M.PHARM.

PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS

MPY201PMRA	**Pharmaceutical Management-I (General, Personnel & Finance)**	**Theory**

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling- a preliminary idea of concepts, processes and techniques.
Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, auditing and budgetary control. Entrepreneurship development.

Understanding Organizations: Meaning, process, types of organization structures and departments, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and analytical testing labs etc.

Professional Managers: 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.

Personnel Management: Job analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.
Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.
Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management, Situational management.

Financial management : Introduction, financial planning and control, working capital management, management of fixed assets.
Accounting and Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information system. Evaluation of Investment decisions by Pay back period, accounting rate of return, net present value methods, break even analysis.

MPY202 PMRA	Pharmaceutical Management-II (Production, Project & Marketing)	Theory

Production management: Fundamentals of production, organization, economic policy, manufacturing economic, 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. Pharmaceutical quality management system.
Production planning and control, production processes- mass job and project; plant location and lay out; work study, materials management-purchase, inventory control and store keeping. Different techniques of inventory management. Productivity management: concepts problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Consideration 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, capsule, injections and special dosage forms.
Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage form. Warehouse design, construction, maintenance and sanitation; Cost effective design, good warehousing practice.

Project management: Project design and management, 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.
Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling, salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Pharmaceutical Marketing: Evolution of marketing concepts; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7P's (Product, Price, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment. Product management. E-Pharma Marketing, Kaisen and six sigma technique.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research Technique, marketing information system, pharmaceutical marketing research area. Database for searching pharmaceutical market of drug products and drug substances
Market Demand and Sales Forecasting: Major concept in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

Books and References Recommended:

1. Marketing management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T. McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management and Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi.
8. Principles and Methods of Pharmacy Management III rd edition Harry A. Smith
9. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill.
10. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
11. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
12. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
13. Business Organization and Management by Shukla M. C.; S. Chand and Company
14. Personal Management by Filippo E. B. Mac Graw Hill.
15. Marketing Management by Kotler Philip.; Prentice Hall of India.
16. Personal Management Tripathi P. C.; S. Chand and Company.
17. Principle and Practice of Marketing in India by Memoria C. B.
18. Principles of Pharmaceutical Marketing by Mickey Smith, C.B.S Publications.
19. Marketing Hand Book Vol. II, Marketing Management by Edwin- E Bobrow, Mark- D. Bobrow.
20. Financial Management by Johnson, R. W.; The Ronald Press.
21. Project Management by Choudhary, S.; Tata Mac Graw Hill.

MPY203 PMRA	Drug Regulatory Affairs-I (Indian Legislation)	Theory

The Drugs and Cosmetics act: Drug & Cosmetic Act : 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Drugs *(*Prices Control*)* Order 1995, Factory Act, Labor Act, The drug and Magic remedies (Objectionable advertisements) act and rules, 1954.

Product Registration : Requirements for registration of pharmaceutical products into India. Preparation of dossier for product registration as per Indian legislative requirements**.**

Documentation: Master formula record (MFR), Master formula card (MFC), Batch processing record (BPR), Packaging records, Standard operating procedure (SOP), Site master file, specifications, Certificate of analysis (COA), Material safety data sheet (MSDS), Method of Analysis (MOA), Annual product review, validation protocols, Stability protocol, T- License, forms, maintenance of records in Pharmaceutical industry.

Regulatory requirements: and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials (schedule Y).

Intellectual property rights: Patent, copyrights, design and trademark. Effect of GATT and WTO on commerce of pharmaceuticals. Importance of patent, Application, processing of patent, Indian Patent Act 1970 and its latest amendments, United state patent, world patent processing. Patent term extension.

Books and References Recommended:

1. Vijay Malik, Law relating to Drugs & Cosmetics.
2. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
3. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
4. www.patentoffice.nic.in
5. www.ep.espace.net
6. www.uspto.gov

MPY204 PMRA	Drug Regulatory Affairs-II (International Legislation)	Theory

Regulatory Agencies : Requirements of cGMP with specific reference of USFDA (21 CFR part 210 and 211), European Medicines Agency (EMEA) guidelines.
Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA brazil guidelines.

Product Registration : Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Preparation of dossier of Drug product and Drug master file.Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act. Regulatory requirements good laboratory practice in US (USFDA 21 CFR part 58)

ICH Guidelines : with specific reference to stability, analytical validation, impurities, pharmacopeias, specification, quality risk management and pharmaceutical development. Preparation of Common technical document (CTD) as per ICH guidelines, electronic documentation and e-filing (e-CTD).

Industrial Guidelines : Guidance for Industry: IR/ MR Solid Oral Dosage Forms Scale - Up and Postapproval Changes (SUPAC)-Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation
Guidance for Industry: Sterile/Non Sterile Semisolid Dosage Forms Scale - Up and Postapproval Changes (SUPAC)-Chemistry, Manufacturing and Controls, In Vitro Release Testing, and In Vivo Bioequivalence Documentation

Guidance for Industry : Dissolution testing of immediate release solid oral dosage forms.
Guidance for Industry : Extended release oral dosage forms: Development, evaluation and application of In Vitro/In Vivo Correlations.
Guidance for Industry : Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System

Books and References Recommended:

1. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals
2. www.fda.gov
3. www.emea.europa.eu
4. www.picscheme.org

Practicals related to Pharmaceutical Management-I (General, Personnel & Finance)

1. Case studies, analysis and report preparation based on the theory.
2. Preparation of ledger and balance sheet.

Practicals related to Pharmaceutical Management-II (Production, Project & Marketing)

1. Case studies, market survey, forecasting, reporting
2. Layout designing of manufacturing facilities for various sterile and non-sterile products.
3. Product planning and market research
4. Preparation of product promotional literature and catalogs.

Practicals Related to Drug Regulatory Affairs-I (Indian Legislation)

1. Preparation of SOP's for operation of manufacturing and analytical equipments.
2. Preparation of MFR, BPR and packaging record for manufacturing of various dosage forms.
3. Validation of mfg. process, equipment, analytical method, disinfectant, and cleaning process.
4. Process validation for various dosage forms.

Practicals Related to Drug Regulatory Affairs-II (International Legislation)

1. Comparison of dissolution profiles and calculation of F1 and F2 values of tablets of innovator/standard and generic manufaturers.
2. Comparison of In-vitro release and calculation of F1 and F2 values of semisolid preparations of innovator/standard and generic manufaturers.
3. IVIVC –through various techniques
4. Preparation dossier of a pharmaceutical product.
5. Experiments to find out the BCS class of pharmaceuticals