M. PHARM. – QUALITY ASSURANCE & REGULATORY AFFAIRS
COURSE STRUCTURE (w. e. f. 2011-12)

I SEMESTER					
Course No.	**Title**	**L(h)**	**T(h)**	**P(h)**	**C**
	THEORY				
MPS1101	Advanced Instrumental Analysis (AIA)	3	1	0	4
MPS1103	Product Development & Formulation (PDF)	3	0	0	3
MPS1151	Introduction to Quality Assurance & Regulatory Affairs	3	0	0	3
	LAB				
MPS1112	Modern Analytical Techniques Lab	0	0	3	2
MPS1132	Preclinical Studies Lab	0	0	3	2
	BREADTH				
MMA1101	Applied Science: Biostatistics	3	0	0	3
	Breadth Paper	3	0	0	3
	Total	**15**	**1**	**6**	**20**
	Total Hours	**22**			
II SEMESTER					
	THEORY				
MPS2101	Biopharmaceutics & Pharmacokinetics (BP)	3	0	0	3
MPS2151	Quality Assurance & Process Validation	3	0	0	3
MPS2153	Regulatory Affairs & Documentation	3	0	0	3
	ELECTIVE(ANY ONE)				
MCR3101 **MPSE111** **MPSE113**	Pharmacovigilance Drug Regulatory Affairs Quality Assurance & Management	3	0	0	3
	LAB				
MPS2152	Regulatory Affairs & Documentation Workshop	0	0	4	4
MPS2154	Quality Assurance & Quality Control Lab	0	0	4	4
	Total	**12**	**0**	**12**	**20**
	Total Hours	**24**			
III SEMESTER					
MPS3151	THESIS	-	-	-	**15**
IV SEMESTER					
MPS4151	THESIS	-	-	-	**20**

Total Credit - 75

Note:
L: Lecture; T: Tutorial; P: Practical; C: Credit
MPS: M. Pharm. Pharmaceutical Sciences Core
MPSE: M. Pharm. Pharmaceutical Sciences ELECTIVE
MMA: Mathematics
MCR: M.S. Pharmaceutical Sciences Core

M. PHARM I SEMESTER
MPS1101: ADVANCED INSTRUMENTAL ANALYSIS (AIA) (4 CREDITS)

1. Analytical Application of Absorption Spectra: 3h
   Absorptiometric assay of Organic Compounds, Structural Analysis.
2. Infrared Spectrophotometry: 6h
   Qualitative uses; Interpretation of I.R. Spectra, Quantitative analysis**.**
3. NMR-Spectroscopy: 8h
   The NMR-Signal, Instrumentation practical consideration, chemical shift, spin-spin coupling, Structure elucidation, investigation of dynamic properties of molecules, quantitative analysis.
4. Mass Spectrometry: 8h
   Theory instrumentation, practical consideration, structure elucidation, detection of impurities, quantitative analysis, application to determination of structure, the gas chromatograph mass spectrometer combination.
5. Optical Rotatory Dispersion: 3h
   Terminology Plain Curves, Rotatory dispersion of ketones, The Axial Haloketone Rule, Octant Rule.
6. Recent trends in chromatography with reference to analysis of drugs and related substances: HPLC, UPLC, HPTLC , GC and hyphenated techniques(LC-MS/ LC-MS/MS).
   8h
7. Theory, Instrumentation and Applications of: 8h
   Thermogravimetric Analysis (TGA), Differential thermal analysis (DTA), Differential Scanning Calorimeter (DSC), X ray Diffraction(XRD).

