COURSE MODULE

Program Title	M. Pharmacy
Department	Quality Assurance
Course Title	Hazards and Safety Management

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

5.1.Course Description:

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

5.2.Course Objectives:

After completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management

- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere

5. COURSE SPECIFICATION :

5.3.Course Identification and General Information

a. Course Title:	**Quality Management Systems**	
b. Course Number/Code	MQA 201T	
c. Credit Hours	Theory	Practical
	60	
d. Study level/semester at which this course is offered	Semester II	
e. Pre-requisite	Basic knowledge of Environment ecosystem, renewable and non renewable sources, Types of hazards, risk management	
f. Co-requisite	-	
g. Program in which the course is offered	M Pharm	
h. Language of teaching the course	English	
i. Prepared by	Dr. J. N. Sangshetti	
j. Approved by HOD		

5.4.Course Description:

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

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

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO-1	Define and understand the concept of ecosystem and environmental hazards
CO-2	Describe different air based hazards and chemical hazards, their control and regulation
CO-3	Explain different fire protection systems and the management of fire in industry
CO-4	Learn different ICH guidelines related to risk assessment and quality risk management

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**	**1**	**1**	**-**
CO-2	**3**	**1**	**1**	**-**	**1**
CO-3	**3**	**-**	**1**	**-**	**-**
CO-4	**3**	**-**	**1**	**1**	**1**
CO-5	**3**	**3**	**1**	**2**	**3**

Correlation levels 1, 2 or 3 as defined below:

1: Slight (Low);

2: Moderate (Medium);

3: Substantial (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**	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes	**03**	**12**
2	**Unit II**	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.	**03**	**12**
3	**Unit III**	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.	**03**	**12**
4	**Unit IV**	Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosionelectricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.	**03**	**12**
5	**Unit V**	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk	**03**	**12**

		assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.		
	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	4%
2	Sessional (Internal Theory exam)	As per schedule of examination	15	6%
3	Continuous Practical Assessment (Sessional Practical exam)	Weekly during practical	20	8%
4	Sessional (Internal Practical exam)	As per schedule of examination	30	12%
5	Final exam (theory)	As per University at end of course	75	30%
6	Final exam(practical)		100	40%
Total			150	**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	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**

10.0. LEARNING RESOURCES:

Sr.No.	Title of Learning Material	Details
1	Text books	1. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications 2. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore 3. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety. 4. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
2	Reference material	1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000 2. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press
3	E-materials and websites	ICH Guidelines
4	Other learning material	-

11.0. FACILITIES REQUIRED:

Sr.No.	Particular of Facility Required
1	Lecture Rooms (capacity for 60 students)
2	Laboratory (capacity for 20 students)
3	Computing resources: PC with latest version and hardware/software and utilization of open source and licensed application software
4	Other resources: Appropriate laboratory tools, Chemicals, Glass ware, Apparatus, Instrumentation

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 online questionnaires

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. Jaiprakash Sangshetti
Location	QA- M.Pharm,
Contact Detail (e-mail &cell no.)	jnsangshetti@rediffmail.com, 9975042784,
Office Hours	10:00 AM to 5:00 PM