PUNJAB TECHNICAL UNIVERSITY, JALANDHAR

M. Pharm. Pharmaceutical Management & Regulatory Affairs

First Semester

Course Code	Course Title	Load Allocation			Marks Distribution			Credits
		L	T	P	Internal	External	Total	
PMRA 511	Pharmaceutical Management-I	4	2	-	20	80	100	5
PMRA 513	Drug Regulatory Affairs- I	4	2	-	20	80	100	5
PMRA 515	Pharmaceutical Management-II	4	2	-	20	80	100	5
PMRA 517	Pharm. Management & Regulatory Affairs Lab.-I	-	-	10	20	80	100	5
	Total	12	06	10	80	320	400	20

Second Semester

Course Code	Course Title	Load Allocation			Maximum Marks			Credits
		L	T	P	Internal	External	Total	
PMRA 512	Pharmaceutical Management-III	4	2	-	20	80	100	5
PMRA 514	Drug Regulatory Affairs- II	4	2	-	20	80	100	5
PMRA 516	Intellectual Property Rights	4	2	-	20	80	100	5
PMRA 518	Pharm. Management & Regulatory Affairs Lab.-II	-	-	10	20	80	100	5
Total		12	06	10	80	320	400	400

THIRD AND FOURTH SEMESTER

Research Work for one year

The thesis shall be presented by the candidate at the end of record academic year. The thesis shall be evaluated as under :

Evaluation of written thesis : MM 200

Presentation of seminar on thesis and viva-voce : MM 100

Total : 300 marks

PMRA 511 Pharmaceutical Management –I

1. **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 4 P's and 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, industrial marketing management, marketing environment, Product management. Concepts of segmentation, targeting and positioning.
2. **Marketing Research:** Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.
3. Introduction to financial management, financial planning and control, working capital management, management of fixed assets. Target Value of Money (TVM), Capital structure, sources of finance. Working capital, Securities, Break Even analysis, trading account and balance sheet.
4. Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework. Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social. Risk analysis.
5. **HR and Corporate Governance:** Recruitment, Training, skill matrix, Appraisals & incentives, promotion, retrenchment, Human values. Alliance/collaborations, licensing, strategies in Pharmaceutical Marketing. Labor welfare and trade unions.
6. **Production Management:** Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.
7. Production planning and Inventory control: production processes - mass, job and project; plant location and lay-out; work study (preliminary idea only), materials management-purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

8. Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, topical and injections.

Suggested Readings / Books

- Marketing Management; by Philip Kotlar.
- Personnel Management and Industrial Relations by P. C. Tripathi.
- Motivation and Personality by Maslow, Abraham, Harper & Row.
- Management "Global Perspective Heinz Weihrich, Harold Koontz.
- Principles and Practice of Management; by: Gupta, Sharma & Bhalla.
- Financial Management by Johnson, R.W.
- Fundamental of Financial Management; by Van Horne, J.C.
- Project Management by Chaudhary, S.

PMRA 513 Drug Regulatory Affairs –I

1. **Pharmaceutical legislations in India:**
   - **a.** Origin, development, scope, objectives and nature of Pharmaceutical legislation in India. History and ethics of profession of Pharmacy.
   - **b.** 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)

     - The Drugs and Cosmetics Act, 1940 and Rules there under.
     - The Narcotics Drugs and Psychotropic Substances Act.
     - Medicinal and Toilet Preparations (Excise Duties) Act, 1955.
     - Drugs (Price Control) Order in force.
     - Copy Right Act, Trade Mark Act, and Biodiversity Act,
     - The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.
     - Prevention of Cruelty to Animals Act.
     - Factory's Act.
     - The Environmental Protection Act
     - Consumer Protection Act
     - Law of Torts
     - Law of Contracts
     - Monopolistic & Restrictive Trade Practices Act

2. **Globalization of Drug Industries:** Export Import Policy of drugs, WHO –certification, Trademarks and copyrights.

3. **Schedule M & U Requirements-** Product development stage documentation, factory procedures – Standard operating procedures (SOPs) and standard test Procedures (STPs).

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

5. **Pharmaceutical Regulatory Process in India:** Hierarchy and working flow of FDA in India, Roles of DCGA and CDSCO in drug control, Drug Control Authority and its documentation in the state.

6. **Good manufacturing practices**:
GMP-WHO and US FDA guidelines, concepts of quality control and quality assurance, manufacturing facilities for tablets, capsule, liquid orals, semisolids and parenterals as per schedule M, cGMP. Pharmaceutical plant location, layout, utility services including HVAC. Certification for pharmaceutical industries, technology transfer guidelines, salient features of ISO 9000 series, total quality management (TQM).

7. **Stability testing:**
Introduction, rate equations, physicochemical and biological factors affecting stability of drugs, degradation pathways, objectives and design of stability testing, accelerated stability studies, real-time stability studies, photostability testing, stability testing of dosage forms, prediction of shelf life, overages, ICH guidelines.

8. **Industrial hazards, safety, pollution control and effluent treatment:**
Introduction, factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, electrical hazards, chemicals hazards and management of over exposure to chemicals, gas hazards and handling of gases, dust explosion and its control, fire prevention and control.