BOOKS RECOMMENDED:

1. Practical Pharmaceutical Chemistry (part II) by Beckett and Stenlake.
2. Optical Rotatory Dispersion by C. D.jerassi (For ORD).
3. Indian Pharmaceutical (Biological & Microbiological Assay).
4. British Pharmaceutical (Biological & Microbiological Assay).
5. UV and Visible Spectroscopy, Chemical Application-C.N. R. Rao.
6. Spectrometric identification of organic compound- Silverstein.
7. Chemical application of IR spectroscopy – C.N.R. Rao.
8. Physical Methods of Organic Chemistry- Weissberger.
9. Interpretation of Mass Spectra of organic compounds-B. Kienicz, C. Djerassi.
10. Application of NMR Spectra to Organic Chemistry-Jackmann.
11. Instrumental Methods of Analysis- Willard.
12. Applications of Absorption spectroscopy of organic compounds – John R. Dyer.
13. Pharmaceutical Experiments on isolated preparations by the staff of the Department of Pharmacology, University of Edinburg.
14. Pharmacological Techniques in Drug evaluation, Vol. 1&2 by Peter E. Siegler, J.H. Meyer.
15. Lewis Pharmacology- James Crossland.
16. Fundamental of Experimental Pharmacology- M.N. Ghosh.
17. Indian Pharmacopoeia.
18. British Pharmacopoeia.
19. United States Pharmacopoeia .
20. Assay of Vitamins by Haskmi

MPS1103: PRODUCT DEVELOPMENT & FORMULATION (3 CREDITS)

Pre-Formulation:

A consideration of physio-chemical charecterstics of medicinal agents in their dosage form.

Physical characteristics:

Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation,wettingof solids, flow characteristics, compressibility, Rheology, Partition coefficient.

Chemical Characteristics:

Degradation-Hydrolytic, oxidative, reductive, photolytic.

Biopharmaceutical Characteristics:

Liquid solubility, dissociation constant, dissolution rate, bulk solubility and diffusibility in diffusion layer, drug stability in G.I.track, complexation.

Stability Testing & Dating of Solid and Liquid Dosage Forms:

Difference in approaches for stability testing of solid and liquids, Kinetic principles, Physical & Chemical stability testing of Pharmaceutical dosage forms and packages.

Quality Control- Process & Dosage forms:

Sources of variations, control of variation-material control and manufacturing control.
Statistical quality control- sampling, testing programme and methods.

Pilot Plant Scale-up Techniques:

Evaluation of formula, equipments, raw materials, process, stability, uniformity. Techniques related to tablets including coating, capsules, liquid dosage forms & semi-solid dosage forms.

Antioxidants Preservatives Colorants and flavourants

Product Development Approach for the following Dosage Forms:

Tablets, Capsules, Sustained release Medication, Injectables Ointments.

Books Recommended:

1. Remington's Pharmaceutical Sciences by Osol et.el.
2. Theory & Practice of Industrial Pharmacy by Lachman.
3. Pharmaceutics of Solids and Solid dosage form by Cartensens.
4. Advance in Pharm. Sciences by bean & Beckett.
5. Pharmaceutical technology by Parrot.

MPS1151: INTRODUCTION TO QUALITY ASSURANCE & REGULATORY AFFAIRS (3 CREDITS)

I. Basic concepts of Quality control & Quality Assurance, Total Quality Management, Philosophy of GMP, cGMP, GLP, ISO. Introduction of ICH guidelines.

II. Organization & functions of the Federal Food & Drug Administration of USA. Federal trade commission Act. The Environmental Pollution Control Act, Other laws related to pharmacy including Tort law, Contract law etc.

III. A detailed study of Food & Drug Laws affecting drug products design, manufacture and distribution in USA.
- The Federal Food. Drugs & Cosmetics Act 1938.
- Druham – Humphrey Amendment 1951.
- Kefauver – Harris Amendment 1962.
- The Drug Listing Act 1972
- Prescription Drug Marketing Act 1987.

IV. Concept and historical development of pharmaceutical product registration. Effect of GATT and WTO on commerce of pharmaceuticals. Introduction to Intellectual Property Rights.

V. Globalization of drug industries, Export Import Policy of drugs, WHO – certification, Trademarks and copyrights.

VI. Regulation & licensing of drugs & cosmetics – recent amendments and other relevant rules. Consumer protection, Factory Act, Loan license.

