SAURASHTRA UNIVERSITY

Re-Accredited Grade B by NAAC

(CGPA 2.93)

UGC Innovative Programme

POST GRADUATE DIPLOMA IN CLINICAL RESEARCH (PGDCR)

One year full time course
(Two semesters)

Revised Syllabus effective from July-2012

Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005

Post graduate diploma in clinical Research (Semester-I and II) Examination
General Rules

O.1 PGDCR:

A candidate for post graduate diploma in clinical research must possess the basic degree in science of this university or any other university recognized by the university (graduates from multidiscipline like MBBS / B.D.S / B.A.M.S / B.H.M.S /B. Pharmacy / BVSC/ B.Sc.(Life sciences) / B.Pharm / B. Physiotherapy etc) & have passed the post graduate diploma in clinical research after keeping terms as laid down, that is two semesters and have completed the courses as laid down in the relevant regulation.

There will be an entrance test and the admission will be based on the merit list prepared by combining 50 % of the entrance test and 50 % of the final year % of the relevant graduate degree.

Enlistment as post graduate diploma student is essential, within one month of the admission to the course. In the registration, candidate must specify the subjects & the paper of study for post graduate diploma in clinical research

O.2 PGDCR:

Post graduate diploma in clinical research semester I and II examinations will be held at the end of each semester and remedial examination will be held during the middle in each semester.

O.3 PGDCR:

Candidates for post graduate diploma in clinical research (semester-I and II) examination shall be examined after they have satisfactorily completed the prescribed courses of study & have kept the term in an institution recognized for the purpose under the recognized post graduate diploma teachers in prescribed subjects.

O.4 PGDCR:

Regular records/test of theories, conducted at the recognized institution, imparting training for this course, shall be maintained for each student & 20% of the total marks for each subject in theory shall be allotted for these records/tests and min. 75 % of attendance is mandatory.

O.5 PGDCR:

The syllabus laid down for various paper of post graduate diploma in clinical research (semester-I and II) examination is attached separately at the end of the rules.

O.6 PGDCR:

No class shall be awarded to the successful candidate at the post graduate diploma in clinical research (semester-I) examination.

O.7 PGDCR:

It is essential to attend seminar/conferences/training/visit of premier hospitals/industry visit in the area of dialysis or other relevant areas.

At the end of First semester, the student has to undertake clinical training at hospitals/clinic for minimum one month period, The summary of the work done in the clinics/hospitals must be submitted at the end of this clinical training.

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R.1 PGDCR:

Semester & Credit system for Various Subjects of PG Diploma in Clinical Research Course

PGDCR Semester – I

Sr. No.	Type of Subject	Subject	Teaching Scheme		
			Theory Hours/week	Practical Hours/week	**Credits**
1	Core – I	Subject specialization – I (**Basics of Clinical Research**)	7	-	**7**
2	Core – II	Subject specialization – I (**Pharmacokinetics and BA/BE studies**)	8	-	**8**
3	Core – III	Subject specialization – III (**clinical trials: Design and regulations**)	6	-	**6**
4	Core – IV	Subject specialization – IV **(Pharmacovigilance and Pharmacoepidemiology)**	6	-	**6**
				Total Credits	**27**

R.2 PGDCR:

PGDCR Semester – II

Sr. No.	Type of Subject	Subject	Teaching Scheme		
			Theory Hours/week	Practical Hours/week	**Credits**
1	Core V	Dissertation	42	-	**21**
				Total Credits	**21**

Total Credits: 48

R.3 PGDCR:

Saurashtra University - Rajkot

PGDCR Evaluation System

- The evaluation system will consist of a component of internal evaluation by the Department as well as final semester end examination conducted by the Saurashtra University. The former will carry a 20% weight and later 80% weight towards the total marks obtained by the student in a given subject.
- After adding the internal marks (maximum 20) with the marks secured by the student in the university examination (maximum 80), the marks will be converted to letter grade as per the following:

    1. 85 - 100 marks - AA grade
    2. 75 – 84 marks - AB grade
    3. 65 - 74 marks - BB grade
    4. 55 - 64 marks - BC grade
    5. 45 - 54 marks - CC grade
    6. 40-44 marks - DD grade
    7. Less than 40 - FF grade

