28/08/2012

RAJIV GANDHI PROUDYOGIKI VISHWAVIDYALAYA

M.Pharm. (Pharmacology)

3rd Semester Elective Course Contents

Elective-I

MPY 301 PCL : CLINICAL RESEARCH

Unit I

New drug discovery process and clinical evaluation of new drugs. Terminologies, Defining the Research Team; roles, responsibilities, organization structure. Clinical trial Site inititation, subject recruitment, exclusion/inclusion criteria, end-points in clinical trial. Informed Consent formates and regulations. Patient counseling and interviewing techniques, Improving patient compliance and patient monitoring. Pharmaco-epidemiology.

Unit II

Clinical research Methodologies: Experimental design: Experimental design in clinical trials, Control in clinical trials, Randomization, Blinding, Statistical Analysis, Experimental planning and monitoring, Recognising sources of bias and minimising its effect, non-parametric and parametric analysis. Case record forms, Statistical quality control.

Unit III

Clinical trial protocol writing and documentations. Sampling techniques, Sampling Design, types of sampling, Probability and non probability sampling, Methods of drawing samples, Sample size determination, Sampling error.
Phases of clinical research.

Unit IV

Performing and interpretation of Clinical Trials: Data collection, Data analysis, meta analysis and reporting. Measuring treatment effects, Racial, gender and ethnic differences in drugs response. Data validation, query management, Softwares in clinical data management. Tables & Graphs, Measures of Central Tendency, Measures of variation, hypothesis testing. Report writing and presentation.

Unit V

Regulatory requirements, essential documents and regulatory submission, supervision of ethics, compliance and audits, Institutional Review Board (Role and responsibility, members and auditing), The Declaration of Helsinki, The Belmont Report, GCP & ICH guidelines, Schedule Y. Country specific trial filing requirement.

Recommended books:

1. Elementary Statistical Quality Control, Volume 25, Burr, I. W., New York: Marcel Dekker, Inc.
2. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA.
3. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA, Informa Healthcare; 4 edition.
4. Clinical Trials by L Duley and B Farrell, BMJ Books, London.
5. Handbook for good clinical research practice WHO Library Catalogue.
6. Artciles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.

7. Design of experiments. A realistic approach by V L Anderson and Robert Mclean, Marcel Dekker, New York, USA.
8. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer.
9. The CRC's Guide to Coordinating Clinical Research, Second Ed, by Karen E. Woodin, CentreWatch Publication.
10. A Guide to Patient Recruitment and Retention by Anderson D. L., CentreWatch Publication.
11. The CRA's Guide to Monitoring Clinical Research, Third Edition by Woodin K. E., CentreWatch Publication.
12. The CRC's Guide to Coordinating Clinical Research, Second Edition by Woodin K E., CentreWatch Publication.
13. Clinical Research Environment in India by Umakanta Sahoo, Faiz Kermani, ICFAI University Press.

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M.Pharm. (Pharmacology)

3rd Semester Elective Course Contents

Elective-II

MPY 302 PCL : BIOLOGICAL EVALUATION OF DRUGS

UNIT-I

Anatomical and physiological considerations of commonly used laboratory animals. Maintenance and breeding of Laboratory animals. Design, management and safety of laboratory for biological evaluation of drugs.

Anatomical specifications, advantage & limitations of various anatomical sites of blood collection in laboratory animals. Specifications of laboratory anesthetic agents, their use in specific condition.

UNIT-II

Bioassays: Principle, types and methods of bioassays, advantages over other assays. Official bioassays. Bioassay of official drugs. Biological standardization of vaccines and sera.

Methods of bioassay of adrenaline, nor-adrenaline, acetylcholine, histamine, angiotensin, d-tubocurarine, insulin, digoxin, oxytocin, estrogen, thyroxine, corticotrophin and somatotrophin.

UNIT-III

Bioassay design and techniques: Experimental models and statistical experimental designs employed in biological standardization. Statistical quality control. Introduction to high-throughput screening and modern techniques like ligand-binding studies and use of tissue culture in biological evaluation of drugs. Development of new bioassay.

UNIT-IV

Toxicity tests, Methods of acute, subacute, and chronic toxicity studies. Elementary knowledge of systemic toxicology, Toxicology of central nervous system, peripheral nervous system, liver, kidney, respiratory system, haematopoietic system, reproductive system etc. Regulatory standards and requirements for toxicity data of various regulatory bodies.

UNIT-V

Clinical trials: Clinical trial designs, Approved procedures, Protocols and regulatory guidelines, i.e., Helsinki declaration, USFDA & ICH guidelines for Clinical trials of drugs, Reviews & approval of Clinical Study, Good Clinical Practices.

Recommended books:

1. Drug Discovery and Evaluation by Vogel HG. Springer, N Y
2. Practical Pharmacology by Burn, J.H. Blackwell Scientific Co. Oxford
3. Screening Methods in pharmacology. Vols I and II by A. Turner, Academic Press.
4. Evaluation of Drug Activities: Pharmacometrics by Lawrence and Bacharach, Academic Press.
5. Drug Bioscreening by Thompson, E.B. VCH, New York
6. Various regulatory guideliens like ICH, GCP, Helsinki, USFDA etc.
7. Pharmacopoeia: IP, BP, USP etc.
8. Transgenic Animal Technology, Second Edition: A Laboratory Handbook by Carl A. Pinkert, Academic press

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M.Pharm. (Pharmacology)

3rd Semester Elective Course Contents

Elective-III

MPY 303 PCL : PHARMACOVIGILANCE

Unit-I

Introduction, Principles of pharmacovigilance, Frequency and importance of adverse drug reaction, Pharmacovigilance methods, Setting up and operating a Pharmacovigilance centre, terminologies, Resources for pharmacovigilance centres, Role of pharmacist, Computer system in recording and interpretation of adverse drug reaction (ADR) information, Interpretation and use of information from spontaneous ADR reporting systems.

