**GUJARAT TECHNOLOGICAL UNIVERSITY**
PHARM.D (PB)
2nd Year

**Subject Name:** Clinical Research
**Subject Code:** 828901

**Scope:** This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development.

**Objectives:** At completion of this course, it is expected that students will be able to:

- Know the concept of new drug development process.
- Understand the regulatory and ethical requirements.
- Conduct the clinical trials in accordance to regulatory and ethical requirements.
- Coordinate the clinical trials and promote quality drug trial research

**Teaching scheme and examination scheme:**

| Teaching Scheme | | | | Evaluation Scheme | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| Theory | Tutorial | Practical | Total | Theory | | Practical | | |
| | | | | External | Internal | External | Internal | |
| 3 | 1 | 0 | 4 | 70 | 30 | 0 | 0 | 100 |

| | Topics | Hrs |
|---|---|---|
| 1 | **1. Drug development process:**<br>Introduction<br>Various Approaches to drug discovery<br>1. Pharmacological<br>2. Toxicological<br>3. IND Application<br>4. Drug characterization<br>5. Dosage form | **06** |
| **2.** | **Clinical development of drug:** | |
| | 1. Introduction to Clinical trials. | **02** |
| | 2. Various phases of clinical trial. | **04** |
| | 3. Methods of post marketing surveillance. | **02** |
| | 4. Abbreviated New Drug Application submission. | **02** |
| | 5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines. | **06** |
| | 6. Challenges in the implementation of guidelines. | **02** |
| | 7. Ethical guidelines in Clinical Research. | **01** |
| | 8. Composition, responsibilities, procedures of IRB / IEC. | **01** |
| | 9. Overview of regulatory environment in USA, Europe and India. | **08** |

| | | |
|---|---|---|
| | 10. Role and responsibilities of clinical trial personnel as per ICH- GCP<br>a. Sponsor<br>b. Investigators<br>c. Clinical research associate<br>d. Auditors<br>e. Contract research coordinators<br>f. Regulatory authority | **05** |
| | 11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment). | **04** |
| | 12. Informed consent Process. | **01** |
| | 13. Data management and its components. | **03** |
| | 14. Safety monitoring in clinical trials. | **03** |

**Text Books:**


**1.** Principles and Practice of Pharmaceutical Medicine. Lionel D. Edward, Aadrew J. Flether, Anthony W. Fos, Peter D. Sloaier. Publisher- Wiley. Latest edition.

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Publisher- Churchill Livingstone. Latest edition.
3. Principles of Clinical Research. Giovanna di Ignazio, Di Giovanna and Haynes. Publisher- Ergode books. Latest edition.
**4.** Essentials of Clinical Research. Glasser. Publisher- Springer. Latest edition.


**Reference books:**


1. Textbook of Clinical Trials. David Machin, Simon Day and Sylvan Green. Publisher- John Wiley and Sons. Latest edition.
2. Clinical Data Management. R K Rondels, S A Varley, C F Webbs. Publisher- Wiley. Latest edition.
3. Goodman & Gilman: JG Hardman, LE Limbard, Publishers- McGraw Hill. Latest edition.


**Other references:**


1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health (Latest guidelines).
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. (Latest guidelines).
3. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi. (Latest guidelines).
4. Websites of regulatory bodies of different countries.
5. Clinical research journal

**GUJARAT TECHNOLOGICAL UNIVERSITY**
PHARM.D (PB)
2nd Year

**Subject Name: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS**
**Subject Code:** 828902

**Scope:** This course is designed to impart knowledge regarding various methods and applications of pharmacoepidemiology and pharmaco-economics in drug safety monitoring, drug approval and regulations

**Objectives:** Upon completion of this course, it is expected that students will be able to -

a. Understand drugs use pattern and their outcome measures
b. Conductpharmaco-epidemiological studies
c. Adopt the tools effectively in evaluating risk and benefit of therapy
d. Conduct pharmacoeconomic studies and evaluate the cost-benefit ratio

**Teaching scheme and examination scheme:**

| Teaching Scheme | | | | Evaluation Scheme | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| Theory | Tutorial | Practical | Total | Theory | | Practical | | |
| | | | | External | Internal | External | Internal | |
| 3 | 1 | 0 | 4 | 70 | 30 | 0 | 0 | 100 |

| Sr. | Topic | Hr |
|---|---|---|
| 1. | **Pharmacoepidemiology :**<br>**Definition and scope:**<br>Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications. | **06** |
| | **Measurement of outcomes in pharmacoepidemiology** Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement | **06** |
| | **Concept of risk in pharmacoepidemiology** Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio | **06** |
| | **Pharmacoepidemiological methods** Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case – cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system. | **22** |
| | **Sources of data for pharmacoepidemiological studies** Ad Hoc data sources and automated data systems. | **04** |
| | **Selected special applications of pharmacoepidemiology** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects. | **08** |
| 2. | **Phrmacoeconomics:** | |
| | Definition, history, needs of pharmacoeconomic evaluations | **02** |

| | | |
|---|---|---|
| | Role in formulary management decisions | **02** |
| | **Pharmacoeconomic evaluation** Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility | **16** |
| **3.** | **Applications of Pharmacoeconomics** | **03** |
| | Software and case studies (assignment discussion) | **02** |

**Text books:**

1. Pharmacoepidemiology and Pharmacoeconomics: Concepts and Practice. K G Revikumar. Publisher- Pharma Med Press. Latest edition.
2. Textbook of Pharmacoepidemiology. Brian L. Strom, Stephen E. Kimmel, Sean Hennessy. Publisher- John Wiley & Sons. Latest edition.
3. A textbook of Clinical Pharmacy Practice: Essential concepts and skills. G Parthasarathi, Karin Nyfort-Hansen, Milap C. Nahata. Publisher- Orient Longman Pvt. Ltd. Latest edition.