- Student failing in examinations may take Remedial University Examination to be held during mid semester exam slots.
- At any point of time student can have maximum 2 backlogs/FF grade pending.
- The performance of a student during semester is indicated in grade card by “Semester Performance Index” or SPI, Which is calculated as follows:

  Each letter grade (AA to FF) will have a corresponding grade point assigned as follow:
  AA = 10
  AB = 9
  BB = 8
  BC = 7

CC = 6

DD = 5

FF = 0

If C(i) is the credit of course I and the grade point secured by the student is G(i) in that course, the SPI is given by the formula

$$\text{SPI} = \sum_{i=1}^{n} C_i G_i / \sum_{i=1}^{n} C_i$$

Where the sum is overall the 'n' courses taken during a semester. In the same way, the cumulative performance of the student is indicated by "Cumulative Performance Index (CPI)" which is calculated essentially by the same formula but the sum being over all the courses taken in the current semester as well as in the preceding semesters. However, in calculating the CPI, any fail grade which the student might have earned but has subsequently passed will be replaced by the passing grade in that subject. The SPI of the corresponding semester will, however, continue to reflect such failures and will not be recalculated.

R.4 PGDCR:

Class and Distinction etc. will be awarded for the degree on the basis of cumulative performance index

- Minimum passing for any component is 40%
- It is mandatory for every student to appear in internal examination conducted by department/P. G. center otherwise he/she is not eligible to appear in university examination.

- Grace marks under various ordinances will not be calculated for S.P.I. and C.P.I.

Post Graduate Diploma in Clinical Research

(PGDCR)

Two semesters
full time course

S. B. Gardi Institute of Pharmacy
Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005

SAURASHTRA UNIVERSITY

Post graduate diploma in clinical Research

(PGDCR) SYLLABUS

Core Subject-I

Basics of Clinical Research Theory

PGDCR-101

(Seven hours per week, 7 credits)

Unit I

Introduction to Drug Discovery and drug Development

Basic pharmacology and clinical research: Basic conceptual knowledge about receptors, drugs, preclinical studies, pharmacodynamic, pharmacokinetic (ADME), drug interactions, clinical research,

Introduction to pharmacoeconomics.

Unit II

Clinical trials

New drug discovery process- purpose, main steps involved in new drug discovery process, timelines of each steps, advantages and purposes of each steps, ethics in clinical research, unethical trials like, Tuskegee trials, Nazi's experiments, Nurembergh trials etc, thalidomide tragedy, Phase-I, II, III, IV trials.

-Introduction and designing

-Various phases of clinical trials

-Post Marketing surveillance – methods

-Principles of sampling

-Inclusion and exclusion criteria

-Methods of allocation and randomization

-Informed consent process in brief

-Monitoring treatment outcome

-Termination of trial

-Safety monitoring in clinical trials

Unit III

Pre clinical toxicology: General principles, Systemic toxicology (Single dose and repeat dose toxicity studies), Carcinogenicity, Mutagenicity, Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity, animal toxicity requirements. (Bhavisha)

Unit IV

Basic terminology used in clinical research: Types of clinical trials, single blinding, double blinding, open access, randomized trials and their examples, interventional study, ethics committee and its members, cross over design, etc…and Institution Ethics Committee / Independent Ethics Committee Data Management in clinical Research

Bioethics: Ethics in clinical trials, history and basic principles of ethics

TEXT BOOKS and REFERENCES:

(1) Basic and Clinical Pharmacology, Prentice hall, International, Katzung, B.G.
(2) Clinical Pharmacology, Scientific book agency, Laurence, DR and Bennet PN.
(3) Clinical pharmacokinetics, Pub. Springer Verlab, Dr. D.R Krishna, V. Klotz
(4) Remington Pharmaceutical Sciences, Lippincott, Williams and Wilkins
(5) Drug interaction, Kven Stockley. Hamsten
(6) Drug interaction, Basic Bussiness Publ, Bombay, J.K. Mehra
(7) Clinical pharmacology and drug therapy Grahame smith and Aronson,
(8) Text Book of Therapeutics Drug and Disease Management Hardbound. Richard A Helms,
(9) Clinical Pharmacy and therapeutics Herfindal E T and Hirschman JL, Williams and Wilkins,

