INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)**
SEMESTER	**1**
COURSE TITLE	**QUALITY CONTROL AND QUALITY ASSURANCE**
COURSE CODE	**13MQ0103**
COURSE CREDITS	**4**

Objective:

1 various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers important aspects like cGMP, QC tests, documentation, quality
certifications, GLP, and regulatory affairs.

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

Course Outcomes: After completion of this course, student will be able to:

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 the of QA & QC departments.

Pre-requisite of course:B.Pharm. Degree holder from an Indian university established by law in India from an institution approved by the Pharmacy Council of India and has scored not less than 55 percent of the maximum marks (aggregate of 4 years of B.Pharm.).

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**Unit-1** 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 Q-series guidelines., Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, a protocol for the conduct of nonclinical testing, control on an animal house, report preparation, and documentation. CPCSEA guidelines.	12

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Contents : Unit	Topics	Contact Hours
2	**Unit-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 layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12
3	**Unit-3** Analysis of raw materials, finished products, packaging materials, in-process quality control (IPQC), Developing specifications (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 the Pharma industry according to Indian, US, and British pharmacopeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopeias).	12
4	**Unit-4** Documentation in the 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
5	**Unit-5** Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, the release of a 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 trademark, copyright, and patents.	12
Total Hours		**60**

Textbook :

1 Good Laboratory Practice Regulations, Sandy Weinberg , Marcel Dekker Series, , 1995

2 Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related Materials , WHO Publications, WHO Publications, 1999

Textbook :

3 Good Laboratory Practice Regulations , Allen F. Hirsch,, Marcel Dekker Series, 1989

4 The drugs and cosmetics act 1940 , Deshpande, Nilesh Gandhi, Susmit Publishers, , 2006

5 Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, With Checklists and Software Package, Taylor & Francis, 2003

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking / Creative**
20.00	25.00	25.00	15.00	10.00	5.00

Instructional Method:

1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

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