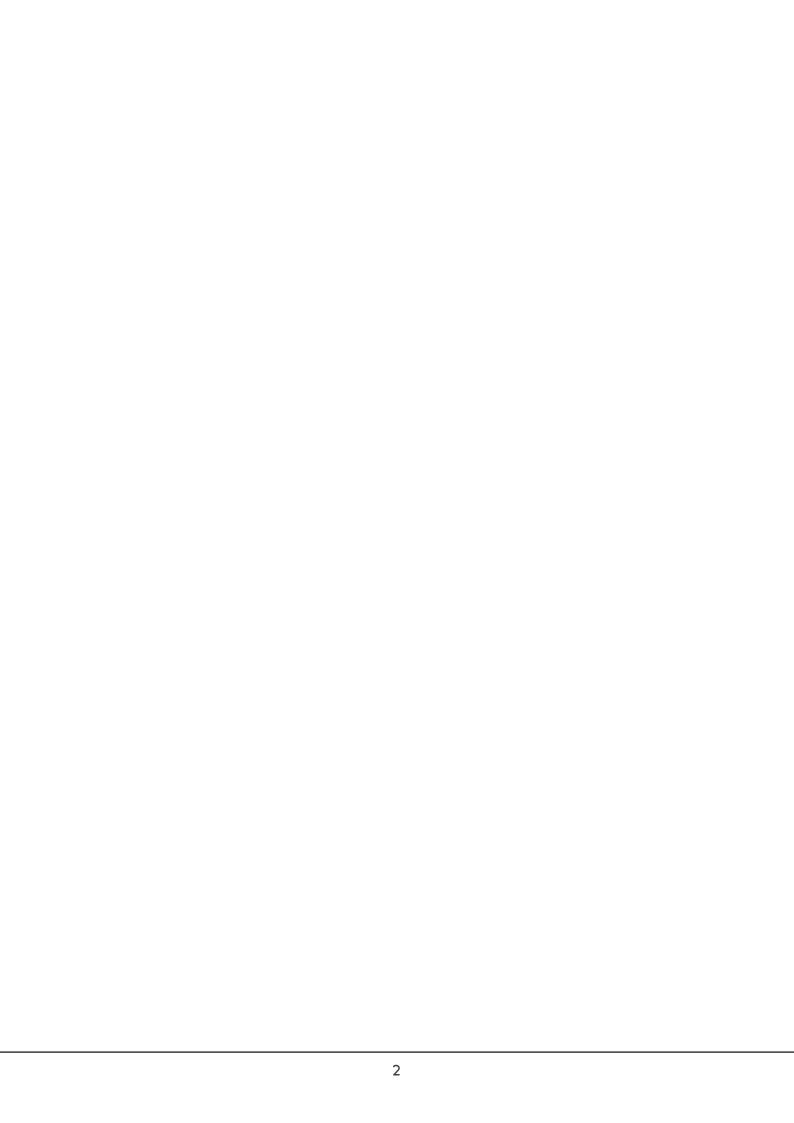
SYLLABUS

MBA-PHARMACY ADMINISTRATION

2022



JSS Academy of Higher Education & Research
Deemed to be University
Re-Accredited "A+" Grade by NAAC
Sri Shivarathreeshwara Nagara, Mysuru - 570015, Karnataka



SI. No	Subjects	Semester I	SI. No	Subjects	Semester II
1	Management Principles and Practice	4	1	Human Resource Management	4
2	Marketing Management, Services marketing	4	2	Strategic Management	4
3	Accounting for Managers	4	3	Total Quality Management	4
4	Managerial & Health Economics	4	4	Financial Management	4
5	Organizational Behaviour	4	5	Business Statistics & Research Methodology	4
6	Managerial Communication	3	6	Management Information System	3
7	Soft skill/Personality development	2*	7 8	Hospital postings Summer internship	2 2*
	Total:	25		Total	27
SI. No	Subjects	Semester III	SI. No	Subjects	Semester IV
1	Operation Management	4	1	Business Law & ethics	4
2	Operation Research	4	2	Project Management	4
3	Entrepreneurship (Workshop)	2*	3	Pricing strategies DPCO	4
4	Pharmacoepidemiology	4	4	Marketing analytics of drug substances	4
5	Retail Pharmacy	4	5	Project Work	8
			6	Electives (one out of three) -	
6	Drug Sales & EXIM	3	6a) 6b) 6c)	Health Informatics or Str. OTC Products or IPR	2
7	Electives-				
7a) 7b)	Basic Health Sciences or Medical Devices	2			
7c)	Pharm. Practice or Int. Pharmacy	2	-		
7d) 8	Management Visit to Pharma Industry	1*			
	visit to i namia maasily	'			
	Total	26		Total	26

MANAGEMENT PRINCIPLES & PRACTICE

MODULE: 1

Development of Management concept: History & growth of management science, Tradition/ Modern management, Evolution of Management theory, Management as a profession, process of management.

Management function & tools: Management levels & skills, Functions & Principles of management, Challenges to manager, System approach.

MODULE: 2

Fundamentals of Planning & Decision –making:

Planning: Nature, Types, Steps, Process, Objectives, MBO, Strategies, Policies, Planning & Forecasting, Hospital Planning.

Decision Making: Nature & process of managerial decision making, Tools & techniques of decision making, Programmed and non-programmed decisions –Modern approaches to decision making under uncertainty-Decision trees.

MODULE: 3

Organizing & Staffing:

Organizing: Nature of organizing and entrepreneuring - formal and informal organizations-Structure and departmentation - line, line and staff, functional, divisional and matrix; span of control-decentralization delegation of authority - the art of delegation-Power and responsibility, Hospital as an organization & role of hospital administrators.

Staffing: Overview of all staffing functions; systems approach to human resource management.

MODULE: 4

Leading: Leader centered Approaches; Trait, Behavior, Power focus; Follower centered approaches –self – leadership, Leadership substitutes focus; Interactive approaches-situational, empowerment, and transformational leadership; Women as leaders; Leaders of the future; Likert's four systems of management- the managerial grid-Robert Blake and Jane Mouton Model - Committees – Nature of committees-Reasons for using committees-Types-Merits and Demerits.

MODULE: 5

Coordinating & controlling:

Coordinating: Need for coordination principles, Techniques of coordination.

Controlling: Process of control for diverse organizations; Setting standard for performance; Measuring actual performance; Responding to deviations; Designing quality and effectiveness into control systems; criteria for effective control; Selecting the focal point of control; Managerial control philosophies-bureaucratic control, organic control; Selecting a control style in today's diverse and multinational organizations; Impact of information technology on organizational control.

Managerial ethics: Codes of Ethics, Ethics committees, Ethics & law, corporate culture & ethical climate.

MARKETING MANAGEMENT & SERVICES MARKETING

MODULE 1

Introduction- Marketing and Marketing Management, importance, value, and scope of marketing.

Core marketing concepts – Needs, Wants, and Demands, Target markets, Positioning, Segmentation, Marketing orientations, marketing mix and classification of goods and services.

Marketing management process (in brief)

CASE STUDY

MODULE 2

Analysing the Marketing Environment

The Microenvironment: The Company; Suppliers; Marketing Intermediaries; Competitors; Publics and Customers

Macroenvironment: The Demographic, Economic, Natural, Technological, Political, Social and Cultural environment that affect the company's ability to serve its customers.

