

Safety-Based Decision Making

Module Information

2022.01, Approved

Summary Information

Module Code	7114PHASCI	
Formal Module Title	Safety-Based Decision Making	
Owning School	Pharmacy & Biomolecular Sciences	
Career	Postgraduate Taught	
Credits	20	
Academic level	FHEQ Level 7	
Grading Schema	50	

Teaching Responsibility

LJMU Schools involved in Delivery	
Pharmacy & Biomolecular Sciences	

Learning Methods

Learning Method Type	Hours
Lecture	20
Workshop	20

Module Offering(s)

Display Name	Location	Start Month	Duration Number Duration Unit
JAN-CTY	CTY	January	12 Weeks

Aims and Outcomes

Aims	To equip students with detailed knowledge and understanding of the regulatory framework covering chemical toxicity prediction in the UK, EU and worldwide. To introduce the risk assessment process in industry and explain the role of the different organisations involved in the process. Students will gain knowledge of how weight of evidence can be used to combine a wide range of data sources to aid chemical toxicity prediction, without the use of animals, and how these approaches are used in industry to make decisions concerning the safety assessment.
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After completing the module the student should be able to:

Learning Outcomes

Code	Number	Description
MLO1	1	Demonstrate knowledge of the key regulatory tests required in the EU and worldwide for chemical toxicity prediction
MLO2	2	Critically assess and interpret chemical and biological data used in chemical toxicity prediction.
MLO3	3	Critically evaluate strategies and approaches used in chemical toxicity prediction in the UK, EU and worldwide.
MLO4	4	Demonstrate expertise to locate, evaluate and reference scientific literature relevant to animal and non-animal testing methods used in chemical toxicity prediction

Module Content

Outline Syllabus	The use of animal testing in regulatory toxicology. Key legislation in the UK, EU, and elsewhere and its implications for animal usage in regulatory toxicology. Alternative methods for chemical toxicity prediction; the importance of Next Generation Risk Assessment (NGRA), focusing on the use of novel chemical and biological approaches in regulatory toxicology. The use of weight of evidence in bringing together data sources to aid chemical toxicity prediction. Data analysis and results presentation – including dealing with experimental error in toxicity studies and conflicting data.
Module Overview	Describes how information is brought together to make decisions concerning the safety of chemicals in everyday use. Real-world examples of safety-assessment strategies commonly used by industry and regulators will be investigated.
Additional Information	Students will acquire knowledge and understanding of the use of weight of evidence in chemical toxicity prediction and the relevant legislation in the UK, EU and elsewhere. Students will be expected to make use of different sources of data and information (drawn from their course and own reading) during the weight of evidence assessment element of the module. The material will be delivered in the context of how "21st century toxicology" approaches are used to assist safety-based decision making in industry; for example application of the ICHM7 guidelines. Delivery of the module will be supported by representatives from organisations involved in developing, using and promoting alternatives to animal testing (e.g. Lhasa Ltd, Unilever and NC3Rs). Lectures, workshops and/or practical sessions involving these organisations will enable students to learn from practitioners in the field.

Assessments

Assignment Category	Assessment Name	Weight	Exam/Test Length (hours)	Module Learning Outcome Mapping
Presentation	Oral presentation	50	0	MLO1, MLO2, MLO3, MLO4
Report	Report	50	0	MLO1, MLO2, MLO3, MLO4

Module Contacts

Module Leader

Contact Name	Applies to all offerings	Offerings
Steven Enoch	Yes	N/A

Partner Module Team

Contact Name	Applies to all offerings	Offerings
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