Recommended Books

- Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
- FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
- Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
- Pharmaceutical Patent Law by John R. Thomas

MPS1112 MODERN ANALYTICAL TECHNIQUES LAB (2 Credits)

1. Determination of λmax. Of given sample using Spectrocolorimeter and validity of Lambert-Beer's Law.
2. Assay of Paracetamol Tablets using UV-Spectrophotometer.
3. Assay of Quinine Sulphate using UV-Spectrophotometer.
4. Assay of Nimesulide Tablets using UV-Spectrophotometer.
5. Assay of Riboflavin Tablets using Fluorescence Spectrophotometer.
6. Assay of Quinine Sulphate tablets using Fluorescence Spectrophotometer.
7. Determination of of Na^+ & K^+ using Flame Photometer.
8. Determination of Dextrose in Dextrose Injection using Polarimeter.
9. Determination of α-Amino Acid using pH-Meter.
10. Assay of Paracetamol in the sample using HPLC.
11. Demonstration of functional groups of the given samples I.R.Spectrophotometer.
12. Assay of Paracetamol in the sample using HPTLC.

MPS1132: PRECLINICAL STUDIES LAB (2 Credits)

1. Experimental Techniques to evaluate the various classes of drugs (in vivo studies) (at least 10-12 experiments).

   A. Drugs acting on GIT: - General screening methods of ulcer activity, intestinal motility, & anti-diarrhoeal
   B. Experiments on toxicology: - Oral, Parentral & skin acute toxicity test.
   C. Experiments on Analgesic & Antipyretic drugs.

Reference:

1. Biological standardization by J.H. Burn, D.J. Finney & L.G. Goodwin.
2. I.P. & B.P.
3. Screening Methods in Pharmacology – R.A. Turner.
4. Evaluation of drug activities by Laurance & Bacherce.
5. Methods in Pharmacology by Arnold Schwartz.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
7. Fundamental of Experiment Pharmacology – M.N. Gl.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
9. Drug Discovery & Evaluation by Vogel HG.
10. Animal Model in Toxicology by Shayne Cox Gad & Christopher P, Chengelis.
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.

MPS2101: BIOPHARMACEUTICS & PHARMACOKINETICS (3 CREDITS)

I. **BIOPHARMACEUTICAL CONSIDERATIONS IN DRUG PRODUCT DESIGN**

1. **Factors Influencing Dosage Form Design**:
   - i) Rate-Limiting step in Drug Absorption
   - ii) Biopharmaceutical Aspects
   - iii) Patient Considerations
   - iv) Manufacturing Considerations
2. **Factors Influencing Drug Dissolution/Bioavailability:**
   - i) Physico-Chemical
   - ii) Pharmaceutical, and
   - iii) Formulation
3. **Rate –Limiting Step in Bioavailability:**
   - i) Disintegration – in vitro, in -vivo
   - ii) *in-vitro* Dissolution Testing
   - iii) *in-vitro* Dissolution to *in-vivo* Absorption correlation including its failure.
   - iv) Dissolution Testing in lieu of Bioavailability Studies.

II. **BIOAVAILABILITY & BIOEQUIVALENCE**

1. Definitions of Related Terms (*UG)
2. Purpose of Bioavailability Studies (* UG)
3. Relative & Absolute Bioavailability
4. Bioavailability Assessment
5. Bioequivalence Studies
   - i) Design of Study ii) Statistical Evaluation
6. Waiver of *in-vivo* Bioavailability & Bioequivalence
7. Ranking of Drugs and Several Formulations of the Drug

III. **DRUG DISTRIBUTION & ELIMINATION**

1. Physiological Factors Influencing Drug Distribution
2. Protein Binding
3. Volume of Distribution
4. Physiological Approach to Drug Elimination
5. Clearance Concepts
6. Dependence of Drug Elimination Kinetics on Clearance & Distribution