CASE STUDY

MODULE-3

Consumer behaviour – characteristics affecting consumer behaviour, The buyer decision process (The five-stage model). **Market segmentation** - bases for segmenting consumer markets. **Brand** - meaning, importance, and building and managing the brands.

The new product development process

CASE STUDY

MODULE-4

Product Life Cycle (PLC) – concept, PLC marketing strategies.

Advertisement – setting advertising objectives, setting the advertising budget, evaluating advertising effectiveness and the return on advertising investment.

Public Relations – The Role and Impact of PR, Major Public Relation Tools

CASE STUDY

MODULE 5

Introduction to Services: meaning, importance, categories, characteristics, marketing challenges in service industry, 7P's of services marketing/ services marketing mix.

Service Quality - The Gaps model, reviewing strategies to close quality gaps, Customer defined service standards – Hard and Soft. CASE STUDY

ACCOUNTING FOR MANAGERS

MODULE 1

Introduction to Accounting- Definition – Accounting for historical function and managerial function – Scope of accounting – Financial accounting and Management accounting – Managerial uses, GAAP, Accounting Principles & Conventions, Accounting Equations, Users of Accounting and Indian accounting standards.

MODULE 2 (simple problems)

Double entry system of accounting: Accounting books – Preparation of journal and ledger, – Preparation of trial balance and - Preparation of Trading, Profit & Loss Account and Balance Sheet from records, financial reporting system in hospital, reports prepared in hospitals.

MODULE 3 (Simple problems)

Non trading accounting-Meaning of non-trading accounting and concern, difference between profit and non-profit, purpose of non-trading concern, capital and revenue items, receipts and payment accounting and income and expenditure statement preparation.

MODULE 4- Working Capital Management

Significance and types of Working Capital – Calculating Operating Cycle Period and Estimation of Working Capital Requirements problems – Financing of Working Capital and norms of Bank Finance – Sources of Working capital – Factoring services – Dimensions of Working Capital Management.

MODULE 5-

Depreciation – Causes – Methods of Calculating Depreciation – Straight Line Method, Diminishing Balance Method and Annuity Method - Ratio Analysis – Uses and Limitations – Classification of Ratios – Liquidity, Profitability, Financial and Turnover Ratios – Simple Problems only.

Text and Reference Books:

- 1. Jelsy Josheph Kuppapally, ACCOUNTING FOR MANAGERS, PHI, Delhi, 2010.
- 2. Paresh shah, BASIC ACCOUNTING FOR MANAGERS, Oxford, Delhi, 2007
- 3. Ambrish Gupta, FINANCIAL ACCOUNTING FOR MANAGEMENT, Pearson, Delhi, 2004
- 4. Fundamentals of FM: Brigham and Houston

Fundamentals of FM: James C Horne

MANAGERIAL AND HEALTH ECONOMICS

Module 1- Introduction to economics

Introduction to economics, definition, scope, basic assumptions, economic analysis-micro, macro, positive and normative, short run, long run, equilibrium-partial, general, basic questions of economics, economic model-circular flow of economics, PPS curve. Introduction to managerial economics, relatedness to managerial function.

Module 2- Introduction to health economics

Health economics- introduction, area of health economics, importance of health economics, scope, concept of health and health characteristics, need of health economics, uniqueness of health as goods and service, health, and economic development, causes of health problems in India, economics evaluation methods-cost benefit, cost minimization, cost utility analysis.

Module 3- Analysis of demand and supply

Introduction to demand, law of demand, demand in health care, elasticity in demand for health care, determinants of health care demand.

Supply in health, law of supply, determinants of supply, elasticity of supply, relation of demand and supply.

Module 4- Markets in health

Study of different markets, features of markets, price and output determinants of perfect competition, imperfect, monopoly, oligopoly, duopoly, cost in health economics,

Module 5-Healthcare financing, insurance

Health care financing-health insurance, types of insurance, IRDA, TPA in health insurance, alternative financing in health care.

References:

- 1. Charles L.Schyltze: National Income Analysis.
- 2. Misra and Puri Economic Environment of Business.
- 3. Health Economics- WHO Public Paper
- 4. Health Economics-NA Cooper & AJ Cuyler.

ORGANISATIONAL BEHAVIOUR

MODULE 1

Organizational Behaviour

Definition, Meaning, Importance, Nature, Scope, Elements of Organizational Behaviour, Approaches to OB, Multidisciplinary Nature of OB, and OB Models. Study of OB at individual level, Group level and Organizational level

MODULE 2

Individual level behaviour:

- Attitudes and values
- Personality Introduction, Features, Determinants of Personality, Theories of Personality: Type, Trait, Psychoanalytical, and Social Learning Theory.
- **Learning –** Meaning, learning theories Classical conditioning, Operant conditioning, Cognitive Theory and Social learning theory.
- Motivation Nature, Importance, Theories of Motivation Maslow's Hierarchy of Needs theory, Douglas McGregor Theory X and Theory Y, Ouchie's Theory Z, Herzberg's Two Factor Theory, Vrooms expectancy Theory

Case Study/ Journal discussion on individual personality and motivational needs

MODULE 3

Group level behaviour-1:

- Teams and Teamwork Introduction, Types of Teams, Team building, Working Teams, and team effectiveness.
- Group Meaning, Differences between Groups and Teams, Types of Groups, Stages of Group Development. Leadership – Meaning, Importance, Functions, Leadership styles, Theories of Leadership - The Managerial Grid, Trait theory. Transactional vs.
 Transformational Leaders, Likert's system 4 Management. Leadership in VUCA Business World

Journal discussion on effective leadership for successful organizations

MODULE 4

Group level behaviour-2:

- **Power and Politics** Introduction, Sources of Power, Organizational politics, Reasons and Managing Political Behaviour.
- **Conflict** Meaning, Types (Individual, Group and Organisation), Conflict resolution styles and Conflict management strategies.

Case study: Role of organizational power in conflict management

MODULE 5

The Organization System:

- Organizational culture: Meaning and definition of organizational culture, managing work force diversity
- Organizational Change & Stress Management: Definition of organizational change, Change Vs transformation, causes of organizational change, consequences of change, resistance to change. Potential sources of organizational stress, consequences of stress and stress management

Case Study: Employee stress management and its impact on organizational productivity

MANAGERIAL COMMUNICATION

Module 1:

Communication- definition, process, methods, importance, effective communication (7Cs), theories, models of communication, barriers to communication

Module 2:

Types of communication- verbal and nonverbal communication
Oral-presentation skills, power point presentation, speech making, debate, group discussion
Written-essay writing, reports, letters, memos, notices, circulars, e-mail communication, press release.

Module 3:

Nonverbal-body language, etiquette

Module 4:

Listening, persuasion, negotiation, Interview-types, interview skills

Module 5:

Meeting-Arranging, conducting, agenda, minutes, etc.

SEMESTER II 10

HUMAN RESOURCE MANAGEMENT

COURSE OBJECTIVES:

This course intends to teach students about human resource management and equip them with knowledge, skills, and competencies to effectively manage people in an organization.

