Course Syllabus
Gyanmanjari Pharmacy College
Semester-1 (M.Pharm.)

Subject: Quality Management Systems (MPHQA11502)

Prerequisite: B. Pharmacy

Rationale: 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 industries.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
				Theory Marks		Practical Marks		CA	
CI	T	P	C	ESE	MSE	V	P	ALA	
4	-	-	4	75	10	--	--	50	150

Legends: CI-Class Room Instructions; T – Tutorial: P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

Course Content:

Chapter No.	Course content	Hrs	% Weightage
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, concept of internal and external customers .Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality,	12	20

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-21part 11, WHO-GMP requirements.	12	20
3.	**Six System Inspection model:** 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, are a clearance/Line clearance.	12	20
4.	**Drug Stability**: ICH guidelines for stability testing of drug substance and drug 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 toICHQ9guidelines.	12	20
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.	12	20
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 Course Content.		

Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1.	Group Discussions and Debates: Faculty will provide topics and organize discussions and debates on various QMS topics such as "The role of ISO certification in the pharmaceutical industry" or "How to improve the efficiency of QMS in a pharmaceutical company and students upload on GMIU web portal.	15
2.	Faculty will ask to students create Standard Operating Procedures (SOPs) for various processes within a pharmaceutical company, focusing on the integration of QMS and upload on GMIU web portal.	15
3.	Faculty will provide topics on real-world scenarios involving QMS issues in pharmaceutical industries (e.g., product recalls, audit findings, or CAPA implementations). Students analyze the problem, propose solutions, and present their findings in the form of presentation or report and upload on GMIU web portal.	20
Total		50

Suggested Specification table with Marks (Theory):75

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	20%	40 %	20%	10%	05 %	05%

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcome:

After learning the course, the students should be able to:	
CO1	To understand the CGMP aspects in pharmaceutical industry.
CO2	To appreciate the importance of the documents.
CO3	To understand the scope of quality certification applicable to pharmaceutical industries To understand responsibilities of QA & QC departments.

Instructional Method:

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

From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.

Reference Books:

[1] Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000

[2] Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

[3] Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001

[4] Corporate Culture and the Quality Organization by James W. Fair field Sonn, Quorum Books, 2001

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

[6] The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

[7] Juran's Quality Handbook, Sixth Edition, Joseph M.Juran and Joseph A. De Feo, ASQ Publications

[8] Root Cause Analysis, the Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.