IV. **PHARMACOKINETICS (based on Plasma & Urinary Excretion Data of Intact Drug)**

1. Compartmental Approach:
   - i) One Compartmental Model
   - ii) Two Compartmental Model

2. Nonlinear (Dose Dependent) Pharmacokinetics:
   - i) Michaelis-Menten Concept
   - ii) Pharmacokinetics of Drugs under Such Situations
     (one compartment model – single dose):
     a) Intravenous Administration, and

b) First-Order Absorption

iii) Time-Dependent Pharmacokinetics

iv) Nonlinear Pharmacokinetics due to Protein Binding

v) Pitfalls in Pharmacokinetic Modelling

BOOKS RECOMMENDED

1. Wagner : Biopharmaceutics & Relevant Pharmacokinetics, Drug Intelligence Publication, 1971.
2. Swarbrick:Current Concepts in Pharmaceutical Sciences (Biopharmaceutics), Lea & Febiger, 1970.
3. Swarbrick: Current Concepts in Pharmaceutical Sciences (Dosage Form Design & Bioavailability), Lea & Febiger, 1973.
4. Niazi: Text Book of Biopharmaceutics & Clinical Pharmacokinetics, Appleton Century Crofts, 1979.
5. Evans et al.: Applied Pharmacokinetics (Principles of Therapeutic Drug Monitoring), Applied Therapeutics, 1980.
6. Gibaldi & Perrier: Pharmacokinetics, 2nd ed. (Revised & Expanded), Marcel Dekker (series in Drugs & Pharmaceutical Sciences – vol. 15), 1982.
7. Gibaldi: Biopharmaceutics & Clinical Pharmacokinetics, 3rd ed., Lea & Febiger, 1984.
8. Ritschel: Graphical Approach to Clinical Pharmacokinetics, 2nd ed., Prous Publishers, 1984.
9. Notari: Biopharmaceutics & Clinical Pharmacokinetics (an introduction), 4th ed. (Revised & Expanded), Marcel Dekker, 1987.
10. Rowland & Tozer : Clinical Pharmacokinetics (Concepts & Applications), 3rd ed., Lea & Febiger – Waverly, 1995.
11. Macheras et al: Biopharmaceutics of Orally Administered Drug, Ellis Horwood (series in Pharmaceutical Technology), 1995.
12. Welling & Tse: Pharmacokinetics (Regulatory, Industrial, Academic Perspectives), 2nd ed., Marcel Dekker (series in Drugs & Pharmaceutical Sciences-vol. 67), 1995.
13. Shargel & Yu: Applied Biopharmaceutics & Pharmacokinetics, 4th ed., Appleton & Lange, 1999.
14. Ratkowsky et al. : "Cross-Over Experiments: Design, Analysis & Applications," Marcel Dekker (series in Statistics: Textbooks and Monograph- Vol. 135)

MPS2151: QUALITY ASSURANCE & PROCESS VALIDATION (3 CREDITS)

I. In process quality controls on various dosage forms – sterile and non sterile SOPs for various operations like cleaning, filling, drying, compression, coating, disinfection, fumigation, sterilization, membrane filtration etc. QA guidelines for human blood products and large volume parenterals.

II. Quality control laboratory – responsibilities and laboratory practices. Routine controls on instruments, reagents, sampling plans, standard test procedures and protocols, control on animal house, data generation and storage, Quality control documentation and audits of QC facilities. Finished product release, quality review, quality audits and batch release documents.

III. Qualification validation and calibration of equipment. Analytical and Bioanalytical method validation, Personnel & process validation with regard to sterile and non sterile products, Asceptic validation.

IV. Introduction to validation of manufacturing facilities I.Q./ O.Q/ and certification, preparation of validation protocols.

V. Validation and security measures for electronic data and computer assisted process. Validation of water and air handling systems.

