**Liverpool** John Moores University

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| Title: | Principles of Toxicology and Drug Safety |
| Status: | Definitive |
| Code: | **6005SBACAP** (117500) |
| Version Start Date: | 01-08-2019 |
| Owning School/Faculty: | Pharmacy & Biomolecular Sciences |
| Teaching School/Faculty: | Pharmacy & Biomolecular Sciences |

| Team | Leader |
|---|---|
| Vicki Anderson | Y |
| Kenneth Ritchie | |
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| Philip Rowe | |
| Christopher Rostron | |
| Lorraine Shaw | |
| Jim Ford | |

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| **Academic Level:** | FHEQ6 | **Credit Value:** | 24 | **Total Delivered Hours:** | 46 |
| **Total Learning Hours:** | 240 | **Private Study:** | 194 | | |

**Delivery Options**
Course typically offered: Standard Year Long

| Component | Contact Hours |
|---|---|
| Lecture | 40 |
| Practical | 3 |
| Workshop | 1 |

**Grading Basis:** 40 %

**Assessment Details**

| Category | Short Description | Description | Weighting (%) | Exam Duration |
|---|---|---|---|---|
| Test | test | | 15 | 1 |

| Category | Short Description | Description | Weighting (%) | Exam Duration |
|---|---|---|---|---|
| Essay | essay | | 15 | |
| Exam | final | | 70 | 2 |

## Aims

*To present, and illustrate the principles and processes of toxicology and the processes involved in the design and development of a new medicinal product.*

## Learning Outcomes

After completing the module the student should be able to:

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|---|---|
| 1 | Gain knowledge of pre-clinical drug tests in vitro, and in animal models |
| 2 | Describe the mechanisms by which drugs are metabolised and excreted, and the factors that influence the rate at which these occur, and to be able to predict the likely fate of organic molecules, especially pharmaceuticals in common use |
| 3 | Describe the mechanisms of toxicity, and the methods to identify toxic effects |
| 4 | Demonstrate an understanding of the phases of clinical trials |
| 5 | Demonstrate an understanding the historical perspectives which have lead to the current guidelines and regulations governing clinical trials |
| 6 | To be able to review recent research papers in the field of patient recruitment and retention |
| 7 | To be able to discuss the advantages and disadvantages of outsourcing of clinical trials |
| 8 | Demonstrate an understanding the importance of appropriate data dissemination of clinical trial results |
| 9 | Demonstrate an understanding the study documentation required for running a clinical trial |
| 10 | Analyse clinical trial data, and perform appropriate statistical tests |

## Learning Outcomes of Assessments

The assessment item list is assessed via the learning outcomes listed:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| MCQ | 4 | 5 | | | | | |
| essay and presentation | 6 | 7 | 8 | | | | |
| EXAM | 1 | 2 | 3 | 5 | 8 | 9 | 10 |

## Outline Syllabus

*•Historical perspectives of clinical trials, and why we have regulations in place in the 21st century, including negligence in clinical research*
*•Drug metabolism and the molecular mechanisms of drug toxicity. The role of antioxidants and the molecular mechanisms of cellular defence*
*•Toxicology and computer-aided prediction of toxicity*

*•Cytotoxicity testing of compounds or novel drugs in vitro and in vivo in animals*
*•Pharmacogenetics and pharmacogenomics*
*•Adverse drug reactions, and reporting adverse drug events*
*•Clinical trial design*
*•Clinical trial set-up, patient recruitment and retention, and outsourcing*
*•Law and ethics in clinical trials*
*•Study documentation including investigator' brochure, protocol, case record form, inspections and audits, and trial master files.*
*•National guidelines, standard operating procedures (SOPs), and Good Clinical Practice (GCP)*
*•Data analysis (statistical)*
*•Aspects of clinical trial closedown, and date dissemination*

**Learning Activities**

Review of current literature in Clinical trials
Understand principles of drug toxicity

**Notes**

Recommended texts books