

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (REGULATORY AFFAIRS)
SEMESTER	3
COURSE TITLE	RESEARCH METHODOLOGY & BIOSTATISTICS
COURSE CODE	13MC0301
COURSE CREDITS	4

Objective:

- 1 This course aims to provide students with a comprehensive understanding of research methodologies and the necessary skills to conduct and present research effectively.

Course Outcomes: After completion of this course, student will be able to:

- 1 Understand the meaning, types, and purposes of research, as well as the significance of conducting a literature survey using authenticated sources.
- 2 Identify research problems, develop research proposals, and assess their cost-effectiveness. Gain knowledge about potential sources for research grants.
- 3 Select appropriate research methods (quantitative, qualitative, questionnaire, etc.) and understand the importance of proper documentation in research.
- 4 Apply biostatistics techniques to analyze research results and determine their significance using various methods of comparison.
- 5 Acquire guidelines for writing a thesis, including the structure from abstract to references. Develop important skills for presenting research, whether orally or through poster presentations.

Pre-requisite of course: Nil

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	General research methodology Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, and blinding techniques.	12

Contents : Unit	Topics	Contact Hours
2	Biostatistics Definition, application, sample size, the importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12
3	Medical research History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, the importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth-telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	12
4	CPCSEA guidelines for laboratory animal facilities Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	12
5	Declaration of Helsinki History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	12
Total Hours		60

Textbook :

- 1 Research in education, John W. Best Jems V. Kahn,, Allay Bacon, 2003

References:

- 1 Methodology and techniques of social research, Methodology and techniques of social research, Wilkinson and Bhandarkar, Himalaya Publishing House , 2003
- 2 Presentation skills , Presentation skills , – Michel Halton , – Indian Society for institute education, 2005
- 3 Practical introduction to copyrights , Practical introduction to copyrights , – Gavin , Mofarlane, 1989
- 4 Thesis projects in sciences and engineering, Thesis projects in sciences and engineering, Richard M. Devis, , Davis, 1980
- 5 Scientist in the legal system , Scientist in the legal system , Ann Labor Science, Henrik Thorén, Niko Soininen, Niina K, 2021
- 6 Thesis and assessment writing , Thesis and assessment writing , Janolthon Anderson, John Wiley & Sons (Sd) , 1994

References:

- 7 Writing a technical paper , Writing a technical paper , Donald Manzel,, John Wilson, 1962
- 8 Effective business report writing , Effective business report writing , Lel and Brown, , W.S. Brown , 1965
- 9 Protection of industrial property rights , Protection of industrial property rights , Purshottam Das , and Gokul Das. , 1965
- 10 Spelling for Millions , Spelling for Millions , – Edna Furness, Russell G. Stauffer, 1965
- 11 Ayurveda and modern medicine , Ayurveda and modern medicine , – R. D. Lele, Russell G. Stauffer, 1965
- 12 How to write and publish a scientific paper , How to write and publish a scientific paper , – Robert A. Day , Cambridge University Press 4th edition, 1994
- 13 Business statistics , Business statistics , J K Sharma, , PHI publication, Pearson Education India, 2006
- 14 Introduction to Statistical Methods-, Introduction to Statistical Methods-, C. B. Gupta, Vikas Publishing House, 1973
- 15 A first course in Mathematical Statistics, A first course in Mathematical Statistics, C. E. Weatherborn, CUP Archive, 1949
- 16 Introduction to Biostatistics, Introduction to Biostatistics, Mahajan,, Arun Bhadra Khanal , 2018

Suggested Theory Distribution:

The suggested theory distribution as per Bloom’s taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
10.00	20.00	25.00	25.00	10.00	10.00

Instructional Method:

- 1 Lectures will be conducted with the aid of a multi-media projector, blackboard, OHP, etc. Assignments based on course content will be given to the students at the end of each unit/topic and will be evaluated at regular intervals. Surprise tests/quizzes/seminars/tutorials will be conducted. The course includes language practices such as group discussion, interviews,etc. to develop the communication skills of the students.

Supplementary Resources:

- 1 <http://www.pharmatext.org>
- 2 <http://www.pharmainfo.net>