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

**Subject:** Quality Control and Quality Assurance (MPHQA11503)

**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-ClassRoom 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: 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. | 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. | 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. | 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. | 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 | 12 | 20 |

| | | | |
|---|---|---|---|
| | waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents. | | |

**Continuous Assessment:**

| Sr. No | Active Learning Activities | Marks |
|---|---|---|
| 1. | **Stability Testing Lab Activities**: Faculty provide and allow students to design and conduct stability testing, record observations, and interpret results to understand shelf-life and degradation patterns and students upload on GMIU web portal. | 15 |
| 2. | Faculty will assign students to develop Standard Operating Procedures (SOPs) and review or revise existing quality-related documents, enhancing documentation skills. And students will upload on GMIU web portal. | 15 |
| 3. | Faculty will organize a mock GMP or ISO 9001 audit with students acting as auditors and auditees. Students prepare report and submit to faculty by uploading on GMIU Portal. | 20 |
| | Total | 50 |

**Suggested Specification table with Marks (Theory):75**

| Distribution of Theory Marks (Revised Bloom's Taxonomy) | | | | | | |
|---|---|---|---|---|---|---|
| Level | Remembrance (R) | Understanding (U) | Appiication (A) | Analyze (N) | Evaluate (E) | Create (C) |
| Weightage | 20% | 44 % | 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 | Gain a comprehensive understanding of the core principles, functions, and frameworks of Quality Assurance (QA) and its significance in the pharmaceutical industry. |
| CO2 | Understand and apply regulatory guidelines, including ICH, WHO, FDA, and ISO standards, ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP). |
| CO3 | Design and implement protocols for validation (process, method, cleaning) and qualification (equipment, systems), establishing robust processes for reliable product quality. |

## 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.

## REFERENCES:

[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, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

[6] Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 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, 3rd edition, 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.

[14] Packaging of Pharmaceuticals.

[15] Schedule M and Schedule N.