M.PHARMACY

PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS

I SEMESTER

Paper 101 - Modern Analytical Techniques
Paper 102 - Research Methodologies
Paper 103 - Pharmaceutical Organization and Production Management
Paper 104 - Indian Drugs Regulatory Aspects
Paper 105 - Pharmaceutical Organization and Production Management - LAB
Paper 106 - Indian Drugs Regulatory Aspects - LAB
Paper 107 - Seminar

II SEMESTER

Paper 201 - International Drug Regulatory Aspects
Paper 202 - Pharmaceutical Management Science - I
Paper 203 - Pharmaceutical Management Science - II
Paper 204 - Drug Regulatory Affairs
Paper 205 - International Drug Regulatory Aspects - LAB
Paper 206 - Pharmaceutical Management Science - LAB
Paper 207 - Seminar

III SEMESTER

Paper 301 - Project Seminar-I (On the proposed project work with aims and objectives) - 50 Marks
Paper 302 - Project work - I

IV SEMESTER

Paper 401 - Project Seminar-II (On the experimentation and results of the project work) – 50 Marks
Paper 402 - Project work - II

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS

FIRST SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 103	Pharmaceutical Organization and Production Management	40	60			100	3
Paper – 104	Indian Drugs Regulatory Aspects	40	60			100	3
Paper – 105	Pharmaceutical Organization and Production Management			40	60	100	2
Paper – 106	Indian Drugs Regulatory Aspects			40	60	100	2
Paper – 107	Seminar					100	2
	TOTAL					700	18

SECOND SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	International Drug Regulatory Aspects	40	60			100	3
Paper –202	Pharmaceutical Management Science - I	40	60			100	3
Paper – 203	Pharmaceutical Management Science - II	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	International Drug Regulatory Aspects			40	60	100	2
Paper – 206	Pharmaceutical Management Science			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

THIRD AND FOURTH SEMESTERS

Paper No.	III Semester	Total	Credits ***
Paper - 301	Project Seminar – I (On the proposed project work with aims and objectives)	50	2
Paper - 302	Project work - I	----	20
	Total	50	22

Paper No.	IV Semester	Total	Credits ***
Paper - 401	Project Seminar – II (On the Completed project work)	50	2
Paper - 402	Project work - II	---	20
	TOTAL MARKS	50	22
	GRAND TOTAL FOR THE COURSE	1500	80

M.PHARM SYLLABUS FOR INDUSTRIAL PHARMACY
I Semester

PAPER 101 - MODERN ANALYTICAL TECHNIQUES
(Paper Common for all Specializations)

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

Unit- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

Unit- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

Unit- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

Unit- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

Unit- V

i. Plasma Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapor phase chromatography
v. Affinity chromatography
vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy by Silversterin

PAPER 102 -RESEARCH METHODOLOGIES
(Paper common for all Specializations)

UNIT I

Statistical Methods:
Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution
Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression, Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV

Design of Experiments
Criteria of a good design with examples.
Principles- Randomization, replication and local control.
Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving
Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

Text & Referrence Books:

1. Fundamentals of Biostatistics by Khan & Khanum, 3rd Revised Edition, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd)

PAPER 103 - PHARMACEUTICAL ORGANIZATION AND PRODUCTION MANAGEMENT

Unit - I

Meaning and Evolution of Management; Planning, Organizing, Staffing, Directing, Co- Ordinating, Reporting & Budgeting (POSDCORB), functions of management with reference to pharmaceutical management. Introduction to budgeting, budgetary control, types of budgets, entrepreneurship development, types of entrepreneurs & characteristics of entrepreneurs. **Understanding Organization:** Types of organization structures; line, line & staff & matrix organizational structure. Resistance to change; Authority & Responsibility; Organizational conflicts, Organizational Communication system. Theory –X, Theory –Y and theory-Z. Motivational Aspects, Maslow's hierarchy of needs, Hedge Berg two factor theory, group dynamics.

Unit - II

Personnel management: Recruitment & selection, training & development, compensation, transfer, promotion, demotion policies, job evaluation, performance appraisal, industrial relations, grievance handling, stress management. Handling strikes, gheraos, arbitration and negotiations, enforcement of discipline, lay off and discharge.