SAURASHTRA UNIVERSITY

Post graduate diploma in clinical Research

(PGDCR) SYLLABUS

Semester – I

Core Subject-II

Pharmacokinetics and BA/BE studies Theory

PGDCR-102

(Eight hours per week, 8 credits)

Unit I:

Clinical Pharmacokinetics: Introduction to clinical pharmacokinetics, Steady-state pharmacokinetic. Linear and non-linear pharmacokinetics.

Absorption: Definition, Mechanism of absorption, Factors influencing the absorption.

Distribution: Definition, Binding of drugs, Physiological barriers, Drug disposition, Factors affecting the distribution.

Metabolism: Definition, Phase-I and Phase-II metabolism with examples.

Excretion: Definition, Clearance, Renal clearance, Hepatic clearance, Factors affecting the excretion of drugs. (Sneha)

Unit II:

Drug Interactions: Definition, Epidemiology, Mechanism of drug interactions, Drug-food interactions.

Adverse Drug Reaction: Epidemiology, Definition and Classification, Predisposing factors, Types of ADRs and their mechanism, Detection and Monitoring of ADR, Identification of ADR.

Therapeutic Drug Monitoring–: Introduction, When and why TDM is required? Necessity of the TDM, Indications for TDM, Protocol for TDM, TDM of selected drugs used in the following disease conditions: cardiovascular disease, CNS conditions etc.

Unit-III

Bioavailability studies

Introduction, Defination, objectives, factors affecting bioavailability, types: absolute vs relative, single vs multiple dose studies, healthy voluntiers vs patient studies, measurement of bioavailability, drug dissolution rate and Bioavailability, invitro-invivo correlation, methods for enhancement of bioavailability

Unit-IV

Bioequivalence

Introduction, Defination, Bases for Determining Bioequivalence

Design and Evaluation of Bioequivalence Studies

Analytical Methods, Reference Standard, Extended-Release Formulations, Combination Drug Products,

Study Designs

Fasting Study, Food Intervention Study, Multiple-Dose (Steady-State) Study

Crossover Designs, Replicated Crossover Design, Evaluation of the Data, Pharmacokinetic Evaluation of the Data, Statistical Evaluation of the Data, Analysis of Variance (ANOVA), Two One-Sided Tests Procedure, Example Bioequivalence, Study Submission and Drug Review Process, Waivers of *In-Vivo* Bioequivalence Studies (Biowaivers) Dissolution Profile Comparison, The Biopharmaceutics Classification System (BCS), Solubility, Permeability, Dissolution, Drug Products for Which Bioavailability or Bioequivalence May Be Self-Evident, Generic Biologics, Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution, Approved Drug Products with Therapeutic Equivalence Evaluations (*Orange Book*),

Text Books and References:

(1) Applied Therapeutics, The clinical uses of Drugs applied therapeutics INC
(2) Text book of Biopharmaceutics, Dr. Brahmankar
(3) Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
(4) 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.
(5) Principles of Pharmacology –The Pathophysiologic Basic –Golan David E.
(6) Pharmacological Basis of Therapeutics-Goodman and Gilman
(7) Pharmacology-Rang and Dale
(8) Essentials of Pharmacotherapeutics-F.S. Barar
(9) Principles of Pharmacology – Paul L. Munson
(10) Pharmacology and Pharmacotherapeutics-R.S.Satoskar
(11) Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
(12) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

(13) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

(14) Clinical Pharmacy and Therapeutics: Roger walker and Clive Edwards,Churchill Livingstone Edinburgh

SAURASHTRA UNIVERSITY

Post graduate diploma in clinical Research

(PGDCR) SYLLABUS

Semester – I

Core Subject-III

Clinical trials: Design and regulations Theory

PGDCR-103

(Six hours per week, 6 credits)

Unit I

Types of clinical trials

Unit II

Design and organization of phase-I, phase-II, phase-III, phase-IV trials

Unit III

Various regulatory requirements in clinical trials, Schedule Y, ICMR guidelines etc.

