RESEARCH METHODOLOGY

UNIT I: General Research Methodology (5H)

Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT II: Literature Survey (10H)

Introductions:Sources of information, need for reviewing literature, primary-secondary and tertiary sources, journals, journal abbreviations, abstracts, current titles, reviews, monographs, dictionaries, text books, current contents, patents.Introduction to chemical abstracts and beilstein, subject index, substance index, author index, formula index and other indices with examples.
Digital: Web resources, E-journals, journal access, TOC alerts. Hot articles: Citation index, UGC infonet, E-books, Impact Factors, Search engines- Google scholar, chemical industry, Wiki-databases, chemSpider, ScienceDirect, SciFinder, Scopus.

UNIT III: Medical Research (10H)

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, 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.

CPCSEA guidelines for laboratory animal facility & Declaration of Helsinki 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.

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

UNIT IV: Ethics and IPR (5H)

Regulatory bodies, practices and compliances, Good Laboratory Practices (GLP), Research Ethics & Misconduct, Patents, Copyrights, GI and Trademarks, Product and process patent, Patent Treaties and Convention, process of filing patent, database of patent, search and retrieval.

References

1. Research Methodology. Methods and Techniques: C. R. Kothari.
2. Paul D Leedy, Jeanne E Ormrod and Jeanne Ellis Ormrod, Practical Research: Planning and Design, Prentice Hall, 2004.

3. Robert V Smith, Graduate Research: A Guide for Students in the Sciences, University of Washington Press, 1998.
4. http://cpcsea.nic.in/Content/55_1_GUIDELINES.aspx dated 07/07/2020
5. https://www.wma.net/wp-content/uploads/2017/01/Wiesing-DoH-Helsinki-20141111.pdf dated 07/07/2020

RECENT ADVANCES IN PHARMACOLOGY

UNIT-1: Pharmacological and Toxicological Screening Methods (15H)

Laboratory Animals: Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. **General principles of preclinical screening**: CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics, Respiratory Pharmacology, Reproductive Pharmacology, Cancer Pharmacology etc. **General principles of immunoassay:** theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. **Cell culture techniques:** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; applications of flow cytometry.

UNIT-2: Cell & Cell Signalling (15H)

Intercellular and intracellular signalling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway etc. Cell death–events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy signalling etc.

UNIT – 3: Applications of genomic & proteomic tools and Pharmacogenomics (15H)

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice.

UNIT – 4: Clinical Research and Pharmacovigilance (15H)

Regulatory Perspectives of Clinical Trials - Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and

Human Participant Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process**.** **Clinical Trials:** Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management .**Methods, ADR reporting and tools used in Pharmacovigilance:** International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

References

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. The Cell, A Molecular Approach. Geoffrey M Cooper.
6. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
7. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
8. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
9. Basic Cell Culture protocols by CherilD.Helgason and Cindy L.Miller
10. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
11. Screening methods in Pharmacology by Robert Turner. A
12. Evaluation of drugs activities by Laurence and Bachrach
13. Methods in Pharmacology by Arnold Schwartz.
14. Fundamentals of experimental Pharmacology by M.N.Ghosh
15. Pharmacological experiment on intact preparations by Churchill Livingstone
16. Drug discovery and Evaluation by Vogel H.G.
17. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
18. Clinical Pharmacokinetics &Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
19. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists. 16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

RECENT ADVANCES IN PHARMACEUTICS

UNIT -1 : Drug Delivery Systems (15H)

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. **Polymers:** Introduction, definition, classification, properties and application. **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals & other drug delivery systems.

UNIT-2: Modern Pharmaceutics (15H)

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & PQ of facilities. **cGMP& Industrial Management -** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance.

UNIT-3: **Regulatory affairs(15H)**

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, post approval regulatory affairs.Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

UNIT-4: **Molecular Pharmaceutics (15H)**

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting.Tumor targeting and Brain specific delivery. **Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. **Micro Capsules / Micro Spheres**:Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. **Pulmonary Drug Delivery Systems :** Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Books recommended:

1. Chien, Y.W. (1992). Novel Drug Delivery Systems. 2nd Ed. revised and expanded. New York: Marcel Dekker.
2. Vyas, S.P., Khar R.K. (2002). Controlled Drug Delivery - concepts and advances. New Delhi: VallabhPrakashan.
3. Jain, N.K. (2001). Controlled and Novel Drug Delivery.1st Ed. New Delhi: CBS Publishers & Distributors.

