Table - 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Common subjects for all specializations except for Pharmaceutical Regulatory Affairs (MRA) and Pharmacy Practice (MPP)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory) (MPAT101T) **60 hours**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs.

Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc.

Simple structure elucidation problems may be included based on UV-IR-NMR data.

Objectives

Upon completion of the course the student shall be able to

- Analytical techniques for identification, characterization and quantification of drugs
- Theoretical and practical skills of instrument handling and use.
- Structural Elucidation of organic compounds using spectroscopic tools

UNIT-1

a) **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b) **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **10 hrs**

c) **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy.

d) **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.

UNIT-II

- **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 hrs**

UNIT-III

- **Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry **12 hrs**
- **Simple structure elucidation problems based on UV, IR, NMR and Mass data.**

UNIT-IV

Chromatography: Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **10 hrs**

a) High Performance Liquid chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography

d) Gas chromatography
e) Ultra High Performance Liquid chromatography
f) Affinity chromatography
g) Gel Chromatography

UNIT-V

a) **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

10 hrs

b) **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.

UNIT - VI

Thermal Techniques:

a) **Thermogravimetric analysis (TGA):** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
b) **Differential scanning calorimetry (DSC):** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.
c) **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

08 hrs

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series
8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.
9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

QUALITY MANAGEMENT SYSTEMS (MQA 102T)	60 Hrs
Scope This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the Pharmaceutical industries. **Objectives** **Upon completion of the course the student shall be able to** • The importance of quality • Tools for quality improvement • Analysis of issues in quality • Quality evaluation of pharmaceuticals • Stability testing of drug and drug substances • Statistical approaches for quality	
COURSE CONTENT	
UNIT-I • **Introduction to Quality: Evolution of Quality** • **Definition of Introduction to Quality**: Evolution of Quality, Definition of Quality, Dimensions of Quality • **Quality as a Strategic Decision**: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies. • **Cost of Quality**: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.	**08 Hrs**
UNIT-II • **Pharmaceutical quality Management**: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	**16 Hrs**
UNIT-III • **Six System Inspection model** : Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self inspection. • **Quality systems**: Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), • **Complaints** - evaluation and handling, Investigation and determination	**12 Hrs**

of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	
UNIT-IV • **Drug Stability**: ICH guidelines for stability testing of drug substances and drug products. • Study of ICH Q8, Quality by Design and Process development report • **Quality risk management**: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	**12 Hrs**
UNIT-V • **Statistical Process control (SPC)**: Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	**08 Hrs**
UNIT-VI • **Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking**: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	**04 Hrs**

REFERENCES

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.
3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.
4. James W. Fairfield-Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.
5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.
6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)	60 Hrs
Scope This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs. **Objectives** **Upon completion of this course the student should be able to** • Understand the cGMP aspects in a pharmaceutical industry • To appreciate the importance of documentation • To understand the scope of quality certifications applicable to Pharmaceutical industries To understand the responsibilities of QA & QC departments.	
UNIT-I • **Introduction**: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	**12 Hrs**
UNIT-II • **cGMP guidelines according to schedule M, USFDA (inclusive ofCDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering**: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	**12 Hrs**
UNIT-III • Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 126 In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	**12 Hrs**
UNIT-IV • **Documentation in pharmaceutical industry**: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. • Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non	**16 Hrs**

regulated markets.	
UNIT-V • **Manufacturing operations and controls**: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.	**08 Hrs**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Sandy Weinberg, Good Laboratory Practice Regulations, 2nd Edition, Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. Sharma P. P., How to Practice GMP's Vandana Publications, Agra, 1991, 127.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Allen F. Hirsch, Good laboratory Practice Regulations, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. Deshpande, Nilesh Gandhi, The Drugs and Cosmetics Act 1940, 4th edition, Susmit Publishers, 2006.
10. D.H. Shah, QA Manual, 1st edition, Business Horizons, 2000.
11. Sidney H. Willig, Good Manufacturing Practices for Pharmaceuticals a plan for total quality control, Vol. 52, 3rd edition, Marcel Dekker Series.
9. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
12. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
13. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)	60 Hrs
Scope This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following Candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in Manufacturing places. **Objectives** **Upon completion of this course the student should be able to** • To understand the new product development process • To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D • To elucidate necessary information to transfer technology of existing products between various manufacturing places	
UNIT-I • **Principles of Drug discovery and development**: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.	**12 Hrs**
UNIT-II • **Pre-formulation studies**: Introduction / concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. • **Solubility, Methods to improve solubility of Drugs**: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	**12 Hrs**
UNIT-III • **Pilot plant scale up** : Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	**12 Hrs**
UNIT-IV • **Pharmaceutical packaging**: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. **Quality control test**: Containers, closures and secondary packing materials.	**12 Hrs**
UNIT-V • **Technology transfer**: Development of technology by R & D, Technology transfer from R & D to production, Optimization and	**12 Hrs**

Production, Qualitative and quantitative technology models. • **Documentation in technology transfer**: Development report, technology transfer plan and Exhibit.	

REFERENCES

1. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd E/d Bhalani publishing house Mumbai.
4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Tablets Vol. I, II, III, 2nd E/d. (1989), Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea & Febriger, Philadelphia.
6. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.
7. Abdou H.M, Dissolution, Bioavailability and Bio-Equivalence, Mack Publishing company, Eastern Pennsylvania.
8. Alfonso & Gennaro, Remingtons Pharmaceutical Sciences, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.
10. D.A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York. 130

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on –
   - Total Quality Management
   - Six Sigma
   - Change Management/ Change control. Deviations
   - Out of Specifications (OOS)
   - Out of Trend (OOT)
   - Corrective & Preventive Actions (CAPA)
   - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)	60 Hrs

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.

UNIT-I • Multidisciplinary nature of environmental studies Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • **Ecosystems**: Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	**12 Hrs**
UNIT-II • Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.	**12 Hrs**
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, MSDS, Labelling guidelines, Management of over-Exposure to chemicals and TLV concept, Disposal of hazardous material.	**12 Hrs**
UNIT-IV • **Fire and Explosion**: Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations • **Fire protection system**: Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers.	**12 Hrs**

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 assessment and Risk management methods and Tools, Preliminary hazard analysis • 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 Hrs**

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. T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5. Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6. H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982.
7. C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
8. Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, An imprint of Elsevier Science.

PHARMACEUTICAL VALIDATION (MQA 202T)	60 Hrs
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	
UNIT-I • **Introduction to validation**: 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 & Validation process and Validation Master Plan. • **Qualification**: 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).	**10 Hrs**
UNIT-II • **Qualification of manufacturing equipment**: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization / Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. • **Qualification of analytical instruments**: UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.	**10 Hrs**
UNIT-III • **Qualification of laboratory equipments**: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus • **Validation of Utility systems**: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	**10 Hrs**
UNIT-IV • **Process Validation**: Concept, Process and documentation of Process Validation. Prospective, Concurrent & 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. • **Analytical method validation**: General principles, Validation of analytical method as per ICH guidelines and USP.	**10 Hrs**
UNIT-V	**10 Hrs**

• Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. • **Computerized system validation**: Electronic records and digital signature - 21 CFR Part 11 and GAMP	
UNIT-VI • General Principles of Intellectual Property: 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.	**10 Hrs**

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

12. LeBlanc D. A. Validated Cleaning Technologies for Pharmaceutical Manufacturing, Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE (MPA 203T) — 60 Hrs

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

UNIT-I

- **INTRODUCTION**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies — **12 Hrs**

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. — **12 Hrs**

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. — **12 Hrs**

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. — **12 Hrs**

UNIT-V

- **Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. — **12 Hrs**

REFERENCES

1. Karen Ginsbury and Gil Bismuth,Compliance auditing for Pharmaceutical Manufacturers. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Shayne Cox Gad, Pharmaceutical Manufacturing Handbook, Regulations and Quality, Wiley-Interscience, A John Wiley and sons, Inc. Publications.
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of microbiological Quality control,CRC Press. 2000.
4. C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden, Laboratory auditing for quality and regulatory compliance. Donald Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

60 Hrs

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

UNIT-I

- **Pharmaceutical industry developments**: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing.
- **Plant layout**: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. **12 Hrs**
- **Production planning**: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT-II

- **Aseptic process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).
- **Advanced sterile product manufacturing technology** : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **12 Hrs**
- **Process Automation in Pharmaceutical Industry**: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & 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.

UNIT-III

- **Non sterile manufacturing process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). **12 Hrs**
- 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. Coating technology**: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT-IV

- **Containers and closures for pharmaceuticals**: 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. **12 Hrs**

UNIT-V

- **Quality by design (QbD) and process analytical technology (PAT)**: Current approach and its limitations. Why QbD is required, Advantages,
- **Elements of QbD, 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. **12 Hrs**
- **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.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th 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) 3rd 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, 1st 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.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Identification of antibiotic residue by TLC
3. Estimation of Chlorine in Work Environment.
4. Sampling and analysis of SO_2 using Colorimetric method
5. Qualification of following Pharma equipment
   a) Autoclave b) Hot air oven
   c) Powder Mixer (Dry) d) Tablet Compression Machine
6. Validation of an analytical method for a drug
7. Process validation of any non-sterile or sterile dosage form
8. Validation of a processing area
9. Qualification of at least two analytical instruments
10. Cleaning validation of one equipment
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, riability Apparatus, Disintegration Tester)
12. Check list for Bulk Pharmaceutical Chemicals vendors
13. Check list for tableting production.
14. Check list for sterile production area
15. Check list for Water for injection.
16. Design of plant layout: Sterile and non-sterile
17. Case study on application of QbD
18. Case study on application of PAT