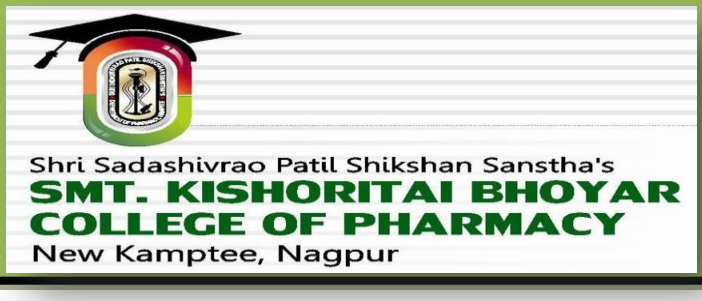
COURSE ON HUMAN VALUES & PROFESSIONAL ETHICS



The Institution offers a Course on Human Values and Professional Ethics

Smt. Kishoritai Bhoyar College of Pharmacy has a special handbook which mentions the professional ethics and the core values to be imbibed by the students and staff. This handbook is made available to all its students and teachers. Apart from this the syllabus which is adopted and followed at the college also includes many subjects spread in the four years of B. Pharm and the 2 years of M. Pharm. These subjects stresses upon the human values and professional ethics. It encompasses the aspects like the Environmental sciences, Pharmaceutical Jurisprudence and Ethics, Regulatory Affairs, Hazards And Safety Management, Audits And Regulatory Compliance, Clinical Research Regulations etc.

The Syllabus of the same is as given below:

Sr. No.	Name of Subject	Course
1	Pharmaceutical Jurisprudence And Ethics	B. Pharm.
2	Regulatory Affairs And Intellectual Property Right	B. Pharm.
3	Environmental Sciences	B. Pharm.
4	Social And Preventive Pharmacy	B. Pharm.
5	Pharmaceutical Regulatory Science	B. Pharm.
6	Regulatory Affairs	M. Pharm.
7	Hazards And Safety Management	M. Pharm.
8	Audits And Regulatory Compliance	M. Pharm.
9	Clinical Research And Pharmacovigilance	M. Pharm.

1. Subject code: 3T6

Pharmaceutical Jurisprudence and Ethics THEORY: 45 Hours (3 Hrs. /week)

1. Historical background of Drug legislation in India. 3 Hrs
Origin and nature of pharmaceutical legislation in India, Its scope and objective, new drug policy and future trends.
2. Code of Ethics for Pharmacists. 2 Hrs
Principles and significance of professional ethics, critical study of code of pharmaceutical ethics drafted by PCI regarding to pharmacist in relation to his job, to his trade, and to medical profession.
3. Pharmacy Act 1948. 6 Hrs
Definition, PCI and State Councils, Composition and Function, Preparation of Registers and qualifications for entry into registers, Educational Regulation and Approval of Courses and Institutions, Offences and Penalties
4. Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976. 4 Hrs
Definitions, restricted and unrestricted preparations, Manufacturing in bond and outside bond
5. Drug Price Control Order 2 Hrs
6. Drugs and Magic Remedies (Objectionable Advertisements) Act 1954. 2 Hrs
Definitions, Prohibited Advertisement, Savings
7. Drugs and Cosmetics Act 1940, Rules 1945. 15 Hrs
Definitions, Advisor bodies DTAB and DCC Composition and function, Drug Control Laboratories and Government Analysts, Drug inspectors, Licensing Authorities, Controlling Authorities and Customs Collectors Provisions Governing Import, Manufacture and Sale of Drugs. Labeling and Packaging of Drugs. Provisions applicable to manufacture and Sale of Ayurvedic Drugs, Provisions Governing Import, Various offences and corresponding Penalties, Broad content of various Schedules of the Drugs and Cosmetic Act and Rules.
8. Narcotic Drugs and Psychotropic Substances Act, and Rules there under 6 Hrs

Definition, Prohibited and controlled operation, cultivation of poppy plants, sale of opium, import and export of narcotics as amended to date, Offences and corresponding penalties.

9. Consumer Protection Act 3 Hrs

10. Medical termination of pregnancy act 1970 and rules 1975 2 Hrs

2. Subject code: 5T6

Regulatory Affairs and Intellectual Property Right THEORY: 45 Hours (3 Hrs. /week)

1. Regulatory Affairs 3 Hrs

Introduction, Importance of regulatory affairs, Funtions of regulatory affairs, Regulation marketing and Violation and Enforcement.

2. Drug regulatory strategy 4 Hrs

Regulatory strategies for different phases of product development:- Regulatory strategy during the preclinical development phase, Regulatory strategy during the clinical development Phase (Phase I, Phase II, Phase III) and Regulatory strategy for the post approval phase.