SPECIFIC OBJECTIVES:

This course intends to teach students-

- 1. The importance of and effective management of human resource in an organization
- 2. Understand the role of human resource in strategic planning
- 3. Understand the legal implications in human resource management
- 4. Current trends in recruitment and selection of employees
- 5. Understand compensation, appraisal, rewards, and employee benefits
- 6. Training and development methods and need for HR audit

LEARNING OUTCOMES:

At the end of the course the students should be able to:

- 1. Understand the importance of human resource management
- 2. Use the different methods of recruitment in procuring human resource
- 3. Design relevant appraisal methods for employee compensation, rewards and benefits
- 4. Have basic knowledge about labour laws
- 5. Organize training and development activities to enhance the knowledge, skill and abilities of their workforce.
- 6. Apply modern trends in human resource management.

MODULE 1

Nature, Scope, objectives, Importance, Strategic HRM, Personnel Management, Functions of HRM, Principles of HRM, Differences between HRM and Personnel Management, Trends in Workforce, managing diversity, challenges in Managing a diverse workforce. HR in Healthcare organizations, Human relations in healthcare services

MODULE 2

Job Analysis- Uses, Process, Methods of collecting Job Analysis data. Job Description, Job Specification, Human Resource Planning- Features, Objectives, Importance, the process of HRP. Recruitment –Sources and methods of recruitment. New approaches to recruitment. Recruitment policies and procedures. Selection – Meaning, Process.

MODULE 3

Placement, Induction, Internal mobility, and separations— Placement, Induction/orientation, Transfer, Promotion, Demotion, Employee separations.

Training and Development - Training vs. Development, Types of Training, Training methods, Evaluation of Training methods.

MODULE 4

Performance and Potential Appraisal – The Performance Appraisal Process, Methods of Performance Appraisal and 360 Degree feedback system, Job evaluation – Meaning, Methods. Employee Grievances and Discipline, Collective bargaining-Types of Bargaining, The process of collective bargaining, Collective bargaining in India, Job stress, counseling and Mentoring. HR Audit in Healthcare services.

MODULE 5

Labour laws – The Industrial dispute act 1947, Industrial Employment (Standing orders) Act 1946, Employees Provident funds Act 1952, Payment of wages Act 1936, Minimum wages act 1948, ESI Act 1948, Workmen Compensation Act 1923, The Trade Union Act 1926.

Labour Economics and Compensation Systems in Health Care, Wage Fixation – Employee incentives and Benefits – ESOPs – Role of Monetary and Non-monetary Benefits, Talent Acquisition, Retention and Management for Healthcare, Employer Employee relations, Emerging trends in HRM in healthcare.

References:

- 1. Human Resource Management text and cases VSP Rao 3rd edition
- 2. Human Resource Management Aswathappa. K
- 3. HRM case studies- Aswathappa. K
- 4. Dessler, Human Resource Management
- 5. Human Resource Management-V.S. Subba Rao.
- 6. HRM concepts & cases- Chhabra TN
- 7. HR in hospital management- Thomas Erickson
- 8. HRM in hospitals- Laws, issues & solutions- D Samuel Abraham
- 9. Personnel and HRM- texts & cases- P Subba Rao.

STRATEGIC MANAGEMENT

COURSE OBJECTIVES

The objective of this course is to help the students understand and explore the concepts of strategies in the form of identification, prioritization, and exploration of opportunities, in the environment

SPECIFIC OBJECTIVES

Specific learning objectives for this course are as follows:

- 1. It helps in identifying the problems in the surrounding environment.
- 2. It helps in identifying the various factors within the organization in terms of strength and challenges.
- 3. It helps the organization to carry out the matter of greatest importance first, by seizing the opportunity that lie in the environment.
- 4. It helps in adequate decision making in the organization and in demonstrating the responsibility towards the society.

LEARNING OUTCOMES

After the completion of the course, students will demonstrate the ability to:

- 1. Preparation for challenges faced by the organization with the understanding of the environment and the internal factors that regulate the organization.
- 2. It helps to understand the various resources in the organization and helps them to improve the resource allocation towards the necessary activities.
- 3. Identify various critical components for better programming of the services in the organizations.
- 4. Articulate the functional requirements of the hospital and help in identifying and securing more funds for organizational growth.

MODULE 1

Introduction - Basic concepts of strategic management; concept of strategy; Business vision, Mission and Objectives. Environment Analysis: External and Internal environment components External Analysis: Macro Environment, Operating Environment, Industry Analysis. Competitive Analysis: Michael Porter's Analysis Internal Analysis: SWOT Analysis, Value Chain Analysis (VCA). The Core Competence: character of core competencies, Relationship between Core Competence & competitive Advantages.

MODULE 2

Strategy Formulation - Developing Alternative Strategies: Strategic Alternatives, Ansoff's Matrix/ Market grid. Strategic Analysis: Portfolio analysis – BCG Portfolio Matrix, GE Multifactor Portfolio Matrix. Corporate Level strategy: Establishing a competency agenda, Pursuing growth through concentration strategies by market penetration their risks and benefits. Growth through product or market development, Horizontal and Vertical Integration strategies. Key drivers for company to diversify. Understand differences in related diversification & unrelated diversification. Competing in foreign markets, various modes of entry benefits and drawbacks, Entry through new startups, Strategic alliances & acquisition. Global Strategies, key drivers for changes in the global strategies. Strategic alliances in health care industry. Healthcare industry and

competitive analysis. Business Level Strategies: Development of concepts for competitive positioning, Cost leadership/ Differentiation/Focus/Broad differentiation strategies & how firms strive to achieve with benefits and drawbacks of each generic strategy. If strategies were generic, then how and why does each firm within industry pursue varying strategies. Strategies in High Technology Industry. Value creation frontier -a desire for firm to be different and competitive. Global Strategy: Global expansion strategies.

MODULE 3

Strategy Implementation: Nature of Strategy Implementation, Linkages between Formulation and Implementation, Importance of strategy Implementation, Mc Kinsey 's 7-S Model, Major Issues in Strategy Implementation. Strategic leadership — Analysing leadership, Role of strategic leader, leader's tasks, leadership approaches and Competitive advantage.

MODULE 4

Strategy Evaluation and Control: Nature of evaluation & control, Characteristic of effective Evaluation, Importance of Strategic Evaluation & control, Strategic controls.

MODULE 5

- Corporate Social Responsibilities
- Social Audit
- Corporate Governance

References

- 1. Business Policy, 2nd Ed. Azhar Kazmi
- 2. Strategic Management, 12th Ed. Concepts and Cases Arthur A. Thompson Jr. and A.J.Strickland
- 3. Management Policy and Strategic Management (Concepts, Skills and Practices) R.M.Shrivastava
- 4. Business Policy and Strategic Management P.Subba Rao
- 5. Strategic Management Pearce
- 6. Strategy & Business Landscape Pankaj Ghemawat

TOTAL QUALITY MANAGEMENT

COURSE OBJECTIVES:

The objective of this course is to provide students with a better understanding of the underlying concepts, emphasizing on Quality, understanding needs, wants, demands and promotion of products and services, as managers and administrators.

SPECIFIC OBJECTIVES:

To learn the basic concepts of quality and quality from organizational point of view. To learn about the Quality Gurus and their Contribution to Total Quality Management To Learn about the Statistical Quality Control Tool, Six Sigma and their applications To Learn about the Concepts of Benchmarking and its Importance in Organisation To learn the internal politics, quality culture, education and training of the organization.

