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VALUE ADDED PROGRAMME A.Y 2024-25

Course Module

Animal Handling and Preclinical Studies

Scope:

This Animal Handling and Preclinical Studies program provides pharmacy students with the flexibility to enhance their academic experience by enrolling each academic year, with the option to take one module per semester. This approach allows students to deepen their expertise in animal research, expand their practical skills, and align their learning with their career goals. The program is designed to offer a comprehensive and adaptable educational experience in preclinical research.

Objectives: Upon completion of the course, the student shall be able,

- Demonstrate proficiency in handling and restraining common laboratory animals, minimizing stress and discomfort during procedures.
- Design and develop preclinical study protocols, including formulating study objectives, endpoints, control groups, and writing comprehensive protocols that meet regulatory guidelines.
- Perform accurate dose calculations and conduct various toxicity studies, such as acute, subacute, and chronic, while evaluating and interpreting toxicity endpoints.
- Understand and apply ethical principles and regulatory requirements.

Chapter	Topic	No of Hours
1	**Introduction to Animal Handling** • Importance of animal handling in pharmaceutical research • Ethical considerations, welfare regulations, and use of PPE • Techniques for handling and restraining mice, rats, and rabbits • Practical training sessions with supervised hands-on experience	6
2	**Preclinical Study Design and Protocols** • Definition, importance, and stages of preclinical studies in drug development • Regulatory requirements and guidelines	6

	• Designing preclinical studies: objectives, endpoints, control groups, and statistical considerations • Developing and writing study protocols, including ethical considerations and approval processes	
3	**Dose Calculations and Toxicity Studies** • Principles of dose calculation for different routes of administration • Determining appropriate doses for efficacy and safety • Conducting acute, subacute, and chronic toxicity studies • Evaluating toxicity endpoints and interpreting results	6
4	**Laboratory Techniques in Preclinical Studies** • Common techniques: blood collection, drug administration routes, monitoring physiological parameters • Advanced techniques: Imaging, histopathology, and molecular biology techniques • Practical sessions with hands-on training in basic techniques and demonstrations of advanced methods • Data collection, statistical analysis, and presentation of preclinical study results	6
5	**Ethical Considerations and Regulatory Affairs** • Ethical guidelines and the 3Rs (Replacement, Reduction, Refinement) • Best practices: humane endpoints, euthanasia, record-keeping • Regulatory framework: key agencies (FDA, EMA), regulations, and guidelines • Documentation: SOPs, study reports, regulatory submissions	6

Principal
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