Rajiv Gandhi Proudyogiki Vishwavidyalaya

M.Pharm. (Quality Assurance)

3rd Semester Elective Course Contents

Elective-I

MPY 301 QA : Pharmaceutical Quality System & Process Validation

Unit-I

Quality System: 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 concepts in pharmaceutical packaging operations. 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.

Unit-III

Pharmaceutical Process Validation: Validation of processes for non-sterile formulations, i.e., Mixing, granulation, drying, compression, coating, blending, homogenization. Validation of processes for sterile formulation, i.e., Cleaning/washing, sterilization, depyrogenation, filling, lyophilization, filtration processes. Validation of packaging line.

Unit-IV

Sterilization Process Validation: Bioburden and overkill approaches, biological indicators, development and validation of sterilization cycles. Calculation of D-value, Z-value and microbial destruction/lethality (F-value). Quality assurance in aseptic processes.

Unit-V

Validation of biological and biotechnological processes, Validation of manufacturing processes in bulk drug industries, personnel validation with regard to sterile and non sterile product manufacturing, Validation of medical devices, Validation and security measures for electronic data and computer assisted process.

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. United States Pharmacopoeia

Rajiv Gandhi Proudyogiki Vishwavidyalaya

M.Pharm. (Quality Assurance)

3rd Semester Elective Course Contents

Elective-II

MPY 302 QA : Pharmaceutical Documentation & Regulatory Affairs

Unit I

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 II

Pharmaceutical documents for production operations: Standard formats, contents, designing and preparation of- Batch Processing Record/Batch Manufacturing Record (BPR/BMR), Batch Packaging records, Batch testing records, Site Master File, Standard Operating Procedure (SOP), Certificate of Analysis (COA), quality specification, Material Safety Data Sheet (MSDS).

Unit III

Pharmaceutical documents for R&D and quality operations: Standard formats, contents, designing and preparation of- Master Formula Record (MFR), Product Development Record (PDR), Drug Master File (DMF), Method of Analysis/Standard Testing Procedure (MOA/STP), Validation master plan, Validation protocols, validation reports, inspection & audit reports.

Unit IV

Standard formats, contents and preparation of SOP and validation documents of various Non-sterile processes, i.e., Mixing, granulation, drying, compression, coating, blending, homogenization; Sterile processes, i.e., sterilization, depyrogenation, Cleaning/washing, filling, lyophilization, filtration processes. SOP and validation documents of packaging operations.

Unit V

ICH guidelines for pharmaceutical quality aspects: Common Technical Documents (CTD), Quality of Biotechnological Products Q5A - Q5E, Specifications Q6A- Q6B, Impurities Q3A - Q3D**,** Stability Q1A - Q1F**,** Pharmacopoeias Q4 - Q4B**,** Quality Risk Management Q9, Pharmaceutical Quality System Q10**,** Electronic documentation and electronic filing**.**

Recommended Books

1. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
2. Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices –John J. Tobin and Gary Walsh
3. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
4. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu
5. ICH guidelines- www.ich.org

Rajiv Gandhi Proudyogiki Vishwavidyalaya

M.Pharm. (Quality Assurance)

3rd Semester Elective Course Contents

Elective-III

MPY 303 QA : Analytical Method & Equipment Validation

Unit-I

Validation of analytical and bioanalytical methods as per FDA, USP and ICH guidelines. Qualification, validation and calibration of analytical instruments. Application of process analytical technology (PAT) in quality assurance.

Unit-II

Designing of Standard Operating Procedure for- UV-visible spectrophotometer, FT-IR, High Performance Liquid Chromatography, HPTLC, Gas Chromatography, XRD, Differential Scanning Calorimetry as per regulatory requirements.

Unit-III

Regulatory guidelines specific to analytical method validation for NDA & ANDA application– USFDA, ICH, USP. PAC-ALTS (Post Approval Changes-Analytical Testing Laboratory Site). Dosage form impurity profile and its validation, method transfer.

Unit-IV

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.

Unit-V

ICH guidelines on analytical & Stability testing- Q2(R1): Validation of analytical procedures, Q1A(R2): Stability testing of new drug substances and products, Q1B: Stablity testing-Photostability testing of new drug substances & products. Q1C: Stability testing for new dosage forms, Q1D: Bracketing & matrixing designs for stability of new drug substances and products, Q1E: Evaluation of stability data.

Recommended Books:

1. Encyclopedia of Pharmaceutical Technology Vol.1-3, Swarbrick, J and Bolyln, J. C., Marcel Dekker, Inc., New York.
2. United States Pharmacopoeia
3. The International Pharmacopoeia
4. ICH guidelines: www.ich.org

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M.Pharm. (Quality Assurance)

3rd Semester Elective Course Contents

Elective-IV

MPY 304 QA : Pharmaceutical Plant- Design & Operations

Unit-I

Regulatory requirements of pharmaceutical manufacturing facilities with reference to cGMP, revised schedule-M and factory act. Facilities Planning: Considerations in the design of a pharmaceutical facility, Location and Layout of facilities, factors affecting location, Location decision models.

Unit-II

Types of Layouts- Product layout, Process layout, Fixed Position and Group Layout along with their merits and limitations. Design and operation of Quality Control Laboratory, Design of utility services – Water, steam, compressed air and gases. Design of effluent treatment plant.

Unit-III

Design, layout and operational facilities with services and utilities for Tablets, Capsules, Liquid orals, Ointments and Dry syrups. Design, layout and operational facilities with services and utilities for injectables and other sterile products, powders ready for reconstitution.

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.

Unit-V

Validation of pharmaceutical plant utilities: Pharmaceutical water system, HVAC system, air handling, air change system, environmental control system. Validation of disinfectants, Validation of cleaning and sanitization of clean room and materials.

Recommended Books:

1. Project Management by Clifford F. Gray and Erik W. Larson Publisher: McGraw Hill company.
2. Pharmaceutical Production facilities: Design and applications by Graham Cole. Taylor & Francis
3. Production/Operations Management by: El wood Bufa Publisher: Wiley Eastern Limited.
4. S. J. Turco, Sterile Dosage Forms: their Preparation and Clinical Applications; Lea &Febiger.
5. F.J. Carleton and J.P.Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.