LEARNING OUTCOMES:

Upon successful completion of the module students will be able to:

- 1. Develop an understanding on quality management philosophies and frameworks
- 2. Develop in-depth knowledge on various tools and techniques of quality management
- 3. Learn the applications of quality tools and techniques in both manufacturing and service industry.

MODULE 1

Quality – Introduction, definition, importance, cost of quality, the evolution of Total Quality Management, Philosophy of TQM Customer focus, employee empowerment, Leadership – Concepts, Quality Gurus, and their contribution-1 (Walter A. Shewhart, W. Edwards Deming, Joseph M. Juran)

MODULE 2

Quality: Quality Gurus and their contributions -2 (Armand V. Feigenbaum, Philip B. Crosby, Kaoru Ishikawa and Genichi Taguchi). Customer Perception and Satisfaction, Customer Complaints, Service Quality, Customer Retention, Continuous Process Improvement Juran Trilogy, PDSA Cycle, 5S, Kaizen, Quality awards and standards - The Malcolm Baldrige National Quality Award (MBNQA), The Deming Prize, ISO 9000 Standards, ISO 14000 Standards

MODULE 3

TQM tools and their implementation – check sheets, scatter diagrams, cause-and-effect diagrams, pareto charts, flowcharts, histograms. Statistical Quality Control (SQC) - importance, categories of SQC – descriptive statistics, statistical process control, and acceptance sampling (only theory and in brief). Supplier Partnership – Partnering, sourcing, Supplier Selection, Supplier Rating, Six sigma – importance and applications to manager and organization.

MODULE 4

Benchmarking – introduction, process and types, House of Quality – concept and importance. Just-In-Time (JIT) - philosophy of JIT (Eliminate Waste, A Broad View of Operations, Simplicity, Continuous Improvement, Visibility and Flexibility), three elements of JIT (JIT manufacturing, TQM and Respect for people)

MODULE 5

Warehousing: Meaning and need for warehousing, Types of warehouses, Characteristics of

an ideal warehouse, Functions of warehousing, Advantages of warehousing Supply Chain Management - meaning, components, bullwhip effect, supply chain for service organisations and major issues affecting supply chain management. Quality and Competitiveness in Business, Zero Defects, Role of Leadership and Commitment in Quality Deployment Quality and Ethics Internal Politics and Total Quality Management, Quality Culture, Education and Training

Text Books:

- 1. Dale H. Besterfiled, et at., "Total quality Management", Pearson Education Asia, Third Edition, Indian Reprint 2006.
- 2. James R. Evans and William M. Lindsay, "The Management and Control of Quality", 8th Edition, First Indian Edition, Cengage Learning, 2012.
- 3. Oakland J.S, Total Quality Management, Butterworth-Heinemann Ltd, Oxford 1989

Reference Books

- Narayana V & Sreenivasan, N.S. Quality Management-Concepts and Tasks New age International 1996
- 2. Zeiri, Total Quality Management for Engineers, Wood Head Publishers
- 3. TQM in Health Care-Huch CH Koch.

FINANCIAL MANAGEMENT

COURSE OBJECTIVE

This course helps the students with an understanding of the tools, techniques, and frameworks commonly used as part of market and industry assessments and engagements involving the substantial operational and organisational analysis. It also highlights the principles of financial analytical tools used to conduct strategic analysis and indicates the link between corporate strategy and performance through measurement frameworks used frequently to provide decision making information to management when required.

SPECIFIC OBJECTIVES

- 1. The management tools and techniques used to design and manage successful organizations
- 2. core financial accounting and control principles
- 3. the work of management accounting, incorporating budget preparation and budget appraisal
- 4. ethical principles and principles of priorities

LEARNING OUTCOMES

- 1. Acquire knowledge about general aspects of business operations.
- 2. Describe the role of accounting information system and its limitations.
- 3. Explain the concepts and procedures of financial reporting, including income statement, statement of retained earnings, balance sheet, and statement of cash flows.
- 4. Identify the basic economic events most common in business operations and be able to report the events in a generally accepted manner, including the impacts of alternative accounting methods on financial statements.
- 5. Tabulate the income tax slabs and understand the dynamic income tax discipline guidelines.
- 6. Locate and analyze financial data from annual reports of corporation
- 7. Communicate financial findings and results in an unbiased manner to a non-technical audience such as decision makers, stakeholders, and the public.

MODULE 1

Introduction to financial management- objectives of financial management, function of financial management, financial planning concept, roles of financial management in organization. Capital Budgeting – Nature of Investment Decisions – Investment Evaluation criteria – Net Present Value (NPV), Internal Rate of Return (IRR), Profitability Index (PI), Payback Period, Accounting Rate of Return (ARR) – NPV and IRR comparison, sources of funds-short term and long-term financing-shares, debentures and bonds, venture capital and other modes of financing.

MODULE 2

Cost accounting - Introduction to cost accounting, objectives, importance of costing, difference between cost and financial accounting, types of cost, types of costing system, preparation of cost sheet and allocation and Apportionment problems, Marginal Costing versus Absorption, concept of standard costing and activity based costing and its application.

MODULE 3

Marginal costing - Marginal cost and Marginal costing - Importance - Break-even Analysis - Cost Volume Profit Relationship – Application of Marginal Costing Techniques, Fixing Selling Price, Make or Buy, Managerial Applications of Marginal Costing.

MODULE 4

Budget - Concept of Budget, Budgeting and Budgetary Control, Types of Budgets and their preparation and Advantages and Limitations of Budgetary Control. Preparation of Flexible budgets— simple Problems — Theoretical concept of Zero-Base Budgeting.

MODULE 5

Taxation System - Income tax act, direct and indirect taxes in India, important concepts of income tax structure in India, introduction to goods and service tax, computation of income from various head (problems).

References:

- 1. Cost and Financial Accounting: Khan and Jain
- 2. Cost and Financial Accounting: I.M. Pandey
- 3. Cost Accounting-Ravi Kishore, Taxman Publications
- 4. Management Accounting-IM Pandey

BUSINESS STATISTICS AND RESEARCH METHODOLOGY

COURSE OBJECTIVES:

The objective of this course is to provide an understanding of statistical concepts and research methodologies that is helpful in healthcare research

SPECIFIC OBJECTIVES:

- Explain basic statistical concepts such as statistical collection, species characteristics, statistical series, tabular and graphical representation of data, measures of central tendency, dispersion and asymmetry, correlation and regression analysis, probabilities
- Apply knowledge to solve simple tasks in healthcare systems
- Independently calculate basic statistical parameters (mean, measures of dispersion, correlation coefficient)
- Based on the acquired knowledge to interpret the meaning of the calculated statistical indicators
- Choose a statistical method for solving practical problems
- Apply conceptual framework of research methodologies in practical setup.

LEARNING OUTCOMES:

Upon completion of this course the student will be able to carry out research in healthcare field using statistical methodologies.

MODULE 1

Introduction to concept of statistics, its uses in business and health care, types of statistics, significance of statistics and scope in hospital administration, vital statistics-nature, scope, concept, problems in collecting vital statistics, sources and need of vital statistics in hospital administration.

MODULE 2

Introduction to data, types, importance of data, errors in collecting data, methods of collecting various data, presentation of data, tabular presentation, graphical presentation.

MODULE 3

Measure of central tendency, Measure of dispersion, Probability and Probability Distribution Uses and application in managerial decision making. Simple problems.

