PAPER II: QUALITY ASSURANCE

GOAL:

- To equip student to be professionally competent to achieve global quality standards in the pharmaceutical industry.

OBJECTIVES:

On completion of the course in Quality Assurance, the candidate must be able to:

- Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
- Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
- Understand the importance of effective documentation.

COURSE DESCRIPTION

THEORY **50hrs (2hrs/week)**

1. Concept and evolution of Quality Assurance and Quality Control, cGMP, TQM **(2hr)**
2. **Overview of ICH Guidelines** - QSEM, with special emphasis on Q-series guidelines**(2hr)(Unit 1&2-20marks**
3. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC) and EMEA covering: (70marks)**
   a. **Organization and Personnel :** Responsibilities, training, hygiene**(2hr)**
   b. **Premises:** Location, design, plan and layout, construction, maintenance and sanitation, environmental control – sterile and non-sterile areas, prevention and containment of contamination.(**2hr)**
   c. **Equipment:** Material Make, Selection process through vendor evaluation, purchase specifications, maintenance, Preventive Maintenance Protocol, Automation **(2hr)**
   d. **Raw materials:** Purchase specifications, maintenance of stores, vendor qualification and evaluation. **(2hr)**
   e. **Manufacture and controls of various dosage forms:** Various tiers of documents pertaining to Manufacturing documents, master formula record, and batch manufacturing

record, standard operating procedures for various operations - cleaning, filling, drying, compression, coating, disinfection and sterilization. **(3hr)**

f. **In-process quality controls:** For sterile and non-sterile dosage forms **(2hr)**

g. **Packaging material controls:** Packaging materials and control of packaging materials **(1hr)**

h. **Quality control laboratory responsibilities:** GLP protocols on non-clinical testing control on animal house, data generation, integration and storage, standard test procedure, retention of sample records. CPCSEA guidelines. (**5hr)**

i. **Finished product release:** Quality review and batch release document**. (1hr)**

j. **Warehousing:** Good warehousing practices, cold chain management and materials management.**(1hr)**

k. **Distribution:** Distribution records, handling of returned goods, recovered materials and reprocessing. **(2hr)**

l. **Complaints and recalls:** Evaluation of complaints, recall procedure and documentation. **(2hr)**

m. **Waste and scrap disposal:** Storage and management of scrap, recycling practices, Disposal procedures and records. **(1hr)**

n. Change management, annual product quality review and parametric release**(2hr)**

o. **Audits:** Types of audits, quality audits of manufacturing processes and facilities, audits of quality control **(3hr)**

p. **Documentation -** Good documentation practices, route cause analysis, corrective action preventive action (CAPA), out of specifications (OOS) and out of trend (OOT) **(3hr)**

4. **Clinical studies-** ICH GCP (E6) guidelines, post marketing surveillance, pharmacovigilance, BABE (bioavailability and bioequivalence) studies. **(2hr)**
5. Concepts and management of contract manufacturing (European guidelines)**(2hr)(Unit 4&5-20marks)**
6. Introduction, scope and importance of IPR. Concept of trade mark, copyright and patents**(2hr)**
7. Product registration guidelines – CDSCO, USFDA. **(2hr)(Unit 6&7-15marks)**
8. Concept of ISO 9001:2008, 14000, OSHAS guidelines **(2hr)**
9. Brief concept of IND, NDA, ANDA, SNDA and PAT **(2hr)(Unit 8&9-15marks)**

PRACTICALS **150hrs (6hrs/wk)**

The following exercise to be worked upon along with documentation.

1. Drawing and discussion on plant layouts.
2. Preparation of Master Formula Record.
3. Preparation of Batch Manufacturing Record.
4. Preparation of Quality control records for dosage forms (3Expts)
5. Quality control tests and interpretation of results according to pharmacopoeial specifications and alerts for tablets, capsules, semisolids and parenterals. (6Expts)
6. Standard operating procedures- for operation and calibration of analytical instrument.(5Expts)
7. Standard operating procedures- for operating pharmaceutical machinery. (3Expts)
8. Verification of compendial methods (3Expts)
9. Case studies: IPQA Failure, Deviation OOS, market recalls, complaints investigation, scale up, Corrective action preventive action (CAPA) (any 4Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the internal assessment marks for theory and practicals separately.

FINAL EXAMINATION PRACTICALS:

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment (group discussion/ topic presentation/case study)	Viva-Voce	Total
20	35	25	20	100

REFERENCES :

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3. McCormick K. Quality (Pharmaceutical Engineering Series). Butterworth-Heinemann; 2002.
4. Gad SC. Pharmaceutical Manufacturing Handbook: Production and Processes. John Wiley & Sons; 2008.
5. Willig SH, Stoker JR. Good manufacturing practices for pharmaceuticals: a plan for total quality control. Marcel Dekker; 1997.
6. Signore AA, Jacobs T. Good Design Practices for GMP Pharmaceutical Facilities. Taylor &Francis Group; 2005.
7. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
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9. 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.
10. Kolman J, Meng P, Scott G. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley; 1998.
11. Waller P. An Introduction to Pharmacovigilance. John Wiley & Sons; 2011.
12. Mann RD, Andrews EB. Pharmacovigilance. John Wiley & Sons; 2007.
13. Niazi S. Handbook of Bioequivalence Testing. CRC Press; 2007.
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15. Medina C. Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics. CRC Press; 2004.
16. Swarbrick J. Encyclopedia of Pharmaceutical Technology. Informa Healthcare; 2007.
17. Chalmers AA. International Pharmaceutical Registration. Interpharm Press; 2000.
18. Hoyle D. ISO 9000 Quality Systems Handbook - updated for the ISO 9001:2008 standard. Routledge; 2012.
19. Edwards AJ. ISO 14001 Environmental Certification Step by Step: Revised Edition. Butterworth-Heinemann; 2003.
20. Mantus D. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics. Informa Healthcare USA; 2008.
21. Chalmers AA. International Pharmaceutical Registration. Interpharm Press; 2000.
22. Ganguli P. Intellectual Property Rights. The McGraw.Hill Companies; 2008

Websites:

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2. http://www.ich.org/about/organisation-of-ich.html
3. http://www.ich.org/about/process-of-harmonisation.html
4. http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html
5. http://cdsco.nic.in/html/gmp/schedulem(gmp).pdf
6. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=210
7. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
8. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf
9. http://ori.hhs.gov/documents/WHOHandbookonGCP04-06.pdf

Journals:

1) Indian drugs.
2) International Journal of Pharmaceutical Quality Assurance.
3) Journal of Pharmaceutical Quality Assurance
4) Pharma Pulse.
5) The Quality Assurance Journal.
6) Pharmaceutical Engineering, International Society of Pharmaceutical Engineers.