Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Pharmacy Practice)
III Semester Course Contents

MPY 301 PP: Advanced Clinical Research

1. Introduction to Clinical research

- Definition and terminology used in clinical trials
- Historical development of Clinical research practice
- Drug development process

2. Clinical trial protocol design

- Planning and execution of clinical trials
- Various phases of clinical trials
- Randomization technique (Simple randomization, Restricted Randomization, Blocking method and stratification)

Types of research design based on controlling method (Experimental, quasi Experimental, & observational methods)Time sequences(Prospective and retrospective),Sampling methods(cohort study, case control study and cross sectional study)

Health outcome measures(clinical and physiological, humanistic and economic)

3. Ethics and guidelines in clinical research

Ethical issues in biomedical research-principles of ethics in biomedical research, Ethical committee (Institutional review board), its constitutions and functions Good clinical practice (ICHGCP guidelines, CDSCO regulations, MPA, European, Japan, Health Canada and MHRA guidelines, Schedule Y and USFDA in the conduct of clinical trials)

4. Clinical research

- Establishing and functioning of contract research Organisation (CRO)
- Roles and responsibilities of clinical trial personnel
- Trial initiation, Volunteer recruitment, trial supplies and site management
- Designing of clinical trial documents
- Monitoring and auditing of clinical trails
- Trial report generation
- Site closure

6. Data management

- Medical writing and ethics of publication
- Clinical data management (Data entry, Data interpretation,Data monitoring and auditing)

Recommended Books:

1. Avery's Drug treatement,4th Edition,1997,Adis International ltd.
2. Designing clinical research,Edtd by Stephen B Hulley,Steven R Cummings

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III Semester Course Contents

MPY 302 PP : Pharmacoepidemiology and Pharmacoeconomics

1. Introduction to Pharmacoepidemiology and its perspective (Industry, academic and regulatory, Hospital)
2. Pharmacoepidemiological study designs and source data
3. Molecular Pharmacoepidemiology
4. Biomedical issues and quality of life measurements in Pharmacoepidemiological research
5. Applications of Pharmacoepidemiology
6. Various Pharmacoeconomic models used in health care and Apilications of Pharmacoeconomics

Recommended Books:

1. Pharmacoepidemiology Edt. Brian L Storm 4th Edn. Wiley Publisher
2. Avery's Drug Treatment. ADIS publication

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III Semester Course Contents

MPY 303 PP : Clinical Pharmacokinetics and Biostatistics

1. **Clinical pharmacokinetics**

- Introduction to Clinical pharmacokinetics
- Clinical pharmacokinetic models

2**. Drug clearance**

- Physiological determinants of drug clearance and volumes of distribution
- Renal and non renal clearance
- Organ extraction and models of hepatic clearance

3. **Estimation and determinants of bioavailability**

4. Drug dosing

- Calculation of loading and maintenance doses
- Dose adjustment in renal failure, Hepatic dysfunction, geriactric and pediatric patients

5. **Therapeutic drug monitoring** (General aspects)

6. **Clinical application of statistical analysis**

- Basic concepts of biomedical statistics
- Descriptive and differential statistics
- Statistical tests-parametric and nonparametric
- Sample size calculation
- Confidence intervals
- Test of significance

Recommended Books:

[1] Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;
[2] International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised 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] Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
[6] Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. 2001,McGraw Hill Publications.

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III Semester Course Contents

MPY 304 PP : TOXICOLOGY

1. Principles of toxicology, Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinectics, mutagenesis and carcinogenesis.

2. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH guidelines S7A, S7B, WHO,

3. Documentation and protocol preparation, knowledge of planning,performing, analyzing, reporting and monitoring of safety pharmacology study.

4. Safety Pharmacology

- Abnormal action of drugs such as tolerance, addiction, habituation, idiosyncracy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis.
- Heavy metals poisoning.
- Behavioural, Inhalation, cellular and sub-cellular toxicity hypersensitivity and immune response, range finding tests.
- *In vivo* -Telemetry applications in safety pharmacology, *In vitro* - patch clamp technique, Langendorff isolated heart preparation

5. Adverse drug reactions and its monitoring.

6. Acute, sub-acute and chronic toxicity studies according to ICH and OECD guidelines.

Recommended Books:

1. Toxicology — Principles and Applications: R.J.M. Niesink, J. De Vries, M.A. Hollinger (eds), CRC Press, Boca Raton, New York, London, Tokyo, 1996.
2. Klassen C.D., Amdur M.O., Doul J Casarett's and Doull's Toxicology New York, McGraw Hill Publishing Ltd. 2001
3. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.
4. karen Baxter ; "Stockley's Drug Interaction" 7th edition ,2006, pharmaceutical press
5. Chi Jen lee, Lucia H Lee, et.al. , "Clinical Trials of Drugs And Biopharmaceutical" 1st edition, 1996, CRC Taylor & Francis group broken sound parkway, NW, Suite.
6. David machin et.al. "Textbook of clinical trials" 1st edition , 2005,Jonh Wiley & sons td ,Chichester, England .