MODULE 4

Correlation - Types of correlation problems on correlation. Multiple correlations. Simple problems.

Regression Analysis – Karl Pearson's Coefficient, Rank Correlation, Spearman's Correlation. Regression Equation, Regression Coefficient. Uses and application in managerial decision making. Simple problems.

MODULE 5

Research Methodology

Meaning, objectives, Motivation, Types of Research, and Steps involved in a Research Design, special emphasis on questionnaire and designing questionnaire for health care research, Types of Errors affecting Research Design, Analytical Research, Research approaches, Significance of Research, Research methods versus Methodology, Research Process and Criteria of good Research, Hypothesis.

Reference:

- 1. Business Statistics- K.P Gupta and M.P Gupta
- 2. Statistics for Management- Levin Rubin
- 3. Research Methodology- Methods and Techniques- C R Kothari

MANAGEMENT INFORMATION SYSTEMS

COURSE OBJECTIVE

The objective of this course is to introduce the students to the Management Information Systems and its application in organizations. The course would expose the students to various classifications of information systems and help them identify their unique role various business solutions. Also gives them an understanding of various computer networks and using MS-Word, Excel and Power point applications.

SPECIFIC OBJECTIVES

- To provide knowledge on classification of information systems and health informatics
- To develop skills in identifying the information system according to business needs
- To develop an interest to appreciate and develop a positive attitude toward the many aspects of the course content

LEARNING OUTCOMES

After the completion of the course, students will demonstrate the ability to

- Describe the role of information technology and information systems in business
- Basic knowledge of concepts and terminology related to information technology
- Interpret how to use information technology to solve business problems
- Articulate the fundamental principles of information systems, analysis, and design.
- Identify various applications of Hospital Information System (HIS) and their functionality.
- Hands on experience of using MS-Word, Excel, and Power point applications.

MODULE 1

Information system – Definition of information system, Evolution of information systems, Classification of information systems and overview on- Operation support systems: TPS, Process control systems, Enterprise collaboration systems, Management support systems: MIS, DSS, EIS/ESS, Specialized information systems: Expert systems, Knowledge management systems, Strategic information systems and Functional business systems. Case Studies: Information needs at various levels of management

MODULE 2

Health Informatics - Definition of Health Informatics, various disciplines of health informatics, information management in healthcare

Concepts of Database management systems – DBMS

Electronic medical record – Definition, Need for EMR, Advantages of paperless data, Role of EMR in health information, functions, and features of EMR, Evolution and Historical Perspective, Information management in an electronic environment, Costs and Benefits of the EMR.

Case studies: Significance of Information security in hospitals

MODULE 4

Hospital Information System - Hospital communication and information system, Computer applications in hospital environment, Application modules of hospital - Registration, Accident & Emergency, OPD services, In-patient ward management and bed distribution, Billing, Operation theatres, Diagnostic services, Dietary services, Drug stores, medical records department, Material management services, Payroll services, information network in hospital system.

Various reports through HIS- OPD management, IP care, medical records department, Human resources department, Nursing services, Central support services, Pharmacy and drug stores.

MODULE 5 (Practicals)

MS-Office:

MS-Word

- Create a new document.
- Open, save and print a document.
- Edit and format text.
- Change the page layout, background and borders.
- Insert headers and footers.
- Insert and edit tables.
- Insert clip art and pictures to documents.
- Perform a mail merge.

MS-Excel

- Examine spreadsheet concepts and explore the Microsoft Office Excel environment.
- Create, open and view a workbook.
- Save and print workbooks.
- Enter and edit data.
- Modify a worksheet and workbook.
- Learn to use functions
- · Create and edit charts and graphics.
- Filter and sort table data.
- Work with pivot tables and charts.

MS- Power point

- Examine slide show presentation concepts and explore the Microsoft Office PowerPoint environment.
- Create a new presentation.
- Modify presentation themes.
- · Add and edit text to slides.
- Add new slides to a presentation.
- · Insert clipart images and shapes to slides.
- Insert and modify tables and charts.
- Insert and edit animations and slide transitions.

References:

- Management Information Systems, James O'Brien, Special Indian Edition, Tata McGraw Hill.
- Management Information Systems, Laudon & Laudon, Pearson Publications
- Management Information Systems, P. Mohan, Himalaya Publications
- Database Management Systems, Raghu Ramakrishnan, Mc Graw Hill Publications

SEMESTER III

OPERATIONS MANAGEMENT

MODULE 1:

Overview and definition of operations management, classification of operations, responsibilities of operations managers at Pharmaceutical Industries

Nature & concept of ware housing, facility location and layout, importance of location, factors, general steps in location and selection decision process, types of layouts, product, process, service facility. Materials Requirement Planning, Operations Scheduling and Production activity control for mass manufacturing, batch processing, projects, and job shop production.

Logistics management: Definition, Goals and Objectives of Logistics Management, Principles in Logistics Management, Functions of Logistics Management, Purchase Activities, Types of Purchases, Negotiations in purchase, Legal Aspects of Purchasing, Materials Accounting and Physical Distribution Logistics, Transportation System.

MODULE 2:

Introduction to material management & stores management: definition, basic scope and importance of Materials Management – Materials Planning, recent trends in Pharmaceuticals Procurement Procedure- Registration of firms – Tender System – Vendor analysis -Purchasing & Purchase Cycle, functions of purchase department, Committee: Purchase, selection and Audit – Receipt & Inspection of Stores – Asset Accounting

MODULE 3:

Inventory control: meaning, scope & definition, Aims and Objectives of Inventory Control, Classification of Inventory, Functions of Inventory Control and Criteria of Inventory Control, Inventory control techniques – EOQ, safety stock, Lead Time, all MBASIC Techniques, ABC analysis, VED Analysis - Distribution, codification & classification – standardization and simplification & variety reduction – Quality Control – Value Analysis, perpetual inventory system.

MODULE 4:

Equipment planning and selection in Pharmaceutical Industries – Steps for Equipment Selection, Equipment Utilisation, purchasing capital equipment – feasibility study – import of goods and equipment's- documentation & clearance – letter of credit –equipment repair and maintenance, calibration, tests, maintenance features, maintenance items, spare parts stocking techniques and polices, Condemnation & Disposal, Condemning board.

MODULE 5:

Productivity and work study: method study, work measurement, work sampling and their applications. Supply Chain Management (SCM): Concept of SCM, components, - Importance of Supply Chain in Pharma Management Objectives & Policies.

- 1. Hospital Store Management an Integrated approach by Shakti Gupta, Sunil Kant.
- 2. Productions and Operations Management by S Anil Kumar and Suresh

OPERATION RESEARCH

REFERENCES

- 1. Operations Research Problems and Solutions, Third Edition by J.K Sharma
- 2. Operations Research APH Publishing Corporation by SR Singh
- 3. Operations Research in Health Care, ANMOL Publications by Sachin Verma
- 4. Quaitative Methods Himalaya Publications Dr P Nagesh, Dr Ramesh

MODULE 1

An overview and significance, features, definitions, scope, phases, methodology, applications and scope of operations research.

LPP – advantages, disadvantages, formulation of LPP solution using Graphic solution method problems limited to two constrains (maximisation and minimisation).

