assurance. LO2 Understand the key concepts of pharmaceutical microbiology including: isolation, identification and classification of contaminants; factors affecting microbial growth and its control, disinfection/sterilisation. • Range and significance of different groups of contaminating microorganisms found in sterile and non-sterile pharmaceutical industries e.g. water, raw, final product. Common misunderstandings regarding microbial contamination. • Sources of contamination/bioburden. • Spore formers, moulds , viruses and prions emerging objectionable organisms. pathogens and their products including endotoxin. • Objectionable organisms, .objectionable organisms, indicator and specified organisms. Significance of biofilms in oligotrophic waters and other environments. Endotoxins and other products. Viruses, viroids and prions. • Emerging problems/issues e.g. new regulations/ phage contamination. • Challenge of microbial metabolic diversity. . • Microbial growth and its control. Physical and chemical methods of disinfection and sterilisation. Biocides and preservatives Validation of control methods Bio indictors. Sterility assurance Biocidal efficacy. LO3 Be competent in the execution, interpretation and communication of pharmaceutically relevant microbial detection, enumeration and identification protocols . • Rationale for microbial monitoring techniques for water, air, surfaces raw and finished products. OOS, trends • Main compendia and other currently approved methods. Rapid and molecular monitoring methods; biosensors, arrays. • Interpretation of microbial results; bioburden, limits out of specification results; trends, alert and action limits. • Phenotypic and genotypic identification, current and rapid methods. Practical component • The practical component contributes to LO1,2 and 3. Students will practice cGood Laboratory and cGood Microbiological Practice and observe due regard to current occupational health and safety as appropriate. • Current compendial microbiological detection, isolation and identification techniques. • Sample preparation, importance of sampling and replication strategies. • Growth based enumeration and enrichement methods and their limitations. Pharmaceutical complex, selective and differential growth media. Water analysis, Membrane filtration Defined substrate tests. Importance of neutralisation methods. • Surface microbiology: Swab tests/contact plates Air quality: Settle plates/ Volumetric air quality. • Bioburden testing and enrichment on liquid and solid samples • Preservative challenge tests. • Sterilisation assurance /Bioindicators. Efficacy of disinfection. Antibiotic resistance. • LAL and other non growth based tests • Gram stains Rapid ID and classification methods (Biolog/API) Use of Bergerys manual.

Assessment Breakdown	%
Continuous Assessment	30.00%
Practical	30.00%
End of Module Formal Examination	40.00%

Special Regulation
“Students must achieve a minimum grade (35%) in both the practical/CA and final examination”

Continuous Assessment

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Other	The assessment strategy is, of, for and as learning. It will establish theoretical competencies, practical abilities and higher order thinking skills. Formative Assessment and feedback will be carried out throughout the module to scaffold learning. It will encompass low stake formative tasks facilitate learning, equivalently distributed throughout the module. Continuous assessment is designed to motivate learners, to establish current skills and competence and to foster autonomous learning, this may include quizzes, presentations, posters and short assignments.	1,2,3	30.00	n/a

No Project

Practical

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	The assessment strategy is, of, for and as learning. It will establish theoretical competencies, practical abilities and higher order thinking skills, in the specific context of laboratory setting, lab reports and laboratory data group discussions	2,3	30.00	n/a

End of Module Formal Examination

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	The assessment strategy is, of, for and as learning. It will establish theoretical competencies, practical abilities and higher order thinking skills. An end of year exam, designed to build upon the previous learning, will be equivalent to 40%.	1,2,3	40.00	End-of-Semester

SETU Carlow Campus reserves the right to alter the nature and timings of assessment

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Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Lecture	12 Weeks per Stage	1.00
Practicals	12 Weeks per Stage	3.00
Independent Learning	15 Weeks per Stage	5.13
	Total Hours	125.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_SAPHA_B	Bachelor of Science (Honours) in Pharmaceutics and Drug Formulation	6	Mandatory
CW_SAASC_D	Bachelor of Science in Analytical Science	6	Mandatory