Unit – III

Role of personnel manager: Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management. Rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. -Stress management.

Unit - IV

Operational Management: Nature and scope of production management: Types of manufacturing systems – batch production and selection: Process planning: Aggregate planning and Master production scheduling: Project management – project planning, scheduling Programme Evaluation Review Technique (PERT) and Critical Path Method (CPM) use.

Unit – V

Materials Management: An introduction to materials management. Material requirement Purchase management, Inventory control, Material handling: Vendor selection Make or buy decision Negotiation: Cost – reduction techniques – Standardization codification and variety reduction: waste management: Value analysis.

Introduction to accounting, book keeping, Systems of accounting, journal, ledger, trial balance and final accounts. Study of computer based systems for accounting with examples.

References:

1. The theory and practice of Industrial Pharmacy Leon Lachman, Ph.D., Lachamn Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates Inc. Consultant Services, Livingstom, New Jersey, Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc Ridgefield Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400017.1987.
2. Pharmaceutical Dosage Forms and Drug Delivery Systems Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G. Popovich , Ph.d., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia, London. 1990.
3. Selected Topics in Industrial Pharmacy, Dr. N. Udupa, 1992, II Edition Varghese Publishing House, Bombay.
4. Admn. E.E. and Ebert RJ: Production and Operations Management, 6th Edition, New Delhi, Prentice Hall of India 1995.
5. Chunawalla and Patel: Production and Operations Management, Himalaya Publishing House.
6. Gopalakrishnan.P and Sudarshan M Hand Book Materials Management New Delhi Prentice Hall of India. 1994.
7. Dutta A.K. Integrated Materials Management New Delhi PhI1986.
8. Buffa E.S. and Sareen: Modern Production Management, New York, John Wiley 2002.
9. Koonz, Weihrich and Aryasri: “Principles of Management”, Tata Mc Graw Hill.
10. Daft : “The Era of Management “,Cengage Learning, New Delhi.
11. K.Aswathappa: “Organizational Behavior – Text, Cases and games”, Himalaya Publishing House, New Delhi,2008,
12. Aswathappa K: “Production and Operation Management”, Himalaya Publishing House, Mumbai.
13. R.Panneerselvam:”Productions and operations Management”,PHI Learning private limited,New Delhi,2009.

Reference Books :

1. Modern Pharmaceutics, Second Edition, Revised & Expand (Volume40) Edited by Gilbert S. Banker, University of Minnesota, Minneapoils, Minnesota; Chistopher T. Rhodes, University of Rhode Island, Kingston, 1990 Marcel Dekker Inc., 270 Madison Avenue, New York 10016.
2. GMP for Pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
3. I.P.., B.P., U.S.P. International Pharmacopoeia.

PAPER 104 - INDIAN DRUGS REGULATORY ASPECTS

UNIT- I

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts / Laws (with latest amendments)

- Package commodities act
- Competition council of India
- Right to information act
- National Pharmaceutical Pricing Authority (NPPA) – Power to fix the maximum sale prices of bulk drugs specified in the First Schedule, calculation of retail price of formulation, power to revise price of bulk drugs and formulations, display of prices of non-scheduled formulations and price list thereof. Study of different forms to be used for submission of these approvals.

UNIT- II

Introduction to IPRs : Intellectual property (IP) versus conventional property. Introduction to 8 different IP mechanisms – patents, industrial designs, and layout designs, plant varieties, geographical indications, copyright, trademark, trade secrets; their characteristics, properties. usefulness of patents for researchers. Factors affecting choice of IP protection; penalties for violation / infringement. IPRs vs. Regulatory affairs- similarities and differences.

Patenting in India : Development of IP law in India. Patent legislation and introduction to current IP laws in India. Amendments in Indian Patent laws and their significance; Requirement for patenting- novelty, inventive step (non obviousness) and industrial application (utility). Patent specification & claims, patent infringement. Procedure for filing patent in India- provisional, complete, divisional, additional and conventional patent applications; forms and fee. Prior art search and sources of patent information – free and paid databases. Patent analysis and land-scaping. Patent Search Maps. Infringement analysis. Concepts of Patent writing in India. Patent cooperation treaty (PCT) route of filing for International patents.