MODULE 2

Transportation Problem - finding IBFS by North West Corner Rule, Vogel's Approximation Method, Least Cost Method and MODI method (Basic problems) – balanced, unbalanced, minimisation and maximisation problems.

Assignment Problem – Finding optimal solution by Hungarian Method (Unbalanced, Maximization and Minimisation problems).

MODULE 3

Job Sequencing - Processing 'n' jobs through 2 machines and 3 machines problem solving using Johnson method.

MODULE 4

Queuing theory – Introduction, features of a queuing system, terminologies of queuing system, empirical queuing models (simple problems). Single server model.

MODULE 5

Project Management – definition, characteristics, objectives, importance, and objectives. **Project Scheduling with CPM – PERT.**CPM - The concepts of critical path and critical activities, location of the critical path, evaluation of the project completion time. PERT–concept, estimates of the time of an activity, determination of critical path, probability estimates.

PHARMACO EPIDEMIOLOGY

MODULE I

Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology Outcome measure and drug use measures Prevalence, incidence, and incidence rate. Monetary MODULEs, number of prescriptions, MODULEs of drugs dispensed, defined daily doses, and prescribed daily doses, medication adherence measurement.

Concept of risk in pharmacoepidemiology Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

MODULE II

Pharmacoepidemiological methods: theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system

MODULE III

Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems. Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects

MODULE IV

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

MODULE V

Occupational Health, Medico Social Work, Health committees, Environmental health, Community health, allocations of Resources in 5 year Plans, Geriatric health, Nutrition health, Mental Health, International health

- 1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
- 2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons. USA
- 3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
- 4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London. 207
- 5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
- 6. Graker, Dennis. Pharmacoeconomics and outcomes.

DRUG SALES AND EXIM

MODULE I

Drug Sales management, sales organization, sales forecasting, sales force management, sales promotion objective Global Pharmaceutical Industry scenario, Indian Pharmaceutical Industry scenario, Specificities of Pharmaceutical Marketing, Role of Marketing in today's organization, Identifying and classifying markets.

MODULE II

Marketing Concepts

Tasks of Marketing and Planning. Differentiating between consumer and customer in Pharmaceutical Marketing. Consumer behavior models. Physician's prescribing habits, Rational and emotional decision making.

MODULE III

Institutional Support - Role of DGFT, RBI, ECGCEXPORT - Basic requirements in Exports-IEC, BIN, RCMC, FSC (Free sale Certificate) Terms of Shipment-Ex-Works, FOB, C&F, CIF, CIFC, FRANCO Export by Sea, Air, Rail / Road Custom Clearance Formalities

MODULE IV

Advanced License, DFIA, DEPG, EPCG

Export Documentation: Pre-shipment: Proforma Invoice, Packing List, Shipping Bill, Inspection Certificate Post-Shipment: Commercial Invoice, Bills of Exchange, Bank Realization Certificate, Certificate of Origin, Bills of Lading/ Airways Bill- Costing and Pricing Terms of Payment

MODULE V

Letter of credit: Shipping Bill - endorsement by ADC & NOC on Bill of Entry for Export / Import of Pharma products. Licensing requirements under Drug & Cosmetics Act and Product registration requirements in overseas countries.

RISKS ASSOCIATED WITH EXIM TRADE: Risks - Commodity, Counterparty, Country and Currency, Exchange Rates - factors affecting Exchange Rates

- 1. Marketing Management by Philip Kotler, 9th ed. PHI, 1997.
- 2. Handbook of Pharmaceutical Marketing in India by Rao, S.V.R.S. Panther Publishers Pvt. Ltd., Bangalore, 1997.
- 3. Principles of Pharmaceutical Marketing by Micky C. Smith.
- 4. Strategies of Pharmaceutical Marketing by Dr. Raja Smarta
- 5. Marketing Planning for Pharmaceutical Industry by John Lidstone with Terry Collier.
- 6. Marketing Principles and Strategy by Henry Assael, The Dryden Press
- 7. Games Plans for Post GATT Era by S.V.R. Subba Rao, Panther

BASIC HEALTH SCIENCES

Course Objectives

Objectives: Upon completion of this course the student should be able to

Explain the gross morphology, structure and functions of various organs of the human body.

Describe the various homeostatic mechanisms and their imbalances.

Identify the various tissues and organs of different systems of human body.

Appreciate coordinated working pattern of different organs of each system

Course Content:

MODULE I

Introduction to human body

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

Cellular level of organization

Structure and functions of cell, transport across cell membrane, cell division, cell junctions

Tissue level of organization

Classification of tissues, structure, location and functions of epithelial, connective, muscular and nervous tissue

MODULE II

Integumentary system

Structure and functions of skin

Skeletal system

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system. Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

Joints

Structural and functional classification, types of joints movements and its articulation

Special senses

Structure and function of eye, ear, nose and tongue

Endocrine system

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland and thymus. Local hormones.

MODULE III

Nervous system

Organization of nervous system, neurons and neuroglia, classification and properties of nerve fibre, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

MODULE IV

Peripheral nervous system:

Origin and functions of spinal and cranial nerves. Structure and functions of sympathetic and parasympathetic nervous system

MODULE V

Endocrine system

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland and thymus. Local hormones

- 1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
- 2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York Page 15 of 161
- 3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
- 4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A
- 5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A

MEDICAL DEVICES

MODULE I

Introduction to Medical Devices. Definition of Medical Devices; Differences between Medical Device and Drug development, Classification of medical devices, The role of each participant/stakeholder, Shared responsibility for medical device safety and performance.

MODULE II

Documentation Management, Good Documentation Practice (GDP), purpose of documentation, The types of cGMP documents, Document and record retention. Basics of Drugs and Cosmetics Act (D&C), CDSCO, Existing regulation in India for medical devices

MODULE III

Basics of the Quality Management System for medical devices (ISO 13485, FDA requirements), Quality Systems Regulation. Medical device safety: Medical device safety and risk management, Effectiveness/performance of medical devices, Phases in the life span of a medical device

MODULE IV

Storage considerations for medical devices; implications on material content. Package development: Packaging materials, design, Testing of packages and labelling; scope of improvisation of the packaging materials.

MODULE V

Introduction to Marketing of Medical Devices, Market Dynamics of Medical Devices, , Hospital and Institutional Marketing of Medical Devices, Challenges in Marketing of Medical Devices, Branding of Medical Device, Service and Support of Medical Devices

- 1. The Pharmaceutical Regulatory Process, 2nd ed. Ira R. Berry, Robert P. Martin
- 2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus.

PHARMACY PRACTICE

MODULE I

Clinical Pharmacy: Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Over the counter (OTC) sales Introduction and sale of over the counter, and Rational use of common over the counter medications.

MODULE II

Hospital and its organization: Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions Hospital pharmacy and its organization: Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

MODULE III

Community Pharmacy: Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Drug distribution system in a hospital: Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, dispensing of drugs to ambulatory patients, and dispensing of controlled drugs. Community pharmacy management Financial, materials, staff, and infrastructure requirements

MODULE IV

Drug store management and inventory control: Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure.