Recommended books: (Latest edition of the books should be referred)

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
2. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical
3. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and
4. Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
5. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good
6. Drug Development Series) – Helene I. Dumitriu.
7. http://cdsco.nic.in
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.

PMRA 515 Pharmaceutical Management –II

1. Introduction: Selling as a Part of Marketing, Sales Management Process, Role of Sales Manager, Concept of Personal Selling, Sales Management and Salesmanship, Process of Personal Selling, Qualities of a Successful Salesman.
2. Goals in Sales Management: Goal Setting Process in Sales Management, Analyzing Market Demand and Sales Potential, Techniques of Sales Forecasting, Preparation of Sales Budget, Formulating Selling Strategies, Designing Sales Territories and Sales Quota.
3. Sales Force Management: Organizing the Sales Force, Designing the Structure and Size of Sales Force, Recruitment and Selection of Sales Force, Leading and Motivating the Sales Force, Training and Compensating the Sales Force, Evaluating sales force performance.
4. Advertisement Management- Advertising - its Purpose and Function
   Advertising Planning & decision making: Planning framework, communication & persuasion process, Social, legal & regulatory factors in Advertising
   Group influence & Word of mouth advertising: Reference group influence on brand choice, factors influencing the degree of group influence
5. Role of media, Selection of Media for Advertising, formulation of message, art of copywriting. Branding & packaging strategies: Brand equity, Image & personality, Packaging decisions, Perceptual mapping of customers, Control aspects of Advertising Advertising Budget
6. Planning for International Marketing: Foreign Market Entry Strategies – Exporting, Licensing, Joint Ventures, Strategic Alliances, Acquisitions, Franchising, Assembly Operations, Management Contracts, Turnkey Operations, Free Trade Zones
   Product Policy and Planning- Product Design and Standardization, Developing an International Product Line, Foreign Product Diversification, International Branding Decisions, International Packaging
7. Advertising & Promotion - International Promotion Strategies- Promotion Mix (Advertising, Sale Promotion, Personal Selling, Public Relation & Publicity), Promotion and Communication, International Advertising – Patterns of Global Advertising, Global Advertising Regulations, Advertising Media, Advertising Budget
8. Export-Import policy in India
   Salient features ; International commercial terms (Incoterms) ; Import-Export documentation - Bill of Exchange, Marine Insurance policy, Invoices and other documents ; Transport documents - Bill of lading, Airway Bill, Letter of Credit – meaning, types of letter of credit ; Financing exports - preshipment credit, post-shipment

Suggested Readings:

1. Advertising Management by Rajeev Batra, John G. Myers and David A. Aeker PHI publications
2. Sales Management, Decision Strategies & cases by Richard R.Still, Edward W. Cundiff, Norman P. Govoni
3. Advertising Practice & theory by C.H. Sangade, Vernon Frybenger, KiM Rotzoll: AITBS publisher & distrinutors.
4. Advertising Practice & Priciples by William Wells,John Burnett, Sandra Moriatry, PHI
5. Contemporary Advertising by William F.Arens, Mc Graw Hill,Irwin

6. Advertising Management by Dr. MananderMohan, Tata Mc Graw Hill

PMRA 517 Pharmaceutical Management and Regulatory Affairs Lab –I

Practical pertaining to the topics covered under theory subjects including case studies, Industrial Visit.

PMRA 514 Drug Regulatory Affairs- II

1. **Introduction to US FDA**: A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on:
   - Organization and functions of FDA, including historical developments.
   - General definitions.
   - Adulterated & misbranded drugs/cosmetics/biotechnological products.
   - OTC drugs, Orphan drugs, Orange Book and Fast Track Products.
   - General penalties as applicable to drugs, cosmetics and biotechnologicalproducts

2. **US FDA-I:** A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on:
   - General drug approval process.
   - Investigational New Drug application.
   - New Drug Application and BLA.
   - ANDA.
   - SNDA, SUPAC and BACPAC.
   - Post marketing surveillance.

3. **US FDA- II**: A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on :
   - Labelling and advertising requirements for drugs, cosmetics and biotechnological products.
   - Introduction to environmental protection laws, as applicable to drugs, cosmetics and biotechnological products, including EPA and OSHA.
   - Common Technical Document and Drug Master Files.
   - Factory Inspection.

4. **International Conference On Harmonisation** Of Technical Requirements For Registration of Pharmaceuticals For Human Use: History, structure and process for hormonisation.

5. **ICH guidelines on quality**: Stability Testing of New Drug Substances and Products Stability Testing : Photostability 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, Impurities: Guideline for Residual Solvents,

6. **ICH guidelines on efficacy**: ICH guidelines on clinical trial and Good Clinical Practice

7. **ICH Guidelines on safety**: Carcinogenicity Studies - Need for Carcinogenicity Studies of Pharmaceuticals and Testing for Carcinogenicity of Pharmaceuticals

Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals.

8. **Production planning & control and documentation** Production scheduling, forecasting, vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls.

Practicals / Assignments / Case studies: To illustrate the topics included under theory.

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh
2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
3. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug
4. Encyclopedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
5. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
6. Export Marketing by Cherian and Parab; Himalaya Publishing House, Delhi

PMRA 518 Pharmaceutical Management & Regulatory Affairs Lab.-II

Practical pertaining to the topics covered under theory subjects.