Recommended Books

- Pharmaceutical Process Validation – Robert A. Nash, Alfred H. Wachter
- Process Validation in manufacturing of biopharmaceuticals: Guidelines – Anurag Singh Rathore, Gail Sofer, G. K. Sofer
- Pharmaceutical Quality Assurance – Mr. Manohar A. Potdar
- Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO

MPS2153: REGULATORY AFFAIRS & DOCUMENTATION (3 CREDITS)

I. An overview of : The D & C Act 1940 and rules there under, The Patents and Designs Act 1970, Trademarks.

II. Preparation of documents for New Drug Application (NDA) as per requirements of FDA and EUDRA guidelines. GMP requirements for FDA, PIC and ICH. Drug Master Files, Site Master Files, Out of specification. Stability studies as per ICH, EUDRA, FDA, Analytical Methodology.

III. Bioanalytical bioequivalence studies – FDA, EUDRA / clinical trials – ICH, E7, E8. / Toxicological studies, / Electronic Records – Signature CID, Accelerated FDA approvals.

IV. Patent discussion with emphases on: Patentable subject matter, Non patentable subject matter, Criteria for getting a patent, Types of patent and its usefulness. Filing procedure for patents, Patent co-operation Treaty. Trade related aspects of IPR.

V. Harmonization of regulatory requirements: Study of ICH common technical documents. Harmonization of Pharmacopoeial standards.

VI. Regulatory considerations of Pre-clinical and clinical evaluations with special reference to legislation and guidelines of good clinical practice in US., European community and Japan.

Recommended Books

- The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
- Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices – John J. Tobin and Gary Walsh
- FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
- Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu
- Pharmaceutical Patent Law – John R. Thomas

MCR3101: PHARMACOVIGILANCE (3 CREDITS)

1. **Pharmacovigilance –**

i) Drug related problems in health care

Types and mechanisms of ADRs, Risk factors for ADRs, Drug – drug interactions, Other causes of drug related problems, Drugs in pregnancy and lactation, Management of patients affected by ADRs, Medication errors 5h

ii) Clinical manifestations of ADRs 5h

Drug related diseases affecting different organ systems (Brief Overview since covered in Clinical Pharmacology)

iii) Spontaneous reporting 5h

Organization, Setting up and running a PhV centre, Patient reporting, Managing individual case report forms, Terminologies, Feed back to reporters, Case assessment, Signal analysis and follow up, Root cause analysis of medication errors

iv) Epidemiological Methods 5h

Drug utilization studies, Cohort event monitoring, Cohort studies, Case control studies, Longitudinal databases of patient records

v) Collection and management of safety data during clinical trials: 5h

Need for good quality safety information, Definition of good safety information, Differing regulations concerning safety data collection requirements, Designing a system to collect good quality information

vi) Post-marketing drug safety: Differences in clinical and post-marketing drug safety 4h

vii). Reporting to the Regulatory Authorities: 5h

Individual case safety reports, Periodic safety update reports, Answering queries from regulatory authorities, Updating product labelling – emphasis on safety changes, Safety reporting requirements, Safety report sources, Follow up of safety reports, Electronic safety reporting – Oracle & other software program available, Safety file retentions

viii) Global pharmacovigilance and safety standards 3h

- Background and introduction to pharmacovigilance
- The WHO and safety reporting
- CIOMS – function and purpose
- ICH – composition and guidelines
- MedRA

ix) Understanding signals and benefit-risk determinations 3h

- Definition of a signal
- Type of signal
- Who should be involved in signal detection process?
- Conducting signal detection in clinical and post-marketing surveillance
- Defining the signal in relation to risk/benefit
- Definitions of risk/benefit – FDA and EU perspective
- Risk/benefit assessments – who does this and where does the information go?
- Safety assessments and risk/benefit – frequency and reporting

