Dr. Rafiq Zakaria Campus
Maulana Azad Educational Trust's
Y. B. CHAVAN COLLEGE OF PHARMACY
(B. Pharm, M. Pharm & Research Centre)
ISO 21001:2018 & ISO 14001:2015 CERTIFIED | NIRF-2022 ALL INDIA RANK 65TH
NAAC ACCREDITATION "A" GRADE WITH 3.23 CGPA SCORE

COURSE MODULE

Program Title	M. Pharmacy
Department	Quality Assurance
Course Title	Audits and Regulatory Compliance

1. **NAME OF INSTITUTION** : Y. B. CHAVAN COLLEGE OF PHARMACY, AURANGABAD

2. **AFFILIATED UNIVERSITY** : DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

3. **DEPARTMENT** : Quality Assurance

4. **PROGRAM TITLE** : M. PHARM.

4.1. Program Specific Outcome:

PSO-1:Highlight advancement in knowledge associated with the quality assurance of Pharmaceuticals, regulatory requirements, Industry associated hazards, audit methodology, product development & technology transfer.

PSO-2:Perform validation of analytical methods, processes, equipment, facilities and prepare documentation as per the Regulatory Standards Leading to Compliance of cGMP.

PSO-3: Independently carry out research work utilizing modern tools, problem analysis skills and analytical skills.

PSO-4:Apply the Quality control and Quality assurance concepts throughout product life cycle.

PSO-5:Analyze the application-based of emerging quality building concepts (QbD) in drug development

5. COURSE SPECIFICATION :

5.1.Course Identification and General Information

a. Course Title:	**Audit and Regulatory Compliance**	
b. Course Number/Code	MPA 203T	
c. Credit Hours	Theory	Practical
	60	---
d. Study level/semester at which this course is offered	Semester II	
e. Pre-requisite	Basic knowledge of ICH guidelines, manufacturing of dosage forms in industry, good manufacturing practices, basics of Microbiology.	
f. Co-requisite		
g. Program in which the course is offered	M. Pharm.	
h. Language of teaching the course	English	
i. Prepared by	Dr. Furquan Khan, Sarfaraz Khan	
j. Approved by HOD	Dr. J. N. Sangshetti	

5.2.Course Description:

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

5.3.Course Objectives:

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

6.0.Course Outcomes (COs) : (Min. 4 and Max. 6)

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO-1	Discuss briefly about audit objectives and their management
CO-2	Understand the role of quality systems and audits in pharmaceutical manufacturing environment
CO-3	Frame a checklist for auditing pharmaceutical industries and learn about audit report
CO-4	Understand the basics of auditing various engineering systems in a manufacturing plant
CO-5	Learn the requirements for auditing vendors supplying various materials and equipment's

6.1. Knowledge and Understanding

(Alignment of PSOs to COs)

Course Code	Program Specific Outcome				
	PSO-1	**PSO-2**	**PSO-3**	**PSO-4**	**PSO-5**
CO-1	**3**	**1**	**-**	**-**	**-**
CO-2	**3**	**2**	**-**	**2**	**-**
CO-3	**3**	**2**	**-**	**2**	**-**
CO-4	**2**	**1**	**-**	**-**	**-**
CO-5	**2**	**2**	**-**	**2**	**-**

Correlation levels 1, 2 or 3 as defined below:

2: Moderate (Medium); 3: Substantial

1: Slight (Low); (High); If there is no correlation, put '-'

6.2.Teaching and Assessment Methods for achieving learning outcome:

Teaching Strategies(methods)/Tools used	Methods of Assessment
Lectures (Constructivist learning) **Collaborative learning (Discussion)** **Project based Learning** **Blended learning** **Inquiry based learning** **Flash cards** **Video** **Equipment models**	**Formative Assessment** **Case study** **Class test** **Multiple choice questions** **Assignments** **Seminar** **Viva Voce** **Synopsis** **Tutorials** **Summative Assessment**

6.3.Tools for the Teaching and learning

Theory subjects	Practical Subjects
• **PowerPoints presentation** • **Videos** • **Flash Card** • **Models** • **Software** • **Charts** • **Smart Boards** • **White boards** • **Online Platform**	• **White boards** • **Glassware** • **Chemicals** • **Instruments** • **Equipment** • **Software** • **Models** • **Plants/Crude Drugs** • **Animal**

6.4.COURSE CONTENT

6.1. Theoretical Aspect:

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
1	**Unit I**	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	**3**	**12**
2	**Unit II**	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.	**3**	**12**
3	**Unit III**	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.	**3**	**12**
4	**Unit IV**	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	**3**	**12**
5	**Unit V**	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	**3**	**12**
	TOTAL		**15**	**60**

7.0. ASSESSMENT MECHANISM:

Sr. No.	Assessment Mechanism	Week due	Marks	Proportion of Final Assessment
1	Continuous Assessment (Theory)	2nd week of every month	10	10%
2	Sessional (Internal Theory exam)	As per schedule of examination	15	15%
3	Continuous Practical Assessment (Sessional Practical exam)	Weekly during practical	-	-
4	Sessional (Internal Practical exam)	As per schedule of examination	-	-
5	Final exam (theory)	As per University at end of course	75	75%
6	Final exam(practical)		-	-
Total			100	**100%**

8.0.STUDENT SUPPORT:

Office hours/week	Other procedures
Two hours minimum	

9.0.TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	**4:00-5:00**	**4:00-5:00**	**4:00-5:00**	**4:00-5:00**	**4:00-5:00**	**4:00-5:00**

10.0. LEARNING RESOURCES:

Sr.No.	Title of Learning Material	Details
1	Text books	• Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C. • Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons,

		Inc., Publications.
2	Reference material	• Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000. • Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
3	E-materials and websites	https://www.fda.gov/drugs/guidance-compliance-regulatory-information
4	Other learning material	Power point presentation, Notes

11.0. FACILITIES REQUIRED:

Sr.No.	Particular of Facility Required
1	Lecture Rooms (capacity for 60 students)
2	Computing resources: PC with latest version and hardware/software and utilization of open source and licensed application software

12.0. COURSE IMPROVEMENT PROCESSES:

12.1. Strategies for obtaining student feedback on effectiveness of teaching:

Course delivery evaluation by students using: Questionnaire forms and onlinequestionnaires

12.2. Other strategies for evaluation of teaching by the instructor or by the department:

Periodic review by Academic Planning & Monitoring Committee and departmental review committee, Observations and assistance of colleagues, External assessments by advisors/ examiners and auditors.

12.3. Process for improvement of teaching:

Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

12.4. Describe the planning procedures for periodically reviewing of course effectiveness and planning for improvement:

Periodic review by departmental meeting , Review of course delivery and outcome through assessment and feedback from all stake holders.

12.5. Course development plans:

Provide inputs for course improvement and update to University Course development Committees (Board of Studies)

13.0. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr. Furquan khan
Location	Department of Quality Assurance
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Office Hours	10:00 AM to 5:00 PM

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