Marwadi University
Faculty of Pharmacy

Subject code: 13PH0705
Subject name: Quality Assurance

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objective: Upon completion of the course the student shall be able to
1. Understand the cGMP aspects in the pharmaceutical industry.
2. Appreciate the importance of documentation.
3. Understand the scope of quality certifications applicable to pharmaceutical industries.
4. Understand the responsibilities of QA & QC departments.

Teaching and assessment scheme:

Teaching Scheme (Hours)			Credits	Theory/ Tutorial Marks			Practical Marks		Total Marks
Theory	Tutorial	Practical		CSE	IA (I)	ESE (E)	TW	Viva (V)	
3	1	0	4	10	15	75	0	0	100

Theory syllabus: **Teaching hours: 45 Hours**

Unit-1 **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP. Total Quality Management (TQM): Definition, elements, philosophies. ICH Guidelines: purpose, participants, the process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines. Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration. NABL accreditation: Principles and procedures.

Unit-2 **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

Unit-3 **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing materials. Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.

Unit-4 **8 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal. Document maintenance in the pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

Unit-5 7 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management

Tutorials will be based on the above syllabus. **Teaching hours: 15 Hours**

Recommended References (Latest edition):

1. Quality Assurance Guide by an organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related Materials Vol. I, WHO Publications.
4. A guide to Total quality management- Kushik Maitra and Sedhan K Ghosh.
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total quality management – Sadhank G. Ghosh.
7. The International Pharmacopoeia – Vol. I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
8. Good laboratory Practices – Marcel Deckker Series.
9. ICH guidelines, ISO 9000 and 14000 guidelines.