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Rajarshi Shahu College of Pharmacy, Buldana

(Approved by AICTE, PCI, New Delhi and affiliated to Sant Gadge Baba Amravati University, Amravati)

Date: 30 /01/2020

NOTICE

All the B Pharm III[rd] year students are hereby informed that Department of Pharmacology is going to organize one week "Certificate Course in Fundamentals of Preclinical Research" at our institute. Interested students must register on or before up to 01 Feb 2020, at 5:00 p.m., and inform their individual confirmation towards the pharmacology department.

Take a note of it.

Program Co-ordinator

Mr. M. N. Deokar

Principal

Dr. S. P. Jain

Principal
Rajarshi Shahu College of Pharmacy
Malvihir, Buldana.

Rajarshi Shahu College of Pharmacy, Buldana

Department of Pharmacology

Organized

"Certificate Course in Funadmental of Preclinical Research"

Course Code – RSCP/PCOL/19-20

(03 - 08 Feb 2020)

To establish and define an internal training program and to ensure the competency of pharma graduates. Training is the key factors for successful laboratory operations.

Co-ordinator

Mr. Mangesh M. Deokar

Assistant Professor

Convener

Dr. Shirish P. Jain

Principal

Principal

Rajarshi Shahu College of Pharmacy

Malvihir, Buldana.

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I. INTRODUCTION

Preclinical research refers to the laboratory testing and experimentation that is conducted before a new drug or medical treatment is tested on humans in clinical trials.

Goals: The main goals of preclinical research are to determine the safety, efficacy, and potential toxicity of a new drug or medical treatment.

Process: Preclinical research typically involves a series of in vitro and in vivo experiments using cell cultures, animal models, and other laboratory techniques.

Key considerations: Some of the key considerations in preclinical research include the selection of appropriate animal models, the design and execution of experiments, and the interpretation of results.

Regulatory requirements: Preclinical research is subject to various regulatory requirements, including the need for ethical review and approval, adherence to good laboratory practices (GLP), and compliance with regulations set forth by organizations such as the FDA and EMA.

Challenges: Some of the challenges associated with preclinical research include the high failure rate of drugs in clinical trials, difficulties in translating results from animal models to humans, and the need to balance scientific rigor with efficiency and cost-effectiveness.

Importance: Despite these challenges, preclinical research plays a critical role in the development of new drugs and medical treatments, and helps to ensure the safety and efficacy of these products before they are tested in human subjects.

Course description:

This certificate course are designed in order to learn and gain knowledge about the different animals used in preclinical research, as well as guidelines for animal house facility and animals care.

In addition to this, in this course we also provide exposure to the students for animal handling as well as knowledge about various routes of drug administration in experimental animals along with its rational. Moreover, topics covered in this course include an introduction to CPCSEA guidelines includes objectives along with importance of 4R's principles. Basic research techniques include animal handling and study of various routes of drug administration. Importantly in addition, this certificate course is frame to cover the safety and efficacy evaluation along with the regulatory requirements for preclinical research and data analysis and interpretation.

Course objectives:

The main objective of course is

1. To learn and acquire knowledge about basic requirement of preclinical research
2. To learn and acquire knowledge about animals used in preclinical laboratory along with their rational
3. To understand the guidelines for animal house facility
4. To understand the importance of guidelines used for animal care.
5. To understand the concept of safety and efficacy of drug used in laboratory
6. To raise the awareness amongst students about requirement of ethical practices during animal experimentation
7. To analyze and understand the safety as well as efficacy of test drugs

Scope:

Certificate program in the fundamentals of preclinical research is designed to provide individuals with a foundational understanding of the principles and practices involved in conducting research in a preclinical setting. The scope of such a program may cover a range of topics related to the design, conduct, and analysis of preclinical studies, including:

- Basic concepts of preclinical research, including the role of animal models and ethical considerations in research.
- Experimental design and hypothesis testing, including the use of controls, randomization, and blinding.
- Data collection and analysis techniques, including statistical methods and data management.
- Study conduct and management, including the selection of appropriate animal models, animal care and handling, and safety considerations.
- Regulatory requirements for preclinical research, including Good Laboratory Practices (GLP) and other relevant guidelines.
- Reporting and communication of study results, including the preparation of scientific reports and manuscripts, and presentation of research findings.

Overall, a certificate program in the fundamentals of preclinical research can be useful for students who are interested in pursuing a higher education and want to make a career in

II. SYLLABUS

Certificate Course in Fundamentals of Preclinical Research is designed to provide students with a comprehensive understanding of the scientific principles and practical skills necessary to conduct preclinical research in biomedical sciences.

The course covers a range of topics, including:

1. **Introduction to Preclinical Research:** This includes an overview of preclinical research, its importance, and the different phases of drug discovery and development.

2. **Introduction to CPCSEA guidelines and Requirement of Animal House Facility:** This includes aim and objectives, principles of 4 R's, constitution and guidelines of CPCSEA as well as IAEC.

3. **Basic Research Techniques:** This encompasses the fundamental techniques used in preclinical research, including animal handling, various routes of drug administration in animals.

4. **Understanding the Basic Concept of Pharmacology and Toxicology:** This includes the principles of pharmacology and toxicology, including the evaluation of the safety and efficacy (LD_{50} & ED_{50}) of potential therapeutics and assessment of any potential side effects.

5. **Understanding Concept of Regulatory Affairs in Preclinical Research:** This covers the regulatory requirements for preclinical research, including good laboratory practices (GLP), animal welfare regulations, and other guidelines.

6. **Data Analysis and Interpretation - Applications of various Statistical tests in Research:** This includes the fundamental principles of statistical analysis, data interpretation, and scientific communication.