4. Shargel, L, Kaufer, I. (2005). Generic Drug Product Development, Solid Oral Dosage forms. Vol.143. New York: Marcel Dekker Inc.
5. Berry, I.R., Martin, R.P. (2008). The Pharmaceutical Regulatory Process.2nd Ed., vol. 185.Drugs and the Pharmaceutical Sciences. New York: CRC press.
6. Guarino, R.A. (2004). New Drug Approval Process: Accelerating Global Registrations. 5th Ed., vol. 190, New York: Marcel Dekker Inc.
7. Lachmann, L., Libermann, H.A., Kanig, J.L. (2013). Theory and practice of industrial pharmacy. 4th Ed., Bombay: Varghese Publishing House.
8. Lachmann, L., Libermann, H.A., Joseph, B. (1989). Pharmaceutical dosage forms: Tablets. 2nd Ed.,vol. I-III. New York: Marcel Dekker.
9. Lachmann, L., Libermann, H.A., Martin, M.R., Banker, G.S. (1996). Pharmaceutical dosage forms: disperse systems. vol. I-II, CRC press.
10. Avis, K.E., Lachmann, L., Libermann, H.A. (1984). Pharmaceutical dosage forms: parentral medications. vol.1. New York: Marcel Dekker.

RESEARCH PROPOSAL PREPARATION AND SEMINAR PRESENTATION

UNIT I: Research Proposal (15H)

Developing a Research Proposal: Format of research proposal, individual research proposal and institutional proposal. Research Report: Format of the research report, style of writing the report, references and bibliography
Application and uses of common softwares in Pharmacy- GraphPad Prism, chemsketch, chemdraw. Auto-Doc 4.0, Design Expert, Mini-Tab 16 etc.

UNIT II: Literature Survey(45H)

Extensive survey of published literature relevant to the chosen topic of research which appeared in referred research journals of national and international repute, edited books, reference books, monographs, survey / study reports, dissertations / theses published in book form, and books / reports containing proceedings of national and international conferences / seminars / symposia. Students have to make a review on the given topic/proposal of research work.
There will be two seminar presentations (*viz*. presentation-I and presentation-II). The Ph.D. seminar courses require students to attend and deliver seminars as per their selected themes. Evaluation will be based on review preparation, participation and on the quality of the talk deliver.

RESEARCH AND PUBLICATION ETHICS

UNIT-1: PHILOSOPHY AND ETHICS (2 HRS)
1. Introduction to philosophy: definition, nature and scope, concept, branches 2. Ethics: definition, moral philosophy, nature of moral judgements and relations.
UNIT-2: SCIENTIFIC CONDUCT (4 HRS)
1. Ethics with respect to science and research 2. Intellectual honest and research integrity 3. Scientific misconducts: falsification, fabrication, and plagiarism. 4. Redundant publications: duplicate and overlapping publications, salami slicing 5. Selective reporting and misrepresentation of data.
UNIT-3: PUBLICATION ETHICS (6 HRS)
1. Publication ethics: definition, introduction and importance 2. Best practices/standards setting initiatives and guidelines: COPE, WAME, etc. 3. Conflicts of interest 4. Publication misconduct: definition, concept, problems that lead to unethical behaviour and vice verse, types 5. Violation of publication ethics, authorship and contributor-ship 6. Identification of publication misconduct, complaints and appeals 7. Predatory publishers and journals
UNIT-4: OPEN ACCESS PUBLISHING (6 HRS)
1. Open access publications and initiatives 2. SHERPA/RoMEO online recourse to check publisher copyright and self-archiving policies. 3. Software tool to identify predatory publications developed by SPPU 4. Journal finder/ journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.
UNIT-5: PUBLICATION MISCONDUCT (6 HRS)
Group Discussions 1. Subject specific ethical issues, authorship 2. Conflicts of interest

3. Complaints and appeals: examples and fraud from India and abroad **Software tools**
Use of plagiarism software like Turnitin, Urkund and other open source software tools.

UNIT-6: DATABASES AND RESEARCH METRICS (6 HRS)

Databases 1. Indexing detabeses 2. Citation detabases: Web of Science, Scopus, etc. **Research Metrics :** Impact Factor of journal as per journal citation report, SNIP, SJR, IPP, Cite Score. Metrics: h-index, g index, i10 index, altmetrics.