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

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: AUDITS AND REGULATORY COMPLIANCE
Subject Code: MQA203T

Scope: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives: Upon completion of this course the student should be able to

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

Teaching scheme and examination scheme:

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

Sr No	Course Contents	Total Hrs
1	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	12
3	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	12
4	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials	12
5	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	12

REFERENCES:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C
2. Pharmaceutical Manufacturing Handbook,Regulations and Quality by Shayne Cox Gad.

Wiley- Interscience, A John Wiley and sons, Inc., Publications
3. Handbook of microbiological Quality control. Rosamund M.Baird, Norman A.Hodges,StephenP. Denyar.CRC Press.2000
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor andFrancis (2005).

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOMES
1	Knowledge about Management of audit.
2	Understand the concept of Role of quality systems and audits in pharmaceutical manufacturing environment.
3	Appreciate the Auditing of vendors and production department.
4	Understand the Auditing of Microbiological laboratory.
5	Knowledge about Auditing of Quality Assurance and engineering department.

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.	41,694/-
2	Pharmaceutical Manufacturing Handbook,Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.	18,245/-
3	Handbook of microbiological Quality control. Rosamund M.Baird, Norman A.Hodges,StephenP. Denyar.CRC Press.2000.	3,074/-
4	Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor andFrancis (2005).	3,500/-