Unit-II

Pharmacoepidemiology: Basic epidemiological principles, cohort studies, Case control studies, Prescription event monitoring, Drug utilization studies, Information sources and system available for pharmacoepidemiological studies, Benefit/harm ratio.

Pharmacogenetics: Genetic polymorphism in xenobiotic metabolizing enzymes, Mechanisms of allelic variation in xenobiotic metabolizing enzymes, Pharmacologic consequences and contribution in ADR of a genetic polymorphism.

Unit-III

Standard operating procedures in Pharmacovigilance, case evaluation- casuality assessment, Managing individual case report forms, Signal analysis, follow-up and Root cause analysis of medication errors. Medical Information System, Risk –benefit assessment and management in Pharmacovigilance, Communicating pharmacovigilance information. Disease specific tool kit. pharmacovigilance of Vaccines, Herbal and other complementary medicines.

Unit-IV

Post-marketing drug safety: Differences in clinical and post-marketing drug safety, Reporting to the Regulatory Authorities: Individual case safety reports, Periodic safety update reports, Answering queries from regulatory authorities, Updating product labeling – emphasis on safety changes, Safety reporting requirements, Safety report sources, Follow up of safety reports, Electronic safety reporting systems and software program available, Safety file retention.

Unit-V

Global Pharmacovigilance System and safety standards, WHO programme for international drug monitoring, Global regulatory requirements and guidelines, Compliance monitoring and Pharmacovigilance inspections, National Pharmacovigilance Programme, Objectives, Programme governance, Reporting structures, Communication and Framework in india. Authority and Industry perspectives, ICH, FDA guidelines.

Recommended books:

1. Pharmacovigilance (2nd Ed) by Ronald D.Mann & Elizabeth B. Andrews, John Wiley & Sons
2. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science

3. Manual of Drug Safety and Pharmacovigilance by Barton L. Cobert, Jones & Bartlett
4. An Introduction to Pharmacovigilance by Waller, Patrick; John Wiley & Sons
5. "Good Pharmacovigilance Practice" MHRA guidelines
6. Various national and international guidelines.
7. Strengthening Pharmaceutical Systems (SPS). Supporting Pharmacovigilance in Developing Countries: The Systems Perspective. Submitted to the U.S. agency for international Development by the SPS Program. Arlington, Va: management Sciences for health. September 2009
8. http://apps.who.int/medicinedocs/en/d/Jh2992e/ Safety of Medicines - A Guide to Detecting and Reporting Adverse Drug Reactions - Why Health Professionals Need to Take Action
9. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdf The safety of medicines in public health programmes: pharmacovigilance an essential tool by World Health Organization 2006
10. http://www.who.int/medicines/technical_briefing/tbs/handbook_antimalarialpharmvigilance.pdf A practical handbook on the pharmacovigilance of antimalarial medicines by © World Health Organization 2007
11. World Health Organization WHO Technical Report Series, No. 850, 1995, Annex 3 Guidelines for good clinical practice (GCP) for trials on pharmaceutical products http://www.pvtoolkit.org/index.php?option=com_content&view=article&id=6&Itemid=10

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M.Pharm. (Pharmacology)

3rd Semester Elective Course Contents

Elective-IV

MPY 304 PCL : PHARMACOLOGICAL DRUG SCREENING

Unit I

Principles, techniques and strategies used in new drug discovery. Methodologies in Evaluation of potential new drug, Types of drug screening models, Correlations between various animal models and human clinical data, Regulatory guidelines in extrapolation of human dose. Application of molecular biology in screeing models. Software assisted screening of drug molecule.

Unit II

Correlation between in-vitro and in-vivo screens, Alternatives to animal screening procedures, patch-clamp technique, Molecular biology techniques, Cell line based assay, Biochemical assay, Radioligand binding assay, Recent development of advanced and automated screening models.

Unit III

Design of Experiments: Objectives, Strategies, Experimental design, Basic principles-replication, Randomization, Blocking, Meaning and purpose of research design, Types of research design, Criteria of a good research design.

Guidelines for design of experiments: Simple Comparative Experiments, Basic statistical concepts, Random variable, Sample mean and variance, Degrees of freedom, Standard and normal distribution, Statistical hypothesis, t-test, P-value, Confidence Intervals, Paired and unpaired comparisons

Unit IV

Pharmacological screening models of new drugs belonging to following categories: Antileishmaniasis, antifilariasis, anthelmintics, Antifertility agents, antiobesity, antiatherosclerotic, eicosanoids, antidiabetics and drug affecting various ion channels like calcium, sodium, potassium,

Unit V

Principle, development methodologies, maintenance and examples of various Transgenic animals and other genetically prone animal models used in screening of various drug categories. Principles of toxicity evaluations, ED50, LD50 and TD values.

Recommended books:

1. Drug Discovery and Evaluation by H. Gerhard Vogel, Springer, N Y.
2. Screening Methods in pharmacology. Vols I and II by A. Turner, Academic Press.
3. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, McGraw Hill
4. Clinical Pharmacokinetics: Concepts and application by Rowland and Tozer, Lippincott
5. Handbook of Experimental Pharmacology by Hofmann, F.B., Springer
6. Fundamentals of Experimental Pharmacology by Gohsh, M.N., Scientific Book Agency, Calcutta.

7. Pharmacological Experiments on Isolated Preparations,by Perry, E&S Livingstone, London.
8. Transgenic Animal Technology, Second Edition: A Laboratory Handbook by Carl A. Pinkert, Academic press