TECH H2101: Aseptic Techniques

Module Title:	Aseptic Techniques
Language of Instruction:	English

Credits:	10

NFQ Level:	6

Module Delivered In	No Programmes

Teaching & Learning Strategies:	This module will be primarily delivered via class room and practical modes supported by appropriate technology such as Blackboard, Videos, Articulate, Virtual Pharmacies. The aim is to built on existing knowledge, revisiting topics and link to other modules and make the module as relevant as possible. Due to the small group size (max 18 students) the practical component is essential to allow the students to develop the required technical competencies, attitudes and behaviours in aseptic techniques and to follow a series of SOPS. Role plan and simulation of working in a ACU will be used. Timely submission of reports written in the standard format is required to develop time management and the ability to follow SOPs correctly. In addition material can be built upon, revisited and become internalised during the practicals and deeper understanding can occur of core principles. Critical thinking will be developing via formative assessment activities. Material will be available on BlackBoard from September, while students are still on placement, to aid with the transmission back to college. To encourage active learning students will consult Blackboard in advance of the class and practicals and carry out short formative exercises. Formative assessment and Class room assessment techniques (CATs) will be used to support monitor and motivate learners. Generic skills linked to key competencies will be developed through all learning activities.

Module Aim:	To allow learners to have the appropriate enduring knowledge and significant learning to develop the core competencies and skills to perform aseptic techniques in a variety of contexts including hospital ACU's and other sterile manufacturing environments

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Explain why microorganisms and other contaminants must be excluded from parenteral and other sterile preparations; explain how microbial transmission can occur and interrupt the chain of infection in the context of aseptic compounding.
LO2	Outline the factors that affect microbial growth and how microorganisms can be controlled by physical and chemical means.
LO3	Describe how sterile medicines can be safely manufactured/compounded in compliance with cGMP/cGPP; explain the importance of cGMP/cGPP, Quality Assurance and Quality Control Systems, in sterile manufacture; including risk assessment, monitoring, validation, verification and the use of documents.
LO4	Indicate the nature of cytotoxic drugs and outline how they can be can be safely, prepared, handled, stored and transported.
LO5	Accurately and competently demonstrate and validate the correct behaviours and aseptic techniques for compounding sterile materials.
LO6	Demonstrate effective personal skills such as leadership, decision making, team work and effective communication.

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.*
Successful completion of year 1 or equivalent

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Module Content & Assessment

Indicative Content
LO 1 Basic microbiology concepts, nosocomial and other pathogens, contamination, cycle of infection, modes of transmission, prevention of transmission in the context of compounding.
LO 2 The principles of microbial growth. Environmental factors that affect growth. Chemical and physical factors used to control growth. Principles of sterilisation and disinfection. Filtration of air and heat labile materials. Types, formats and mode of action of commonly used disinfectants. Efficacy of disinfectants
LO 3 Principles of the process of manufacturing/preparation of sterile materials/parenteral drugs, types of medicines. Identifying hazards and minimising risks posed by parenteral drugs to the patient. Possible sources of contamination in the manufacturing/preparation process. Minimising risks. Clean room behaviour, checking, clothing. Clean room design. Isolator and transport technology. Importance of Environmental Monitoring. The importance of quality. Principles of cGMP/cGPP, application to compounding. Risk assessment. Distinction between Quality Control and Quality Assurance. Monitoring and auditing of the process, validation and compliance, corrective action and preventative action. Product quarantine. The importance of adhering to SOPs. Making improvements and validation of improvements, problem solving, identifying improvements. Relevant documentation and their use, SOP, Worksheets, labels , records.
LO 4 Nature and use of cytotoxic drugs. Hazards involved in the preparation, transport and storing of cytotoxic drugs. Recommendations for the safe handling, preparation, storage and transportation. Emergency protocols.
LO 5 Practical component. Laboratory Health and Safety, identifying hazards, and minimising risks in the compounding unit. Spills and sharps. PPE. Carry out environmental, hard surface and air microbial monitoring from a range of environment, recording and interpreting data. Recognising the presence of microorganisms, enumerating microorganisms on microbial media. Correct personal behaviour and attitudes in a clean environment including correct hand washing , gowning, hand placement Accuracy when drawing up and delivering liquids, measuring and weighing. Correct demonstration and validation of hand washing, cleaning, sterilisation and disinfection techniques. Compliance with SOPs. Determining the factors that affect the efficacy of a disinfect Preparation and checking of sterile equipment such as trays, syringes, needles, vials, infusion bags used in sterile compounding. Safe use and disposal of syringes, vials and ampoules and other equipment. Accurate and aseptic compounding of sterile products, in process checking and line clearance. Correct disposal. Working in a unidirectional air flow environment. Transfer techniques. Labelling and quarantine Accurate record keeping and report writing.
LO 6 Practicals and other learning activities will develop key generic skills appropriate to Level 6; examples include: Planning and organisation of work Report writing ,including reflective writing, maintenance of records Checking Reading, summarising and paraphrasing of standards, policies and procedures Carrying out routine testing, recording and interpreting data. Making decisions based on data. Dealing with emergencies e.g. spills. Problem solving Group work Presentations

Assessment Breakdown	%
Continuous Assessment	10.00%
Practical	40.00%
End of Module Formal Examination	50.00%

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	Multiple choice questions, short answer tests and specific assignments based on guided reading	1,2,3,4,5,6	10.00	Sem 2 End

No Project

Practical

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	Practical reports . Assignments. Open book short answer test. A practical demonstration will be given to ensure that the required learning outcomes have been reached. An alternative practical assessment is available for students with prior experiential learning.	1,2,3,4,5,6	40.00	Sem 1 End

End of Module Formal Examination

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	2 hour exam	1,2,3,4,5,6	50.00	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	30 Weeks per Stage	1.00
Laboratory	30 Weeks per Stage	1.00
Estimated Learner Hours	30 Weeks per Stage	1.67
	Total Hours	110.00