



# **C. U. SHAH UNIVERSITY**

## **Wadhwan City**

**FACULTY OF:** Pharmaceutical Sciences

**DEPARTMENT OF:** Pharmaceutical Quality Assurance

**SEMESTER: II**

**CODE:** MQA 201T

**NAME:** Hazards and Safety Management

### **Teaching & Evaluation Scheme:-**

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme										Total
		Th	Tu	Pr	Total		Theory				Practical						
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam				
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs			
MQA201T	Hazards and Safety Management	4	0	0	4	4	15	1	75	3	--	--	--	--	100		
							10 (CM)	--									

### **SCOPE:**

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.

### **OBJECTIVES:**

At 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.

### **COURSE OUTLINE:**

Sr. No	Course Content	Hours
1	<b>Multidisciplinary nature of environmental studies:</b> 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	12



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	<b>Ecosystems:</b> Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	
2	<b>Air based hazards:</b> 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.	12
3	<b>Chemical based hazards:</b> 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.	12
4	<b>Fire and Explosion:</b> 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 explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems - relief valves, flares, scrubbers.	12
5	<b>Hazard and risk management:</b> Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk 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.	12
Total		60

### **REFERENCES:**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press.



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**FACULTY OF:** Pharmaceutical Sciences

**DEPARTMENT OF:** Pharmaceutical Quality Assurance

**SEMESTER: II**

**CODE:** MQA 202T

**NAME:** Pharmaceutical Validation

### **Teaching & Evaluation Scheme:-**

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
		Th	Tu	Pr	Total		Theory				Practical				
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MQA202T	Pharmaceutical Validation	4	0	0	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

### **SCOPE:**

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

### **OBJECTIVES:**

At completion of this course, it is expected that students will be able to understand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

### **COURSE OUTLINE:**

Sr. No	Course Content	Hours
1	<p><b>Introduction to validation:</b> Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification &amp; Validation process and Validation Master Plan.</p> <p><b>Qualification:</b> User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).</p>	10



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2	<p><b>Qualification of manufacturing equipment:</b> Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.</p> <p>Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.</p>	10
3	<p><b>Qualification of laboratory equipments:</b> Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus</p> <p>Validation of Utility systems: Pharmaceutical water system &amp; pure steam, HVAC system, Compressed air and nitrogen.</p>	10
4	<p><b>Process Validation:</b> Concept, Process and documentation of Process Validation. Prospective, Concurrent &amp; Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.</p> <p>Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.</p>	10
5	<p><b>Cleaning Validation:</b> Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).</p> <p>Validation of facilities in sterile and non-sterile plant.</p> <p>Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP</p>	10
6	<p><b>General Principles of Intellectual Property:</b> Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.</p>	10
Total		60



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### **REFERENCES:**

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press



# **C. U. SHAH UNIVERSITY**

## **Wadhwan City**

**FACULTY OF:** Pharmaceutical Sciences

**DEPARTMENT OF:** Pharmaceutical Quality Assurance

**SEMESTER: II**

**CODE:** MQA 203T

**NAME:** Audits and Regulatory Compliance

### **Teaching & Evaluation Scheme:-**

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme										Total
		Th	Tu	Pr	Total		Theory				Practical						
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam				
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs			
MQA203T	Audits and Regulatory Compliance	4	0	0	4	4	15	1	75	3	--	--	--	--	100		
							10 (CM)	--									

### **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

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

### **COURSE OUTLINE:**

Sr. No	Course Content	Hours
1	<b>Introduction:</b> Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	<b>Role of quality systems and audits in pharmaceutical manufacturing environment:</b> 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	<b>Auditing of vendors and production department:</b> Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12



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4	<b>Auditing of Microbiological laboratory:</b> Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12
5	<b>Auditing of Quality Assurance and engineering department:</b> Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12
Total		60

**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, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).



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**FACULTY OF:** Pharmaceutical Sciences

**DEPARTMENT OF:** Pharmaceutical Quality Assurance

**SEMESTER: II**

**CODE:** MQA 204T

**NAME:** Pharmaceutical Manufacturing Technology

### **Teaching & Evaluation Scheme:-**

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
		Th	Tu	Pr	Total		Theory				Practical				
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MQA204T	Pharmaceutical Manufacturing Technology	4	0	0	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

### **SCOPE:**

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

### **OBJECTIVES:**

At completion of this course it is expected that students will be able to understand,

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

### **COURSE OUTLINE:**

Sr. No	Course Content	Hours
1	<b>Pharmaceutical industry developments:</b> Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. <b>Plant layout:</b> Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. <b>Production planning:</b> General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	12
2	<b>Aseptic process technology:</b> Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). <b>Advanced sterile product manufacturing technology :</b> Area planning &	12





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	<p>environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities &amp; utilities equipment location, engineering and maintenance.</p> <p><b>Process Automation in Pharmaceutical Industry:</b> With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals &amp; Large Volume Parenterals (SVP &amp; LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.</p>	
3	<p><b>Non sterile manufacturing process technology:</b> Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed &amp; coated), Capsules (Hard &amp; Soft).</p> <p>Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.</p> <p>Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.</p>	12
4	<p><b>Containers and closures for pharmaceuticals:</b> Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.</p>	12
5	<p><b>Quality by design (QbD) and process analytical technology (PAT):</b> Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, and Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.</p>	12
Total		60



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### **REFERENCES:**

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy 3<sup>rd</sup> ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5<sup>th</sup> ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2<sup>nd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4<sup>th</sup> ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3<sup>rd</sup> Edition. Bhalani publishing house Mumbai
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1<sup>st</sup> Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.



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**FACULTY OF:** Pharmaceutical Sciences

**DEPARTMENT OF:** Pharmaceutical Quality Assurance

**SEMESTER: II**

**CODE:** MQA 205P

**NAME:** Quality Assurance Practical - II

### **Teaching & Evaluation Scheme:-**

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme									
		Th	Tu	Pr	Total		Theory				Practical				Total	
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam			
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs		
MQA 205P	Quality Assurance Practical-II	--	--	12	12	6	--	--	--	--	30	6	100	6	150	
											20 (CM)	--				

### **PRACTICALS:**

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO<sub>2</sub> using Colorimetric method
7. Qualification of following Pharma equipment
  - a. Autoclave
  - b. Hot air oven
  - c. Powder Mixer (Dry)
  - d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area.
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT