School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

Pharmaceutical Quality Control & Quality Assurance

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Course Title: Pharmaceutical Quality control & Quality Assurance
Course Type: FELLOWSHIP
Duration: 360 Hours (can be structured as 24 Credits)
Mode: Lectures, Practicals/Hands-on, Project

Overview

Pharmaceutical Quality Control (QC) tests raw materials, in-process samples, and finished products (tablets, parenteral) against pharmacopoeia specs like IP/USP/BP to verify identity, purity, and potency. Quality Assurance (QA) proactively establishes GMP/GLP systems, SOPs, audits, and ICH Q-series guidelines to prevent defects across the product lifecycle. QC is reactive and batch-specific, while QA is preventive and holistic, covering facility design, documentation (CTD/eCTD), and risk management via QbD/TQM. Together, they ensure regulatory compliance (Schedule M, USFDA, WHO) and patient safety in pharma manufacturing. This course structure directly applies these principles through modular training and projects

Objectives:

- 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 and regulatory affairs.
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Course Outcome:

CO No	Course Outcome
CO1	This module covers the concepts, evolution, and scope of Quality Control, Assurance, GMP, ICH Q-series, GLP (including CPCSEA), TQM, QbD, ISO standards, and NABL accreditation principles.
CO2	It explores cGMP guidelines from various regulators, personnel responsibilities and training, plant design/layout, sanitation, sterile areas, warehousing, and equipment/raw material management.
CO3	The focus is on analyzing raw materials, packaging, IPQC, and finished products; developing ICH-based specifications; and QC testing for dosage forms like tablets, capsules, and parenteral per global pharmacopoeias.
CO4	This module details three-tier documentation (policies, procedures, records), SOPs, batch records, audits, electronic data, controlled documents, and regulatory submissions like CTD/eCTD and DMFs.
CO5	It addresses sanitation, processing, packaging, IPQC, product release, deviations, yields, sterile controls, reprocessing, waste handling, and an introduction to intellectual property rights.

Teaching & Learning Methods:

Lectures deliver foundational concepts like GMP, ICH guidelines, and cGMP across modules. Interactive seminars and group discussions foster analysis of TQM, QbD, and regulatory comparisons. Hands-on lab sessions cover raw material analysis, IPQC testing for dosage forms, and documentation exercises like SOPs and batch records. Case studies on NABL accreditation, plant layouts, and manufacturing controls simulate industry scenarios. Assessments via quizzes, audits, and presentations evaluate Bloom's-level outcomes in quality management

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module 1: Quality Assurance and Quality Management (45 hours)

- Concept, evolution, and scopes of Quality Control and Quality Assurance.
- 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.
- Total Quality Management (TQM): Definition, elements, philosophies.
- Quality by design (QbD): Definition, overview, elements of QbD program. ISO 9000 & ISO14000: Overview, Benefits, Elements
- NABL accreditation: Brief introduction and Principles

Module 2: Organization, personnel and Equipment (45 hours)

- cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA.
- 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.
- Equipments and raw materials: Equipments selection, purchase specifications, maintenance.

Module 3: Analysis of raw materials (15 hours):

- 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, parenteral, ophthalmic and surgical products.

Module 4: Documentation in pharmaceutical industry (30 hours):

- Three tier documentation, Policy, Procedures and Work instructions, and records. Basic principles- Maintenance, retention etc.
- Standard operating procedures.
- 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.

Module 5: Manufacturing operations and controls (15 hours):

- 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, and handling of waste and scrap disposal.
- Introduction, scope and importance of intellectual property rights.
- Concept of trademark, copyright and patents.

Practical/Hands-on Component: 8 Credits (120 Lab Hours)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
    - Total Quality Management
    - Six Sigma

- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p
20. Forced degradation studies of some drugs.
21. Interpretation of spectras by IR, NMR and MASS
22. Demonstration of functional groups of the given samples by IR Spectrophotometer.
23. Solubility studies of weakly acidic and weakly basic drugs.

Project: six Credits (90 Self Study/Research Hours)

- **GMP Audit Simulation**: Conduct a mock audit of a pharmaceutical plant layout using Schedule M and USFDA cGMP, documenting deficiencies and corrective actions in a 25-page report.
- **QbD Method Development**: Design a Quality by Design approach for tablet IPQC testing per ICH Q8/Q9, including risk assessment and specification validation with simulated data analysis.
- **Documentation System**: Create a three-tier documentation framework (SOPs, MBR/BMR) for sterile product manufacturing, including eCTD mock submission and audit trail.
- **Raw Material QC Validation**: Validate analytical methods for three raw materials (e.g., APIs per ICH Q2/Q6) against IP/BP/USP, with store management protocols and yield calculations.
- **Manufacturing Controls Case Study**: Analyze cross-contamination risks in parenteral production, proposing change controls, reprocessing SOPs, and IP patent review.

REFERENCES

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.

2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra
4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma
6. A Textbook of Pharmaceutical Quality Assurance by K. P. R. Chowdary, Pharmamed Press.
7. Basic Tests for Pharmaceutical Substances - WHO (1991)
8. The Drugs and Cosmetic Act 1940 by Vijay Malik
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10. SOP Guidelines by D.H. Shah
11. Quality Assurance Guide by OPPI
12. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
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14. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
15. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
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22. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.