UNIT- III

Schedule M, M1, M2 & U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production of Active Pharmaceutical Ingredients (APIs), other raw materials (including packaging materials) used in drugs & cosmetics.

Schedule M, M1, M2 &U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production aspects of various drugs & cosmetic formulations (solid, parenteral and semi solid preparations).

Pilot plant scale- up techniques: Pharmaceutical pilot plant, pilot plant design, case studies for above preparations. Basic requirements for design of product, facility, equipment selection and personnel.

Schedule M, M1, M2 &U general requirements and special provisions DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to quality control & quality assurance aspects of various drugs & cosmetic formulations (solid, parentaral and semi solid preparations).

UNIT- IV

General requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to marketing of various drugs & cosmetic formulations (solid, parentaral and semi solid preparation). Introduction to uniform code of marketing practices for the Indian pharmaceutical industry (UCPMP).

Indian Good Clinical Practices guidelines: National regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Schedule Y of Indian Drugs and Cosmetics Act 1940, Role of Regulatory affairs in Developing clinical trial protocols, Clinical phase, Preclinical Phase, Manufacturing phase and Marketing Phase.

UNIT- V

Hierarchy and working flow of DCGA in India. Regulations and documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

WHO certification, Trademarks and copyrights. National Accreditation Board for testing and Calibration Laboratory (NABL) certification and accreditation procedure. The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000.

References:

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
2. Pharmaceutical Jurisprudence, G.K. Jani.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh.
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
7. Pharmaceutical Patent Law – John R. Thomas.
8. Original laws published by Govt. of India.
9. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
10. Laws of Drugs in India by Hussain.
11. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.

PAPER 105 - PHARMACEUTICAL ORGANIZATION AND PRODUCTION MANAGEMENT - LAB

1. Organization/ Business case presentations.
2. Survey of market research to collect information regarding management of a given disease and/or disorder.
3. Group discussions and case studies based on theory.
4. Layouts for production of API and Pharmaceutical formulations (Tablets, capsules, ophthalmic, parenteral and other formulations)
5. Preparation of trial balance, preparation of final accounts, inventory measurement methods

PAPER 106 - INDIAN DRUGS REGULATORY ASPECTS - LAB

1. Testing of glass, rubber, plastic & metal packaging materials and preparing document for submission for approval.
2. Stability testing of an API, a pharmaceutical excipient, pharmaceutical dosage forms (solid, parenteral & semi solid) as per regulatory requirements and preparing required documents for submission
3. Quality control testing of finished product (solid, parenteral & semi solid dosage forms) as per Indian Pharmacopoeial requirements and preparing required documents for submission.
4. Patent writing for a given modification in the composition of a dosage form (minimum of 2 protocols).
5. Preparation of documents for submitting a patent file through Patent cooperation treaty (PCT) route.
6. Preparation of Dossiers to be submitted to the CDSCO/DCGA for a solid/parenteral/ semi solid dosage forms.

2nd SEMESTER

PAPER 201 - INTERNATIONAL DRUG REGULATORY ASPECTS

UNIT- I

Generic drug product development: Introduction, Hatch-Waxman update, Drug product performance- in vitro, Abbreviated New Drug Application (ANDA) Regulatory Approval Process, paragraph IV drug product application. Bioequivalence and drug product assessment- in vivo, scale- up, post approval changes, post marketing surveillance, outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Formats for marketing authorization submission to WHO, USFDA, EU. Data privacy Protection, Pharmaceutical Labeling, Advertising and Promotion, Risk Management in regulatory affairs.

Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, novel therapies, special categories [Over - the - counter (OTC) products, herbal medicines and Homeopathics]. Obtaining New Drug Application (NDA), ways and means of US Registration for foreign drugs, Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), medical devices, Environmental concerns and regulations. 21 Code of Federal Regulations (CFR) Part 11 and LIMS (Laboratory Information Management System).

UNIT- II

FDA Approval indications and other considerations: Data procession for Global submission, Text and Tabular exposition- Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) format, working with contract research organization (CRO), industry and FDA liaison, role of European Commission Competent Authorities and Notified Bodies and USFDA authorities.

Nonclinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigational medicinal product Dossier (IMPD) & Investigator Brochure (IB), new product applications for global pharmaceutical product approvals, US NDA vs. Global CTD Formats, ANDA & Supplemental Abbreviated New Drug Application (SNDA), CTD and eCTD for registration of pharmaceuticals for Human use, combination products & controlled release systems.

Centralized procedure for marketing authorization: legal basis – scope. Procedure for submission of application – preauthorization, inspections (GMP inspection) – pre authorization inspection (GCP inspection) – Scientific evaluation of the application – CPMP (Committee for Proprietary Medicinal Products) opinion and follow up action.

UNIT- III

Harmonization of regulatory requirements- The International Conference on Harmonization (ICH) process, guidelines to establish quality, safety and efficacy (carcinogenicity studies - need for carcinogenicity studies of pharmaceuticals and testing for carcinogenicity of pharmaceuticals, Genotoxicity- a standard battery for Genotoxicity testing of pharmaceuticals) of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards. Health Insurance Portability and Accountability Act of 1996 (HIPAA)- A new requirement to clinical study process, Code of Federal Regulations (CFR)/ International Conference on Harmonization (ICH) / EU GCP obligations of Investigators, sponsors & monitors.

UNIT- IV

Stability Testing of New Drug Substances and Products Stability Testing: Photo-stability testing of new drug substances and products, stability testing for new dosage forms, bracketing and matrixing designs for stability testing of new drug substances and products. Evaluation of stability data, impurities in new drug substances, impurities in new drug products, guidelines for residual solvents.

UNIT- V

Quality evaluation and batch release: change control, deviation-(planned and unplanned), corrective action and preventive action (CAPA), Handling of non-conformance, vendor evaluation process, out of specification (OOS), batch reconciliation and finished goods release, market recalls & market complaints.

Joint International Pharmaceutical Excipients Council (IPEC) – Pharmaceutical Quality Group (PQG) Good Manufacturing Practices guidelines for pharmaceutical excipients.

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144
3. 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.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
8. HIPAA and Human Subjects Research: A Question and Answer Reference Guide by Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. Drugs: From Discovery to Approval, Second Edition by Rick Ng
11. New Drug Development: A Regulatory Overview, Eighth Edition by Mark Mathieu
12. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
13. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
14. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh

PAPER 202 - PHARMACEUTICAL MANAGEMENT SCIENCE - I

UNIT- I

History, growth of Indian Pharmaceutical Industry. Global scenario of Indian pharmaceutical Industry and pharmaceutical market past and present.

UNIT- II

Pharmaceutical marketing : Introduction of pharmaceutical marketing, evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented modern concept); market segmentation; concept of marketing mix, role of 7 P's (product, price, promotion, place, physical evidence, process, people) in pharmaceutical marketing management, corporate planning & strategy, pharmaceutical industrial marketing management. pharmaceutical marketing en vironment. E-Pharma marketing.

UNIT- III

Supply Chain Management : Scientific purchasing, quality control, problems of productivity, stores organization, location of stores, receiving, inspection of materials, issue from the store, control of stores and stocks, store accounting and records. ABC analysis, VED (Vital, Essential, Desirable), Fast moving, Dormant moving & Obsolete (FDO), Economic Order Quantity (EOQ).

UNIT- IV

Product design planning : Selection of product, new product development and product differentiation, pricing, promotion.

Marketing research: definition and importance, Pharmaceutical marketing research techniques, marketing information systems, pharmaceutical market research area.

UNIT- V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Legal Environment of Business: Need for government regulations; financial regulations, Equity market & SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws -Direct and Indirect.