- Changes in risk/benefit – how to manage and review existing profile

x) Standard operating procedures (SOPs) in relation to pharmacovigilance 3h

- Types of SOPs required
- Production and sign off of SOPs
- SOP maintenance
- SOP training

xi) The role of the qualified person (QP) 3h

- Contract versus permanent.
- Essential attributes of the QP
- The duties of the QP
- What the QP must do
- Internal audits of the company pharmacovigilance activities

xii) Audit

- Contracting out pharmacovigilance 3h
- Preparation for a regulatory inspection
- Scope of the pharmacovigilance inspection
- Conduct of the pharmacovigilance inspection
- The pharmacovigilance inspection report
- When things go wrong
- Corrective actions following a pharmacovigilance inspection

xiii) Narrative Writing – 3h

Books

1. Pharmacovigilance (2nd Edition) – Ronald D. Mann & Elizabeth B. Andrews, John Wiley & Sons
2. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
3. Good Pharmacovigilance Practice – MHRA
4. Manual of Drug Safety and Pharmacovigilance – Barton L. Cobert, Jones & Bartlett Publishers
5. Dictionary of Pharmacovigilance – Amer Alghabban, Pahrmaceutical Press
6. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons
7. Pharmacovigilance (2nd Edition) – Ronald D. Mann & Elizabeth B. Andrews, John Wiley & Sons
8. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
9. Good Pharmacovigilance Practice – MHRA
10. Manual of Drug Safety and Pharmacovigilance – Barton L. Cobert, Jones & Bartlett Publishers
11. Dictionary of Pharmacovigilance – Amer Alghabban, Pahrmaceutical Press
12. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons

MPSE111 DRUG REGULATORY AFFAIRS (3 CREDITS)

1. Concept and historical development of pharmaceutical product registration. Effect of GATT and WTO on commerce of pharmaceuticals Introduction to IPR, Schedule Y, NDA, ANDA. 6h
2. Globalization of drug industries, Export – in port policy of drug WHO certification. 6h
3. Batch Processing / Sample Analysis – Documentation & SOPs. 6h
4. 21 CFR Part 11 Compliance. 6h
5. FDA(21 CFR Part 320) / EMEA/ANVISA/Indian (CDSCO) Guidelines for BA / BE studies 6h
6. ICH QESM. 2h
7. GCLP Guidelines 4h

Books Recommended:

1. Guidance for preparing documents that meets Regulatory Requirements by Janet Gough.
2. FDA Regulatory Affairs by Donglas J Pisano & David Mantus.
3. FDA Guidelines.
4. ICH Guidelines.

MPSE113: QUALITY ASSURANCE & MANAGEMENT (3 CREDITS)

I. Organization and personnel, responsibilities, training, hygiene, records. Equipment - selection purchase specifications, maintenance, clean in place and sterilize in place methods (TP & STP).
II. Premises - Location, design, plant layout, construction maintenance & sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.
III. Raw materials – Purchase specifications, stores, control and selection of vendors, Manufacture of and controls on dosage forms, Manufacturing documents, master formula, batch formula records, SOPs, Quality audits of manufacturing processes and facilities.
IV. Packaging & Labeling controls, Lime clearance, reconciliation of labels, cartons and other packing material. Good ware housing practices & material management. Waste and scrap disposal procedures and their records, Distribution and its records, Handling of returned goods and recovered materials.
V. Complaints & Recalls: Evaluation of complaints, Recall procedure, Related records & documents.
VI. FDA Guidelines

i. Dissolution testing of immediate release Solid Oral Dosage forms (1).
ii. Extended Release Oral Dosage forms: Development, Evaluation, and Applications of In Vitro/In Vivo Correlations (1).
iii. Waiver of In Vivo Bioavailability and bioequivalence Studies for immediate release solid oral dosage forms Based on Biopharmaceutics Classification system (1)
iv. PAC-ALTS: Post approval changes – Analytical Testing Laboratory Site (1).
v. SUPAC IR – Immediate release solid oral dosage forms: Scale up and approval changes: Chemistry Manufacturing and controls In Vitro dissolution testing, and In Vivo bioequivalence documentation (1).
vi. Drug Metabolism / Drug Interaction Process in drug development process: Studies In Vitro (1).
vii. In Viva Metabolism or drug interaction studies – Study design, Data analysis and recommendations for Dosing and Labeling (1)

