Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)

Accorded Under 2(F) & 12(B) Of UGC, NBA & NAAC "B" Accredited Anantapuramu, Andhra Pradesh-515721

M. Pharmacy – Department of Pharmaceutical Quality Assurance

Quality policy:

Endeavoured to Provide & practice assurance in of pharmaceuticals in development, quality control, production, distribution, and inspections.

Programme Outcomes:

1. Interpret the requirements for testing of raw materials, in-process samples, and finished product in accordance with pharmacopoeia standards.
2. Predict a variety of Quality Control activities including developing QC policies and Standard Operation Procedures, analyzing and archiving data, and interpreting results.
3. Evaluate the performance of a variety of laboratory equipment used in pharmaceutical industrial labs.
4. Assess instruments malfunction and troubleshoot the analytical equipment failure in compliance with regulatory requirements.
5. Identify and analyze unexpected results during routine analyses and find the solutions based on scientific and regulatory considerations by implementing preventive action and corrective action programs.
6. Apply a working knowledge of GMP (Good Manufacturing Practice), GLP, ISO 9000 requirements to the manufacture of pharmaceuticals.
7. Understand the concept of quality systems and compliance in the regulated industry and the role of quality assurance.
8. Understand the use of controlled documentation.

Course outcomes:

Name of the course: Modern pharmaceutical analytical techniques (MQA 101T)

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the instruments

Name of the course: Quality management systems (MQA 102T)

1. The importance of quality
2. ISO management systems
3. Tools for quality improvement
4. Analysis of issues in quality

5. Quality evaluation of pharmaceuticals
6. Stability testing of drug and drug substances
7. Statistical approaches for quality

Name of the course: Quality control and quality assurance (MQA 103T)

1. Understand the cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments.

Name of the course: Product development and technology transfer (MQA 104T)

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3. To elucidate necessary information to transfer technology of existing products between various manufacturing places

Name of the course: Hazards and safety management (MQA 201T)

1. Understand about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the industry environment.
4. Ensure safety standards in pharmaceutical industry
5. Provide comprehensive knowledge on the safety management
6. Empower an ideas to clear mechanism and management in different kinds of hazard management system
7. Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Name of the course: Pharmaceutical validation (MQA 202T)

1. The concepts of calibration, qualification and validation
2. The qualification of various equipments and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipments employed in the manufacture of pharmaceuticals

Name of the course: Audits and regulatory compliance (MPA 203T)

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

Name of the course: Pharmaceutical manufacturing technology (MQA 204T)

1. The common practice in the pharmaceutical industry developments, plant layout and production planning
2. Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing