

**PHAR S8021: Health and Safety for the (Bio)  
Pharmaceutical Industry**

Module Details	
Module Code:	PHAR S8021
Full Title:	Health and Safety for the (Bio)Pharmaceutical Industry <b>APPROVED</b>
Valid From::	Semester 1 - 2020/21 ( September 2020 )
Language of Instruction:	English
Duration:	1 Semester
Credits::	5
Module Owner::	<ul style="list-style-type: none"><li>• annamarie rogers</li><li>• Edel Healy</li></ul>
Departments:	Life and Health Sciences
Module Description:	The aim of this module is to provide students with a knowledge of health and safety legislation relevant to the biopharmaceutical industry including the ability to recognize, evaluate and manage the relevant hazards through a range of relevant risk assessment techniques

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	Module Learning Outcome Description
MLO1	Evaluate the statutory requirements for the management of relevant hazards in the Biopharmaceutical Industry
MLO2	Design appropriate risk assessment methodology and implement safety management systems.
MLO3	Appraise chemical classification, labelling and Packaging requirements and biological agent risks according to current legislation and codes of practice
MLO4	Assess methods of Environmental Monitoring and waste management
MLO5	Evaluate how workplace health hazards can be monitored and controlled
Pre-requisite learning	
<b>Module Recommendations</b> <i>This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named DkIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).</i>	
No recommendations listed	

<b>Module Indicative Content</b>
<b>Safety, Health and Welfare at Work Act 2005 and associated regulations</b> Identify the employers and employee's role with regard to health and safety in the manufacturing sector. Know the essential components of a Safety Statement.
<b>Risk Assessment</b> Principles of Risk Assessment; Undertake a risk assessment; Determine control measures, procedures and required documentation e.g. HAZOP ,SWIFT
<b>Chemical Hazards</b> Chemicals Act; Classification, Labelling & Packaging Regulations; Chemical Hazards; Code of Practice (chemical agents); REACH
<b>Biological Hazards</b> Biological Agents Regulations; Biohazards; Methods of prevention, control and disposal of biohazards; Biosafety; Code of practice for health and safety at work (biological agents) Regulations 2013 and 2020
<b>Occupational Hygiene</b> Evaluation of health hazards; Mechanisms of control; Ventilation Control; Respiratory Protection mechanisms.
<b>Environmental Hazards in Manufacturing</b> Waste storage and disposal, emissions, environmental impact of raw materials and packaging. Environmental Management System.
<b>Machine, Gas, Electricity &amp; Fire Safety</b> 2007 Safety, Health and Welfare at Work (General Application) Regulations; Audits and safety checks; Control systems; Fire safety, protection and extinction

Module Assessment	
Assessment Breakdown	%
Course Work	30.00%
Project	50.00%
Practical	20.00%
<b>Module Special Regulation</b>	

## Assessments

Part Time On Campus			
<b>Course Work</b>			
<b>Assessment Type</b>	Class Test	<b>% of Total Mark</b>	30
<b>Marks Out Of</b>	0	<b>Pass Mark</b>	0
<b>Timing</b>	End-of-Semester	<b>Learning Outcome</b>	1,2,3,4,5
<b>Duration in minutes</b>	0		
<b>Assessment Description</b> A 2 hour in-class exam			
<b>Project</b>			
<b>Assessment Type</b>	Project	<b>% of Total Mark</b>	50
<b>Marks Out Of</b>	0	<b>Pass Mark</b>	0
<b>Timing</b>	n/a	<b>Learning Outcome</b>	2,3,4
<b>Duration in minutes</b>	0		
<b>Assessment Description</b> Complete a chemical/environmental/biological risk assessment			
<b>Practical</b>			
<b>Assessment Type</b>	Practical/Skills Evaluation	<b>% of Total Mark</b>	20
<b>Marks Out Of</b>	0	<b>Pass Mark</b>	0
<b>Timing</b>	n/a	<b>Learning Outcome</b>	2,3
<b>Duration in minutes</b>	0		
<b>Assessment Description</b> Students will complete two virtual H&S lab simulations (based on chemical & biological safety) and complete a quiz upon completion.			
No Final Examination			
<b>Reassessment Requirement</b>			
<b>No repeat examination</b> <i>Reassessment of this module will be offered solely on the basis of coursework and a repeat examination will not be offered.</i>			

## Module Workload

This module has no Full Time On Campus workload.

### Workload: Part Time On Campus

<i>Workload Type</i>	<i>Contact Type</i>	<i>Workload Description</i>	<i>Frequency</i>	<i>Average Weekly Learner Workload</i>	<i>Hours</i>
Lecture	Contact	Lecture	Every Week	2.00	2
Practical	Contact	Chemical Safety & Biosafety Virtual Laboratories	Once per semester	0.20	3
Independent Study	Non Contact	No Description	Every Week	3.00	3
Directed Reading	Non Contact	No Description	Every Week	3.00	3
				Total Weekly Learner Workload	8.20
				Total Weekly Contact Hours	2.20

## Module Resources

*This module does not have any book resources*

*This module does not have any article/paper resources*

### Other Resources

Website, HSA. (2005), Website: Health and Safety Authority 2005, Safety, Health and Welfare at Work Act 2005, Ireland, HSA,  
<http://www.hsa.ie/eng/Legislation/Acts/Safety Health and Welfare at Work/SI No 10 of 2005.pdf>

Website, HSA. (2020), Code of practice for the safety, health and welfare at work (biological agents) Regulations 2013 and 2020., Health & Safety Authority, Dublin, Ireland, HSA,  
[https://www.hsa.ie/eng/news\\_events\\_media/news/news\\_and\\_articles/code\\_of\\_practice\\_for\\_the\\_safety\\_health\\_and\\_welfare\\_at\\_work\\_biological\\_agents\\_regulations\\_2013\\_and\\_2020.html](https://www.hsa.ie/eng/news_events_media/news/news_and_articles/code_of_practice_for_the_safety_health_and_welfare_at_work_biological_agents_regulations_2013_and_2020.html)

Website, HSA. (2018), 2018 Code of Practice for the Chemical Agents Regulations, Ireland, HSA,  
[https://www.hsa.ie/eng/Publications\\_and\\_Forms/Publications/Chemical\\_and\\_Hazardous\\_Substances/Chemical\\_Agents\\_COP\\_2018.pdf](https://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/Chemical_Agents_COP_2018.pdf)

Website, HSA. (2015), A Guide to Non-Respiratory Personal Protective Equipment (PPE) for use with Chemical Agents in the Workplace, Ireland, Health & Safety Authority, Dublin, Ireland, HSA,  
[https://www.hsa.ie/eng/Publications\\_and\\_Forms/Publications/Chemical\\_and\\_Hazardous\\_Substances/A\\_Guide\\_to\\_Non-Respiratory\\_Personal\\_Protective\\_Equipment\\_PPE\\_for\\_use\\_with\\_Chemical\\_Agents\\_in\\_the\\_Workplace.html](https://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/A_Guide_to_Non-Respiratory_Personal_Protective_Equipment_PPE_for_use_with_Chemical_Agents_in_the_Workplace.html)

Website, EPA. Environmental Protection Agency,  
<https://www.epa.ie>