Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard, Amargadh – Bhichari, Rajkot. Mo. 9099063150, 9727753360

Bachelor of Pharmacy
Subject Code: BP706TT
SEMESTER: VII
Subject Name: Quality Assurance

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course the student shall be able to

1. understand the cGMP aspects in a pharmaceutical industry
2. appreciate the importance of documentation
3. understand the scope of quality certifications applicable to pharmaceutical industries
4. understand the responsibilities of QA & QC departments.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP **Total Quality Management (TQM):** Definition, elements, philosophies **ICH Guidelines**: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines **Quality by design (QbD)**: Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation** : Principles and procedures	10
2.	**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. **Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	10
3.	**Quality Control:** Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	10
4.	**Complaints:** Complaints and evaluation of complaints, Handling of return	8

	good, recalling and waste disposal. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records	
5.	**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management	7

Recommended Books (Latest Editions)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.
4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOME
1	Understand the concept of Quality Assurance & Quality management system, TQM and QbD.
2	Understand the requirement of premises, raw material and equipments.
3	Understand the cGMP aspects in a pharmaceutical industry and Q.C.
4	Appreciate the importance of documentation and handling of complaints.
5	Knowledge regarding to Calibration & Validation, Warehousing.

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	Quality Assurance Guide by organization of Pharmaceutical Products of India.	300/-
2	Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.	5,258/-
3	Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.	1,499/-
4	A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh.	44,921/-
5	How to Practice GMP's – P P Sharma.	2,500/-
6	ISO 9000 and Total QualityManagement – Sadhank G Ghosh.	876/-
7	The International Pharmacopoeia – Vol I, II, III, IV- General Methods	38,650/-

	of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.	
8	Good laboratory Practices – Marcel Deckker Series.	9,321/-
9	ICH guidelines, ISO 9000 and 14000 guidelines (K.P.R choudhary).	4,643/-