

Subject Code: MQA103T	Subject Title: QUALITY CONTROL AND QUALITY ASSURANCE
Pre-requisite Subject	- NONE -

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

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

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)		
Lecture	Tutorial	Practical	Credit	Theory (T)		Total Marks
				University Assessment	Continuous Assessment	Theory
4	NA	NA	4	75	25	100

	Subject Contents		
Sr. No.	Topic	Total Hours	Weight (%)
1	UNIT I Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12	20
2	UNIT II 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.	12	20
3	UNIT III 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 dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12	20

4	UNIT IV 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 Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	12	20
5	UNIT V 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, 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, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	12	20

List of References:

Reference Books:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, 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, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. ICH guidelines
7. ISO 9000 and total quality management
8. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
11. Packaging of Pharmaceuticals. 15. Schedule M and Schedule N.
12. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
13. 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.
14. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.