

**QUALITY CONTROL AND QUALITY ASSURANCE**  
(MPT 2013)

**Scope**

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, GLP and regulatory affairs.

**Objectives**

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

**THEORY**


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| 1. Concept and Evolution of Quality Control and Quality Assurance<br>Good Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.<br>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.  | 60 Hrs<br>12 Hrs |
| 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. CPCSEA guidelines.  | 12 Hrs           |
| 3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)<br>Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials. | 12 Hrs           |
| 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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.  | 12 Hrs           |
| 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.   | 12 Hrs           |

**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, Excipients 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, 4<sup>th</sup> edition, Susmit Publishers, 2006.
10. QA Manual - D.H.Shah, 1<sup>st</sup> edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control - Sidney H. Willig, Vol. 52, 3<sup>rd</sup> 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. 13.Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.



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