3. Drug regulatory authorities and agencies: - 4 Hrs

United states food and drug administration (USFDA), Therpeutic goods administration (TGA), Medicines and healthcare regulatory agency (MHRA), International conference on harmonisation (ICH), World health organization (WHO), Ministry of health, labor and welfare (MHWL) in Japan, Central drugs standard control organization (CDSCO), Indian pharmacopoeia commission (IPC)

4. Investigational new drug application (INDA) 3 Hrs

Introduction, The content and format of an IND application, Maintaining an IND

5. New drug application (NDA) 3 Hrs

Introduction, FDA Guidelines, Assembling applications for submission, NDA contents.

6. Abbreviated new drug application (ANDA) 2 Hrs

Introduction, Requirements for filing ANDA,

7. Drug master file (DMF) 2 Hrs

Introduction, Types of DMF, DMF submission.

INTELLECTUAL PROPERTY RIGHTS

8. Introduction 4 Hrs

Understanding Intellectual property rights (IPR) and review of IPR regime: - Copyrights, Trademarks, Geographical indications, Appellations of origin, Industrial designs, and Intellectual property laws in India.

9. Patent legislation 6 Hrs

Patent Act 1970, Patentability criteria, Patentable subject matter, Patent amendment (1999, 2002, 2005).

10. Patent procedure, filing, search and licensing. 3 Hrs

11. Patent infringement issues and freedom to operate. 2 Hrs

International treaties and conventions on IPR; Trade related Intelletual property rights (TRIPS), Paris convention, World trade organization (WTO), General agreement on trade and tariff (GATT), Patent cooperation treaty (PCT). 3 Hrs

12. Other Features: Hatch-Waxman Act, Compulsory licensing, Laws related to Biosimilars. 6 Hrs

3. BP 206 T.

ENVIRONMENTAL SCIENCES (Theory) 30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content: Unit-I 10hours

The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources: Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II 10hours

Ecosystems

Concept of an ecosystem.

Structure and function of an ecosystem.

Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III 10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

4. BP 802T

SOCIAL AND PREVENTIVE PHARMACY Hours: 45

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:

After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related tohealth and pharmaceutical issues

Course content:

Unit I: 10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: 10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: 10 Hours

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National 159

5. BP804 ET:

PHARMACEUTICAL REGULATORY SCIENCE 45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

Objectives: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content: Unit I 10Hours

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II 10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA. Regulatory authorities and agencies. Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III 10Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV 08Hours

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V 07Hours

Regulatory Concepts

Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.

6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene

9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

M. PHARMA SYLLABUS:

6. MPH 104T

REGULATORY AFFAIRS THEORY 60 Hrs

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- ✓ To know the approval process of
- ✓ To know the chemistry, manufacturing controls and their regulatory
- ✓ importance
- ✓ To learn the documentation requirements for
- ✓ To learn the importance and

Objectives:

- Upon completion of the course, it is expected that the students will be able to
- understand
- The Concepts of innovator and generic drugs, drug development
- process
- The Regulatory guidance's and guidelines for filing and approval
- process
- Preparation of Dossiers and their submission to regulatory agencies in
- different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

1.a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.
b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs 12 Hrs

2 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. 12 Hrs

3 Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). 12Hrs

4 Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. 12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.
Berry and Robert P.Martin, Drugs & Pharmaceutical Sciences,Vol.185,Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

7. MQA 201T

HAZARDS AND SAFETY MANAGEMENT THEORY 60Hrs

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

1. Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources
Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. 12 Hrs

2. Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system. 12 Hrs

3 Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards. 12Hrs
Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

4 Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosionelectricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. 12 Hrs

5 Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services. 12 Hrs

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press 133

8. MPA 203T

AUDITS AND REGULATORY COMPLIANCE THEORY 60 Hrs

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

1. Introduction: Objectives, Management of audit, Responsibilities,Planning process, information gathering, administration,Classifications of deficiencies 12 Hrs

2. Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries. 12 Hrs

3. Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging. 12 Hrs

4. Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. 12 Hrs

5. Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. 12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

9. MPL 204T

CLINICAL RESEARCH AND PHARMACOVIGILANCE THEORY 60 Hrs

Scope: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives: Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial Demonstrate the types of clinical trial designs.
- Explain the responsibilities of key players involved in clinical trials Execute safety monitoring, reporting and close-out activities.
- Explain the principles of Pharmacovigilance Detect new adverse drug reactions and their assessment Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

1. Regulatory Perspectives of Clinical Trials: Conference Origin and Principles of International on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human ParticipantSchedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process. 12 Hrs

2. 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 12 Hrs

3. Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial MonitoringSafety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR. 12 Hrs

4. Basic aspects,terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance. 12 Hrs

5. Methods, ADR reporting and tools used inPharmacovigilance 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. 12 Hrs

6. Pharmacoepidemiology, pharmacoeconomics, safety pharmacology. 12 Hrs

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. 229

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. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.

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