INDL H4R03: Industrial Microbiology and Biopharmaceuticals

Module Title:	Industrial Microbiology and Biopharmaceuticals
Language of Instruction:	English

Credits:	10

NFQ Level:	8

Module Delivered In	No Programmes

Teaching & Learning Strategies:	This module will be taught as three lectures per week over 30 weeks. The practical element will consist of 30 hours and will include a site visit to an industry of relevance to the course. Any course-related issue or questions that may arise will be discussed at lectures. Course lecture summaries, course calendar, announcements and other course-related information will be available on Blackboard, a virtual learning environment. Students can contact lecturer outside of class hours to discuss formative feedback given on written reports and group project work.

Module Aim:	The aim of this module is to introduce students to the principles of industrial microbiology, bioprocessing and biochemistry as applied in an industrial context and also to provide the microbiology and cell biology knowledge base for students to successfully enter the pharmaceutical and biopharmaceutical industries.

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Discuss the bioprocessing technologies used in the biotechnology industry.
LO2	Demonstrate a firm knowledge of industrial microbiology.
LO3	Apply skills successfully in an industrial bioprocessing environment.
LO4	Understand the interrelationship between biological processes and engineering and process technology.
LO5	Detail the production of the main products of the biotechnology industry.
LO6	Apply skills in the microbiology lab in traditional pharmaceutical companies.
LO7	Understand the basics of clean-room technology and be able to function in such a work environment.
LO8	Understand the importance of pyrogens and microbial contamination in pharmaceutical and biopharmaceutical processes and products.
LO9	Display fundamental knowledge of biopharmaceutical processes enabling them to work successfully in companies employing biopharmaceutical processes.
LO10	Demonstrate sufficient knowledge base to enable graduates to rise to managerial level in such companies in the medium to longer term.
LO11	Understand GMP as it applies on the microbiological side of these industries

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 3 or equivalent

INDL H4R03: Industrial Microbiology and Biopharmaceuticals

Module Content & Assessment

Indicative Content
Industrial Bioprocessing. Upstream bioprocessing: essential features of a fermenter, different kinds of fermenters, sterilisation and maintenance of sterility, gas exchange/mass transfer, heat production, provision of services and scale-up. Downstream processing: separation technologies, centrifugation and filtration, cell disintegration, solvent extraction and other purification techniques. Screening for metabolites. Strain improvement. Culture management. Inoculum preparation. Substrates for industrial fermentations. Regulation of enzyme activity and synthesis. Metabolic control and the overproduction of desirable metabolites. Primary and Secondary metabolism. Scale-up. Fermentation systems, services and ancillary equipment. Fermenter control and instrumentation. Mass transport and aeration. Sterilization and the maintenance of sterility. Batch, fed-batch, continuous and immobilized systems. Productivity and Yield Coefficients. The production of genetically engineered products.
Industrial Microbiology Production of organic acids, amino acids, industrial enzymes and other metabolites. The use of microorganisms in the food and beverage industries. The production of starter cultures and fermented food products. The microbiology of mushroom production, alcohol, lactic acid and yeast production. Single Cell Protein. The production of antibiotics, including the development of chemotherapy, the properties of chemotherapeutic agents, testing, isolation and strain improvement. Bioassays of antibiotics. An introduction to the different groups of antibiotics, including structures, modes of action. Antifungal agents, antiviral agents. Antibiotic production: The synthesis of natural and semi-synthetic antibiotics; fermentation conditions and downstream processing. The use of immobilized enzymes. Microbial biotransformations.
1. Pharmaceutical and Health Care Microbiology A review of the microbial ecology of the factory environment. Aseptic processing. Clean-room technology; design and work practices. Production of parenteral, topical, oral and ophthalmic pharmaceutical products from a microbiological point of view, and their microbiological requirements and standards. Microbial endotoxins; detection, removal, avoidance, validation and their importance in the pharmaceutical industry. LAL testing. Spoilage and preservation of pharmaceuticals. Terminal sterilization and aseptic packaging. Unit-dose and multi-dose packaging. The use of preservatives. Multiphase systems. Formulation and ingredients. Chemical disinfectants, antiseptics and preservatives and their evaluation. Microbiological testing procedures of a range of pharmaceutical products. Chemical and physical sterilization processes, survivor curves, heat, gas and radiation sterilization. Filtration. Manufacture of sterile products. Validation procedure and sterility testing. Microbiological aspects of Quality Assurance as it applies to the pharmaceutical industry. The role of quality control, formulation design, GMP and post-market surveillance in the industry
Biopharmaceutical Science Animal tissue cultures: Establishing animal cells in tissue culture. Cell strains. Continuous cell lines. Properties of normal and transformed cells. Media and growth conditions for mammalian cell cultures. Applications of animal cell cultures. Traditional and modern approaches to vaccine technology. Adjuvants. The biotechnology of biopharmaceuticals: Haemopoiesis and leukocyte differentiation. The biology, production and clinical uses of various cytokines: the interferons, and interleukins. Treatment of disease conditions using cytokine blocking. Production and uses of haemopoietic growth factors and hormones of therapeutic interest. Blood products, clotting factor, anticoagulants, enzymes of therapeutic value. The therapeutic use monoclonal antibodies. Production of other therapeutically useful substances by recombinant DNA technology. An introduction to gene therapy and stem cell research.
Practical The practical component will consist of 30 hours in the lab. The sessions will cover practicals/demonstrations of bioprocessing technologies to include the following: the operation of a 16L pilot plant fermenter, demonstration of induction/catabolote repression of a model system for the production of a microbial protein such as β galactosidase in E. coli, demonstration of cell disintegration technologies such as X Press, sonication and toluene treatment, some downstream processing including centrifugation, gel filtration and other chromatography techniques and freeze-drying, with emphasis on yields and process losses, the isolation of an antibiotic-producing organism (polymyxin-producing Bacillus) from soil and its growth to pilot plant scale.

Assessment Breakdown	%
Continuous Assessment	10.00%
Practical	20.00%
End of Module Formal Examination	70.00%

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	Specific relevant assigments	1,2,6,9,10	10.00	n/a

No Project

Practical

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	Practical and site visit report	1,2,6,9,10	20.00	Sem 1 End

End of Module Formal Examination

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	No Description	1,2,3,4,5,6,7,8,9,10,11	70.00	End-of-Semester

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

INDL H4R03: Industrial Microbiology and Biopharmaceuticals

Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Lecture	30 Weeks per Stage	3.00
Laboratory	30 Weeks per Stage	0.67
Estimated Learner Hours	30 Weeks per Stage	2.67
Work - based Learning	30 Weeks per Stage	0.33
	Total Hours	200.00