Documents in clinical study

Investigator Brochure (IB), Protocol & Amendment in Protocol , Case Report Form (CRF), Informed Consent Form (ICF) , Content of Clinical Trial Report Essential Documents in Clinical Trial

Good Clinical Practice: ICH guidelines

Indian GCP guidelines (CDCSO guidelines)

ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y

Roles & Responsibility of various clinical trial personnel like Sponsor, Investigator, Monitor, Auditors as per ICH GCP and ICMR guidelines

Unit IV

Study of various clinical trials (completed or ongoing)

Clinical Trial Application in India

Import & Export of Drug in India

Investigational New Drug application (IND)

Abbreviated New Drug Application (ANDA)

New Drug Application (NDA)

Reference books:

(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) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

(6) Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh

(7) Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.

(8) Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.

(9) Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.

(10) Comprehensive Pharmacy Review- Shargel Leon

(11) Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers

(12) A textbook of Clinical pharmacy practice- Parthasarthi G.

(13) Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004

(14) Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002

(15) Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002

(16) Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006

(17) Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002

(18) Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication **7.** Bert Spilker. Guide to Clinical Trials. **8.** Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009

(19) Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006

(20) Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

(21) Various Guidelines like: ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996. ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects. Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices– Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.
Schedule Y

SAURASHTRA UNIVERSITY

Post graduate diploma in clinical Research

(PGDCR) SYLLABUS

Semester – I

Core Subject-IV

Pharmacovigilance and Pharmacoepidemiology Theory

PGDCR-104

(Six hours per week, 6 credits)

Unit-I

Pharmacovigilance

Scope, definition and aims of pharmacovigilance Adverse drug reactions – Classification, mechanism, predisposing factors and causality assessment. Role of clinical pharmacist in Reporting, evaluation, monitoring, prevention and management of ADR

Adverse drug reaction reporting and monitoring

Drug induced diseases

Unit-II

Pharmacoepidemiology

Definations: epidemiology,

Disease distribution, disease determination, disease frequency, ,

Aims of epidemiology,

Difference between epidemiology and clinical medicines,

Epidemiological approach,

Measurements in epidemiology, (rates, ratios, and proportions)

Measurement of mortality: international death certificate, limitations and use of mortality data, mortality rates and ratios, crude death rates, specific death rates, case fatality ratio, proportional mortality ratio, survival rate, standardize rates, direct standardization, indirect standardization,

Measurement of morbidity: Incidence, Prevalence, uses of prevalence, relationship between incidence and prevalence,

Epidemiological methods:

(1) Descriptive epidemiology:

Time distributions:

(1) Short term fluctuations: Types of Epidemics- single exposure/point source exposure epidemics, continuous exposure epidemics, propagated epidemics, slow epidemics

(2) Periodic fluctuations

(3) Long term fluctuations

Place Distributions:

-International variance, National variance, Rural-Urban variations, Local distributions.

Person distributions:

(2) Analytical epidemiology:

Case control study:

Selection of cases, selection of controls, matching, measurements of exposure, analysis, odds ratio, bias in case control study., advantages, disadvantages and some examples of case control study

Cohort study :

Concept, framework, prospective and retrospective cohort study, combination of prospective and retrospective cohort study, elements of cohort study, relative risk, attributable risk, advantages, disadvantages and examples of cohort study.

(3) Experimental epidemiology:

Randomized controlled trials: Protocol, selecting reference and populations, randomization, manipulation, follo-ups, assessment, study designs in randomized trials like parallel and cross over study, Types of randomized controlled trials: clinical trial, preventive trials, risk factor trials, cessational trials, trial of aeitiological agents,

Reference books:

(1) 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.

(2) Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

(3) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

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SAURASHTRA UNIVERSITY

Post graduate diploma in clinical Research (PGDCR) SYLLABUS

Semester – II

Core Subject-V

Dissertation

PGDCR-201

(21 credits)

Introduction to Dissertation work,
Practical training/dissertation work.