References:

1. Phillip Kotler: "Marketing Management", 11/e, Pearson Publishers, New Delhi, 2003
2. K Aswathappa: "Human Resource and Personnel Management", Tata McGraw Hill, New Delhi, 2007.
3. Aswathappa K: "Production and Operation Management", Himalaya Publishing House, Mumbai.
4. I.M Pandey: "Financial Management", 9/e, Vikas Publishing, 2004
5. Rajan Saxena: "Marketing Management, 2/edition, Tata McGraw Hill, New Delhi, 2008.
6. Shashi K Gupta & Sharma, Financial Management, Kalyani Publishers
7. Buffa, Production and Operations management
8. Business Environment, Francis Cherunilam, Himalaya Publications

PAPER 203 - PHARMACEUTICAL MANAGEMENT SCIENCE - II

UNIT- I

Formulation and Production Management: Locating production and service facilities - layout planning and analysis. Material handling for various pharmaceutical products, service facilities and preventive maintenance in pharmaceutical companies-group and individual replacement.

UNIT- II

Introduction to automation requirements: supervisory control and data acquisition (SCADA) and programmable logic controller (PLC) based process controls.

UNIT- III

Market demands and sales forecasting: major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.Social and legal and ethical issue of pharma marketing, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) code of pharmaceutical marketing practices, pharma guidelines for Direct-to-consumer advertising (DTC advertising) and Organization of Pharmaceutical Producers of India (OPPI) guidelines for Pharmaceutical marketing in India

UNIT- IV

Strategic marketing : SWOT Analysis, GAP Analysis, Porter's five-force model, Ansoffs Matrix. Role of customer in marketing, importance of consumer behavior, customer relationship management (CRM). Nature of international marketing, evaluating international marketing, develop international marketing objectives, Formulate product marketing strategies, market entry and overseas distribution system, pricing.

UNIT- V

Functions of finance management; performance evaluation through ratio analysis & funds flow statement; project preparation, other ethical aspects of Pharmaceutical promotion and advertisement. Effect of Competition Council of India (CCI) on Pharma industry.

REFERENCE BOOKS :

1. Phillip Kotler: "Marketing Management", 11/e, Pearson Publishers, New Delhi, 2003
2. K Aswathappa: "Human Resource and Personnel Management", Tata McGraw Hill, New Delhi, 2007.
3. Aswathappa K: "Production and Operation Management", Himalaya Publishing House, Mumbai.
4. I.M Pandey: "Financial Management", 9/e, Vikas Publishing, 2004
5. Rajan Saxena: "Marketing Management, 2/edition, Tata McGraw Hill, New Delhi, 2008.
6. Shashi K Gupta & Sharma, Financial Management, Kalyani Publishers
7. Buffa, Production and Operations management
8. Business Environment, Francis Cherunilam, Himalaya Publications

PAPER 204 - DRUG REGULATORY AFFAIRS
(Paper Common for all Specializations)

Unit - I

Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities

Unit - II

Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.

Unit - III

Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.

Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

Unit - IV

Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability , study design, presentation documentation and statistical analysis

Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

Unit - V

Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations

References:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.
7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987

Paper 205 - INTERNATIONAL DRUG REGULATORY ASPECTS - LAB

1. The general stages of drug development from R & D to marketing.
2. List the various types of manufacturer – FDA interactions that can occur during the drug development process.
3. Requirements for registration of ANDA as per ICH CTD/eCTD format.
4. Preparation of documents required for paragraph IV drug product application.
5. The general process by which new molecular entities (NMEs) are identified through pharmaceutical approaches.
6. Types of IND applications and structures of each type.
7. Requirements to complete an IND application and IND review process.
8. Requirements for a new drug application (NDA) & NDA submission process.
9. FDA's review of submitted NDA application/FDA's requirements for changes to an approved NDA
10. Clinical trial protocol preparation / clinical data requirements for approval of controlled release NDA
11. Post NDA approval responsibilities of a sponsor.
12. General study of ICH guidelines with special reference to ICH Q7, Q8, Q9 and Q10
13. Compliance requirements for bioavailability & bioequivalence studies.
14. Patent challenge/ non infringement case studies.
15. Qualification of disintegration test apparatus/friability test apparatus/dissolution test apparatus
16. Qualification of UV-Vis spectrophotometer.
17. Comparison of D & C Act with that of other regulations such as USFDA, UKMCA, EDQM, South Africa MCC, Brazilian ANVISA, Australian TGA

Paper 206 - PHARMACEUTICAL MANAGEMENT SCIENCE - LAB