MODULE V

Education and training program in the hospital: Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Ambulatory Services Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. Participation in Public Healthcare Programmes of State Government, Central Government and WHO information services

Drug and Poison information center, Sources of drug information, Computerized services, and storage and retrieval of information

- 1. Merchant S.H. and Dr. J.S. Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
- 2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
- 3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
- 4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008

INT. PHARMACY MANAGEMENT

MODULE I

Overview of world business and framework of international marketing: Definition of international marketing, international dimensions of marketing, domestic vs. international marketing, process of internationalization, benefits of international marketing. World market environment: Political environment-Political systems, political risks, indicators of political risk, analysis and measures to minimize political risk

MODULE II

Legal environment- Legal systems, legal form of organization, multiplicity of legal environment, bribery, branch vs. subsidiary, counterfeiting, gray market. Cultural environment- Culture and its characteristics, influence of culture on-Consumption; thinking; communication process and cultural universals. World Trade Organizations (WTO)- Structure and overview of agreements.

MODULE III

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.

MODULE-IV

Pricing in global marketing: International pricing strategy- Role of pricing, price standardization, pricing decisions, price distortion, transfer pricing, methods of financing and means of payment. FDA Enforcement powers, other federal laws affecting pharmaceutical industry.

MODULE-V

Advertising and promotion: International promotion strategies- Promotion mix (Advertising, sales promotion, personal selling, public relation, and publicity), promotion and communication. International advertising- patterns of global advertising, global advertising regulations, advertising media, and advertising budget.

- 1. International Marketing Analysis and Strategy, Sak Onkuisit. Johns. Shaw, Prentice Hall of India Pvt. Ltd. New Delhi 110 001.
- 2. Global Marketing Management, Warren J. Keegan, Prentice Hall of India Pvt. Ltd., New Delhi 110 001.
- 3. International Marketing, Vern Terpstra, Ravi Sarathy, Publisher Harcourt Asia Pvt. Ltd.
- 4. Global Marketing, Johny K. Johnsson, Publisher Erwin McGraw Hill, New Delhi.

SEMESTER IV

BUSINESS LAW AND ETHICS

COURSE OBJECTIVES:

To help students understand the ethical aspects of an organization and the legal issues concerning the setting up and the adequate functioning of an organization, and the judicious use of this knowledge in the day-to-day administration of care.

SPECIFIC OBJECTIVES:

This course intends to teach students-

- The basic terminologies and concepts in ethics and law
- The practice of ethical principles in an organization.
- The impact of legal issues in an organization.
- To understand the pharmacy sector regulations for the establishment of the pharmacy and also the current legal issues regulating the hospitals.
- To understand the concepts regulating human resource management in an organization.

Course

Module I

Introduction to Business Ethics The nature, the purpose of ethics and morals for organizational interests; Ethics and Conflicts of Interests; Ethical and Social Implications of business policies and decisions; Corporate Social Responsibility; Ethical issues in Corporate Governance., Nature of Ethics, Ethical Concepts and Theories, Morals and Values,

Module II

Categories of management morality Ethical Problems-Dilemma at Work-Sources and, Resolutions Corporate Ethical Leadership ,need of ethics in business, Distinction between values and ethics, Kohlberg's six stages of moral development (CMD), Ethics in Workplace Individual in the organisation, discrimination, harassment, gender equality.

Module III

Managerial Ethics: Categories of management morality, Ethical Problems-Dilemma at Work-Sources and Resolutions, Overview of Creative Accounting-Its role in business scandals, a) Partnership deed (b) Power of Attorney (c) Lease deed (d) Affidavit (e) Indemnity bond (f) Gift deed

Module IV

Legal Aspects of Business - Society, State and Law, Enforceability of Law, Mercantile Law., The Negotiable Instruments Act, 1881, The Payment of Bonus Act, 1965, The Employees' Provident Funds and Miscellaneous Provisions Act, 1952, The Payment of Gratuity Act, 1972.

Module V

Indian Contract Act, 1872 – Contract defined, Elements of valid contract, Classification of contracts, Offer and acceptance, Consideration, Capacity to contracts, Free consent, Legality of object and consideration, Illegal agreements, Termination of contracts, Breach of contract, Indemnity and guarantee, Laws of agency, Companies Act, 1956 – Nature and kinds of companies, Formation, Memorandum, Articles, Prospectus, Capital – shares, debentures, borrowing powers, minimum subscription, Appointment of Directors; Winding up of companies (Including Amendments)

- 1. Business Ethics and Corporate Governance, 2009 Edition. Murthy C.S.V. Himalaya Publishing
- 2. Business Laws: Second Edition by Sujit Kumar Das, Pankaj Kumar Roy
- 3. Business Ethics and Corporate Governance by Vijay Rupani, Himalaya Publishing

PROJECT MANAGEMENT

Introduction

The use of projects and project management continues to grow in our society and its organizations. Businesses regularly use project management to accomplish unique outcomes with limited resources under critical constraints.

Specific objectives

- To understand the development and implementation of all project's procedures
- To understand efficient communication and supervision of the project's team.
- To understand inputs and their application to meet project's pre-defined objectives.

Learning objectives

Project management is a field that keeps growing in knowledge and interest at a considerable rate. Understanding project management objectives in-depth is the first step to success, as it would fully make us realize what it takes to be an efficient, effective, and competitive project manager in a shifting, complex and at times unpredictable environment.

Module -I: Project Management: Introduction, meaning and scope, Need for Project Management, Project management Knowledge Areas and processes, The Project Manager (PM) – roles and duties of PM, Phases of Project Management Life Cycle, Essentials of project management philosophy.

Module-II: Project Identification and Formulation: Project Identification, Project Formulation stages – feasibility analysis, techno-economic analysis, project design and network analysis, input analysis, financial analysis, cost-benefit analysis and pre-investment analysis, Appraisal report and Detailed Project Report (DPR).

Module-III: Project Management and Selection – Introduction, project selection criteria and models – Types of project selection models (numeric and nonnumeric): The Operating Necessity, The Competitive Necessity, Comparative benefit Model, Profit/Profitability and Window-of-Opportunity Analysis, Project management maturity, Project Portfolio Process (PPP).

Module-IV: Introduction to clinical project management: Project management systems. Project management process: Project organization, planning and scheduling, network, resources estimates, resource planning, resource levelling, project control, progress, reporting and validation.

Module-V: Project and business management theory in the context of a clinical trial. Implementation and co-ordination of the project plan with an emphasis on communication and project promotion and monitoring

References

- 1. Project Management: A Managerial Approach Jack R. Meredith, Samuel J. Mantel
- 2. Project Management: The Managerial process Erik Larson, Clifford Gray
- 3. Project Management: John M. Nicholas and Herman Steyn, Pearson Education
- 4. Project Management by Harvey Maylor

PRICING STRATEGY DPCO

Scope: To provide inputs for a strategic overview since costs are a key differentiator in determination of brand success worldwide.

OBJECTIVES: Upon completion of this course the student should be able to:

- 1. Understand the concept of cost.
- 2. Regulatory bodies in pricing.
- 3. Justifying the cost of a particular product.

Course Content:

MODULE I

An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management, price communicates, psychological effects of pricing and folklore & facts in pharmaceutical industry.

MODULE II

Cost Benefit Analysis with reference to Strategic Business Decision Making. Value Analysis and Value Engineering, Wastage Control, Business Process Re-engineering, , Cost Reduction and Control. Product Life Cycle Costing. Activity Based Costing and Target Costing

MODULE III

Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Novel Over the counter (OTCS), herbal medicines and Homeopathic obtaining New Drug Application (NDA), Abbreviated New Drug Application (ANDA) for generic drugs, ways and means of US Registration for foreign drugs, Chemistry, Manufacturing, and controls (CMC)

MODULE IV

Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA. Regulatory requirements for contract research organization.

Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) Format, working with Pharmaceutical Industry.

MODULE V

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures.

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

MARKET ANALYTICS OF DRUG SUBSTANCE

MODULE I

Marketing Research a) Primary and Secondary Research b) Sampling Techniques-Probability and Non-Probability c) Questionnaire Design d) Data Collection e) Data Analysis. **Big data analytics** Tools and techniques of data collection- Validity and reliability of tools. Quantitative tools--questionnaire, ranking and rating scales and scales.

MODULE II

Primary and secondary sources of data, Use of library and the internet sources for collection of data, data clustering. Application of data analysis techniques- Types of data-nominals, ordinal, interval, and ratio conditions on data for the use of parametric and non-parametric Tests

MODULE III

Testing of hypothesis-chi-square test, t-test, Z test, F test. Multivariate analysis, cluster analysis, discriminant analysis, correlation and regression analysis, factor analysis, Use of SPSS in data analysis

MODULE IV

Sampling Methods, Use of random numbers, Estimation from the sample data, Standard error, Stratification, Systematic Sampling, two stage methods and cluster sampling. Inference from Observational Data (review of tests of hypotheses derived from normal distributions, (e.g. t, Chi-Square test, F, tests of independence and associations, estimation and confidence intervals)

MODULE V

Non-parametric tests Analysis of variance and design of experiments and Multivariate Methods (Factor analysis, Discriminate function, Multiple discriminate analysis, Cluster analysis, Multidimensional scaling, Applications, and Computer Packages).

- 1. Fundaments of Business Analytics by RN Prasad and Seema Acharya, Wiley India Publication
- 2. Win With Advanced Business Analytics by Jean Paul Isson and Jesse S. Harroitt, Wiley Publication, 2013
- 3. Successful Business Intelligence: Secrets to Making BI a Killer App by Cindi Howson, Tata McGraw Hill Edition 2012.

HEALTH INFORMATICS

Introduction

Healthcare is an ever-changing science. As new research and clinical experience broaden our knowledge, changes in treatment and drug therapy are required. Health informatics is for health professionals who wish to understand the principles and applications of information and communication methods and technologies in healthcare.

Specific objectives

- 1. To understand the diverse applications of technology in health as well as unique challenges in health care.
- 2. To understand interventions that can improve upon existing interventions and communication processes.

Learning outcome

This subject offers an intuitive understanding of the basic theoretical concepts needed to understand informatics – to understand the available information and how effectively the information is communicated.

Module I:

Health Informatics: Definition of Health Informatics, various disciplines of health informatics, History of Health Informatics, Role of Information Technology in Healthcare

Module II:

Information Systems in Healthcare: Information management systems, formal and informal information systems, characteristics of information systems, purpose of healthcare information systems

Module III:

Electronic Health Record (EHR): Introduction to EHR, role of EHR in healthcare, the quality impacts of EHR, Advantages and disadvantages of EHR.

Module IV:

Specialized applications for health informatics: Tele Medicine, Public health informatics-public health surveillance tasks, Consumer Health Informatics- technologies focused on the needs of patients and care providers

Module V:

Health Information Security & Cyber Laws: Security challenges, privacy issues, Information security acts- Information Technology Act 2000, National Cyber Security Policy 2013 and Digital Information Security in Healthcare Act (DISHA).

Reference Books:

- 1. Guide to Health Informatics- Enrico Coiera, 3rd Edition 2015, CRC Press- Taylor & Francis Group. ISBN: 978-1-4441-7049-8
- 2. Health Informatics- Barbara M. Hayes and William Aspray. The MIT Press2010. ISBN: 978-0-262-01432-8
- 3. Pharmacy Informatics. Philip O. Anderson, Susan M. McGuinness, Philip E. Bourne, CRC Press- Taylor & Francis Group, 2010. ISBN: 978-1-4200-7175-7

STRATEGY OTC PRODUCTS

Scope: To make the candidate appreciate the reasons, strategy, planning, management for a company going for OTC and forecasting the life of the OTC product.

Objectives: Upon completion of this course the student should be able to:

- 1. Familiarize with basic concepts of promotion management and examine where and why an ethical brand can go OTC.
- 2. Understand the steps and investment needed to ensure a smooth transformation from a decision to go OTC to going to market.

Course contents

MODULE I

Introduction, Different terminologies of drug products, Strategy formulations of OTC marketing companies, General marketing strategies of OTC, Decision area strategies, Strategies for market leaders, Strategies for new & switched OTC pharmaceutical products, Marketing strategies and product life cycle of OTC products and Product life cycle analysis (PLC)

MODULE II

Reasons for going OTC: Meaning and the downsize of the decision. 5 M's in Advertising. (Mission, Money, Media, Message and Measurement). The strategy and its short-term results. The risk and the responsibility. Retail and Prescription Audit for OTC.

MODULE III

Advertising and promotion strategies of OTC. Advertiser-Advertising Agency Relationship, Social and Economic Effects of Advertising. Communication models. Marketing mix factors and Advertising. Advertising research.

Cases of Various successful brands after promoting them Over the Counter

MODULE IV

Merchandising and store management- Branding strategies, Merchandise purchasing process, Store Management. Store layout, design and visual merchandise- Store interior, exterior and security Store interior, exterior and security, Visual Merchandising for OTC drug retailing

MODULE V

Future Drivers of OTC Pharmaceuticals- The impact of technology on the OTC market, OTC pharmaceuticals: growth or maturity: in India and global Market, Development in OTC Pharmaceutical Marketing

- 1. Marketing Management (Pearson) by Philip Kotler, Kevin Keller, Koshy and Jha
- 2. Marketing Management by Rajan Saxena

INTELLECTUAL PROPERTY RIGHTS

Scope: This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives: Upon completion of this course the student should be able to:

- 1. Assist in Regulatory Audit process.
- 2. Establish regulatory guidelines for drug and drug products
- 3. The Regulatory requirements for contract research organization

Course contents

MODULE I

Definition, need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory notebook, Non-obviousness in Patent.

MODULE II

Pharmaceutical products and process and patent protection, Role of GATT, TRIPS, and WIPO. Brief introduction to Trademark protection and WHO Patents. IPR's and its types. Major bodies regulating Indian Pharmaceutical sector.

MODULE III

Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee, and co-owners Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.

MODULE IV

Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System, Background, Salient Features and Impact of International Treaties / Conventions like Paris Convention, Berne convention World Trade Organization (WTO)World Intellectual Property Organization (WIPO)Trade Related Aspects of Intellectual Property Rights (TRIPS) Patent Co-operation Treaty (PCT), Madrid Protocol

MODULE V

Patent in validation process in India, US, and Europe, IPR related to copyright, trademark, trade secret and geographical indication. Patent application writing Claim construction and claims. Hatch- Waxman provision for IPR

References:

- 1. The Pharmaceutical Regulatory Process, 2nd ed. Ira R. Berry, Robert P. Martin
- 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 Development Series, Vol1 by Helene I. Dumitriu
- 4. IPR Handbook for pharma students and researchers. Parikshit Bansal
- 5. Basic Concepts of Intellectual Property Rights. Manipal Universal Press. Manthan D Janodia.