INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)**
SEMESTER	**1**
COURSE TITLE	**QUALITY MANAGEMENT SYSTEM**
COURSE CODE	**13MQ0102**
COURSE CREDITS	**4**

Objective:

1 This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industry.

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

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

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

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Contents : Unit	Topics	Contact Hours
1	**Unit-1** Introduction to quality: Evolution of Quality, Definition of Quality, Dimensions of Quality., Quality as a strategic decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality., Customer focus: Meaning of customer and customer focus, classification of customers, customer focus, customer perception of quality, factors affecting customer perception, customer requirements, meeting customer needs and expectations, customer satisfaction and customer delight, handling customer complaints, understanding customer behavior, the concept of internal and external customers, case studies., Cost of quality: Cost of quality, categories of cost of quality, models of the cost of quality, optimizing costs, and preventing the cost of quality.	12
2	**Unit-2** Pharmaceutical quality Management: Basics of quality management, total quality management (TQM), Principles of six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical quality management – ICH Q10, knowledge management, quality metrics, operational excellence, and quality management review. OSHAS guidelines, NABL certification, and accreditation CFR-21 part 11, WHO-GMP requirements.	12
3	**Unit-3** Six system inspection models: Quality management system, production system, facility and equipment system, laboratory control system, materials system, packaging and labeling system. concept of self-inspection., Quality systems: Change management/ change control. Deviations, out of specifications (OOS), out of trend (OOT), Complaints - evaluation and handling, investigation and determination of root cause, corrective & preventive actions (CAPA), returns and recalls, vendor qualification, annual product reviews, batch review, and batch release. Concept of IPQC, area clearance/ line clearance.	12
4	**Unit-4** Drug stability: ICH guidelines for stability testing drug substances and products. Study of ICH Q8, Quality by design, and process development report., Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking, and filtering according to ICH Q9 guidelines.	12
5	**Unit-5** Statistical process control (SPC): Definition and importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	8

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Contents : Unit	Topics	Contact Hours
6	**Unit-6** Regulatory compliance through quality management and development of quality culture benchmarking: Definition of benchmarking, Reasons for benchmarking, types of benchmarking, benchmarking process, advantages of benchmarking, limitations of benchmarking.	4
Total Hours		**60**

Textbook :

1 Implementing Juran's Road Map for Quality Leadership, Benchmarks and Results, Endres, Wiley, 2000

2 Understanding, Managing and Implementing Quality, : Frameworks, Techniques, and Cases, Jiju Antony; David Peerce, Routledge, 2002

3 Management in the Fortune 1000: The CEO Report , Edward E. Lawler; Susan Albers Mohrman; George Benson, , Jossey-Bass, , 2001

4 Corporate Culture and the Quality Organization, James W. Fairfield-, Sonn, Quorum Books, 2001

5 The Quality Management Sourcebook: An International Guide to Materials and Resources , Christine Avery; Diane Zabel, Routledge, 1997

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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