GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL ANALYSIS

SEMESTER: II

Subject Name: QUALITY CONTROL AND QUALITY ASSURANCE
Subject Code: MPA203T

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

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

1. 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

Sr No	Course Contents	Total Hrs
1	Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines QSEM, with special emphasison Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of nonclinical testing, control on animal house, report preparation and documentation	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines	12
3	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials	12
4	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data	12
5	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product,	12

	process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging	

REFERENCES:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rdrevisededition, Volume I&II, Mumbai,1996.
2. Good Laboratory Practice Regulations, 2ndEdition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I &II, 2nd edition, WHO Publications,1999.
4. How to Practice GMP's– P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II,III,IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepient sand Dosage forms,3rdedition,WHO,Geneva,2005.
6. 6. Good laboratory Practice regulations– AllenF. Hirsch, Volume 38, Marcel DekkerSeries, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940– Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual– D. H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control– Sidney H.Willig, Vol. 52, 3rdedition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package).Taylor&Francis;2003
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley &Sons; 2008