Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Industrial Pharmacy) **30/04/2013**
II Semester Course Contents
MPY-201-IP : Pharmaceutical Quality Assurance

Unit I

Pharmaceutical Quality Management System: Total Quality Management (TQM), six sigma concept, Quality by Design (QbD) vs Quality by Testing (QbT) concept, Official and non-official quality control tests for tablets, capsules, liquid orals, semisolids, injectables and other sterile products with their acceptable limits as per official books and regulatory requirements. In-process quality control (IPQC) testing of dosage forms.

Unit II

Quality assurance in contract manufacturing. Sources and control of quality variation- material, machine, man, method and environment. Quality testing of raw material, in-process material and finished products. Quality assurance in analytical laboratory. Quality assurance concepts in pharmaceutical packaging operations.

Unit III

Pharmaceutical manufacturing documentation (PMD) – Guidelines for designing and implementation of PMD programme. Advantages and applications of pharmaceutical documentation, Regulatory requirement of pharmaceutical documentation: Standard practices in preparation, issue, use and archival of documents, records, reports and disposal of documents.

Unit IV

Validation of pharmaceutical manufacturing facility: Purpose, approaches, planning, change control. Area qualification of non-sterile production area. Qualification of sterile production area, media fill test, aseptic processing area. Validation of pharmaceutical plant utilities: Pharmaceutical water system, HVAC system, air handling, air change system, environmental control system.

Unit V

Organizational & personnel responsibilities. training and records. equipment selection, User Requirement Specifications (URS), maintenance of analytical instruments. Standard practices in Quality control laboratory, Calibration and certification of equipments. Validation of disinfectants, Validation of cleaning and sanitization of clean room and materials.

Recommended Books

1. Pharmaceutical Process Validation – Robert A. Nash, Alfred H. Wachter
2. Process Validation in manufacturing of biopharmaceuticals: Guidelines – Anurag Singh Rathore, Gail Sofer, G. K. Sofer
3. Pharmaceutical Quality Assurance – Manohar A. Potdar
4. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO.
5. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
6. Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices – John J. Tobin and Gary Walsh
7. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
8. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu

Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Industrial Pharmacy)
II Semester Course Contents
30/04/2013
MPY- 202-IP : Industrial Management

Unit I

Pharmaceutical Management: Meaning, 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.

Unit II

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.

Unit III

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.

Unit IV

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.

Unit V

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.

Books Recommended:

1. Principles and Methods of Pharmacy Management III rd edition Harry A. Smith
2. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill.
3. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
4. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
5. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
6. Business Organization and Management by Shukla M. C.; S. Chand and Company
7. Personal Management by Filippo E. B. Mac Graw Hill.
8. Personal Management Tripathi P. C.; S. Chand and Company.
9. Project Management by Choudhary, S.; Tata Mac Graw Hill.

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M. Pharm (Industrial Pharmacy) **30/04/2013**

II Semester Course Contents

MPY- 203-IP: PHARMACEUTICAL REGULATIONS

Unit I

FDA's Product Approval Processes

A. New Drug Approval Process.

B. Generic Drug Approval Process.

C. Biologics Approval Process.

USFDA: Regulations. Effects of patent and trademark laws. Patent certification in drug approvals.

Unit II

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.

Unit III

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

Unit IV

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

Unit V

The role of patents in the approval process

i. The Patent Listing ("Orange Book") Requirement

ii. The "Paragraph IV" Certification and Notice Requirement

iii. ANDA Filing As An Act of Infringement

iv. The Automatic 30-Month Stay of ANDA Approval

v. 180-Day Exclusivity for first paragraph IV filers

Books Recommended:

1. Code of federal regulation. www.fda.gov.
2. I. R. Berry, *The pharmaceutical regulatory process*, Marcel dekker.
3. L. Shargel, I. Kanfer, *Generic drug product development solid oral dosage forms*, Marcel dekker.

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M.Pharm. (Industrial Pharmacy) **30/04/2013**
II Semester Course Contents
MPY- 204-IP : PHARMACEUTICAL PACKAGING TECHNOLOGY

Unit I

Functions of packaging, Packaging management, Package development, packaging and stability, packaging specification, Regulatory aspects of pharmaceutical packaging. Packaging material science: Basic materials used in packaging, their properties, method of manufacturing and applications-Paper, Plastics, Glass, Metal, and Elastomers.

Unit II

Containers and closures: Closure Systems: Basis of closure system, Types/mechanism of closure system, Sealing and adhesion techniques, Materials used for closure systems.

Introduction and applications of Glass containers, Plastic containers, Collapsible tubes, Plastic tubes, Aerosol containers, Closures, Liners, and Rubber stoppers.

Introduction and applications of Form-Fill-Seal (FFS) technology.

Unit III

Packaging techniques and machineries: Tamper resistant and child resistant packages: Introduction, method of preparation, and applications of Blister and Strip packs, Film Wrappers, Bubble packs, Shrink seals, Sachet and Pouches, Tape seals, Breakable caps, Sealed tubes, Aerosol containers, etc.

Unit IV

Quality control and quality assurance of packaging materials: Detection of defects in packaging materials, Quality testing of formed packs, Quality testing of containers and closures, Testing of child resistance and temper evidence property of packaging materials. Quality control tests for containers and closures as per Indian Pharmacopoeia.

Unit V

Legal and regulatory requirements: Requirements of labels and labeling as per Drug & Cosmetics act and rules. Product / patient information literatures. Regulatory aspects of storage, handling and distribution of packaging materials with special emphasis on cGMP and cGLP requirements.

Books recommended:

1. Dean, D.A.; Evans, E.R.; and Hall I.H., *Pharmaceutical Packaging Technology.*
2. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, *The Theory and Practice of Industrial Pharmacy.*
3. *Drug and cosmetic Act and Rules.*