**Reference Books:**

1. Pharmacoeconomics and outcomes: Applications for patient care, case studies. Graer D W, Lee J, OdomT D, et al. Publisher- Lippincott Williams and Wilkins. Latest edition.
2. Introduction to Applied Pharmacoeconomics. F. Randy Vogenberg. Publisher- McGraw-Hill. Latest edition.
3. Pharmacoepidemiology. Brian L Storm. Publisher- John Wiley and Sons, Ltd. Latest edition.
4. Clinical epidemiology- How to do clinical Practice Research. Brian Haynes, David L Sachett. Publisher- Lippincott Williams and Wilkins. Latest edition.
5. Park's textbook of Preventive and social medicine. K Park. Bhanot Publishers. Latest edition.

**Other references:**

- WHO website (for epidemiology data)

**GUJARAT TECHNOLOGICAL UNIVERSITY**
PHARM.D (PB)
2nd Year

**Subject Name: Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring**
**Subject Code:** 828903

**Scope:** This course is designed to make the students to understand and apply pharmacokinetic principles in designing / individualizing dosage regimen. Also, enable the students to interpret the plasma drug range, and hepatic / renal function in optimizing the drug therapy.

**Objectives:**
On completion of the course, the student shall be able to
1. Design the drug therapy regimen for individual patient
2. Interpret and correlate the plasma drug concentration with patient's thera- peutic outcome.
3. Recommend dosage adjustment for patients with renal/ hepatic impairment
4. Detect and manage drug –drug interactions

**Teaching scheme and examination scheme:**

| Teaching Scheme | | | | Evaluation Scheme | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| Theory | Tutorial | Practical | Total | Theory | | Practical | | |
| | | | | External | Internal | External | Internal | |
| 2 | 1 | 0 | 3 | 70 | 30 | 0 | 0 | 100 |

| Sr. | Topic | Hr |
|---|---|---|
| 1. | **Introduction to Clinical pharmacokinetics** | 01 |
| 2. | **Design of dosage regimens:** Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients. | 07 |
| 3. | **Pharmacokinetics of Drug Interaction:** a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion. | 03 |
| 4. | **Therapeutic Drug monitoring:** a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs). c. Indications for TDM. Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations | 20 |
| 5. | **Dosage adjustment in Renal and hepatic Disease.** a. Renal impairment b. Pharmacokinetic considerations c. General approach for dosage adjustment in Renal disease. d. Measurement of Glomerular Filtration rate and creatinine clearance. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics | 10 |

| | | |
|---|---|---|
| **6.** | **Population Pharmacokinetics.** a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feed back. c. Analysis of Population pharmacokinetic Data. | **05** |
| **7.** | **Pharmacogenetics**<br>a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.<br>b. Genetic Polymorphism in Drug Transport and Drug Targets.<br>c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations | **04** |

**Text Books:**

1. Biopharmaceutics and Applied Pharmacokinetics. Leon Shargel. Publisher- Prentice Hall. Latest edition.
2. Applied Pharmacokinetics& Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Publisher- Lippincott Williams & Wilkins. Latest edition.

**Reference books:**

1. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. Steven How-Yan Wong, Irving Sunshine. Publisher- CRC Press. Latest edition.
2. Clinical pharmacokinetics. Soraya Dhillon, Andrzej Kostrzewski. Publisher- Pharmaceutical Press. Latest edition.
3. Clinical Pharmacokinetics. Rowland and Tozer. Publisher- Williams and Wilkins. Latest edition.
4. Principles of Clinical Pharmacology. Arthur J Atkinson. Publisher-TNQ books and Journals Pvt Ltd. Latest edition

**Other references:**

1. Therapeutic Drug monitoring, Clinical guide. Abbott Diagnostics. Published by Abbott.
   Journals – Clinical Pharmacokinetics, Therapeutic drug monitoring

**GUJARAT TECHNOLOGICAL UNIVERSITY**
PHARM.D (PB)
2nd year

**Subject Name: Clerkship**
**Subject Code:** 828904

In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

**GUJARAT TECHNOLOGICAL UNIVERSITY**
PHARM.D (PB)
2nd Year

**Subject Name: Project work**
**Subject Code:** 828905

**Scope:** To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work. (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

**Objectives:** The main objectives of the project work is to— (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and (ii) develop the students in data collection, analysis and reporting and interpretation skills.

Methodology.— To complete the project work following methodology shall be adopted, namely:— (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher; (ii) project topic shall be approved by the Head of the Department or Head of the Institution; (iii)project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics; (iv) project work shall be approved by the institutional ethics committee; (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14. (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.
(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
(iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
(iv) Evaluation shall be done on the following items: **Marks**
   a) Write up of the seminar (7.5)
   b) Presentation of work (7.5)
   c) Communication skills (7.5)
   d) Question and answer skills (7.5)

**Total** (30 marks)

(v) Final evaluation of project work shall be done on the following items:

**Marks**

a) Write up of the seminar (17.5)

b) Presentation of work (17.5)

c) Communication skills (17.5)

d) Question and answer skills (17.5) **Total** (70 marks)

*Explanation*.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.