Recommended Books

- Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance, Second Edition by Guy Wingate
- ISO 9000 Quality Systems Handbook - updated for the ISO 9001:2008 standard, Sixth Edition: Using the standards as a framework for business improvement by David Hoyle (Paperback - July 10, 2009)
- Total Quality Management: Strategies and Techniques Proven at Today's Most Successful Companies (Portable Mba Series) by Stephen George and Arnold Weimerskirch (Hardcover - Feb. 1998)
- Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries by Syed Imtiaz Haider and Erfan Syed Asif

MPS2142: QUALITY CONTROL LAB.

(4 CREDITS)

1. Study of Components of GLP.
2. Study of documentation procedures in Quality Assurance.
3. Study of effect of change in solvent, pH on the U.V. Spectrum of given compound.
4. Comparison of I.R. Spectrum of compound and its derivative along with interpretation.
5. Study of drug-excipient interaction using DSC.
6. Study of Polymorphs using DSC
7. Analysis of Pharmacopoeial drug using HPLC.
8. Finger printing of Herbal preparation using HPTLC technique.
9. Evaluation of packaging material and containers.
10. Filling of Investigational New Drug (IND) as per FDA-format and registration detail.
11. Filling of Abbreviated New Drug Application (ANDA) as per FDA-format and registration.
12. Filling of Indian Patent Format & Procedure.
13. Study of Protocol preparation of Risk Management in Pharmaceutical Industries.
14. Study of Dissolution Profile for a given drug formulation.
15. Study of cases in the patent litigation of pharmaceuticals
16. Calibration and Validation of UV-Vis spectroscopy.
17. Calibration and Validation of IR spectroscopy.
18. Preparation of SOPs

MPS2152: REGULATORY AFFAIRS & DOCUMENTATION WORKSHOP

(4 CREDITS)

Case studies and documentation related to Regulatory Affairs

M. PHARM III SEMESTER (15 CREDITS)

MPS3151: Thesis:

- **Thesis Seminar**

M. PHARM IV SEMESTER (20 CREDITS)

MPS4151: Thesis:

- **Presentation, Submission and Viva-Voce**

BREADTH PAPERS

MMA1101: BIOSTATISTICS (3 Credits)

1. **Introduction:** 1h
   Relevance and the scope of Statistics.
   Difference between 'Descriptive' and 'Inferential' Statistics; Relationship between them

2. **Sampling Methods** 4h
   Introduction of sampling, probability and non probability sampling, sampling procedures – simple random, stratified, systematic, cluster and multistage sampling, concept of sampling distribution.

3. **Statistical Inference** 6h
   Statistical estimation – point and confidence interval estimations, Introduction of statistical hypothesis and testing, comparison of population mean with sample means, comparing two sample mans, comparison of population proportion with sample proportions, comparing two sample proportions, comparison of more than two samples, introduction of non parametric statistical tests.

4. **Correlation and linear regression** 6h
   Introduction of correlation & regression concepts, estimation of correlation coefficient, regression coefficients, assumption of tests of hypothesis in linear regression, variance of sample estimates of the parameters, confidence intervals in regression analysis, non linear regressions, weighted and transformations in regression analysis, application of linear regressions - standard curves in drug analysis and drug stability studies, analysis of covariance.

5. **Concepts of Inferential Statistics** 4h
   Basics of Statistical Inference
   Sampling distribution
   Estimation – Point estimation, Interval estimation
   Parameter, Statistic, Concept of a hypothesis, Research Hypothesis, Null Hypothesis, Level of Significance, Comparison of means of two samples, Comparison of sample proportion with population proportion, Comparison of two sample proportions,
   Degrees of Freedom, Critical Value, Table value, Type I and Type II errors, Rules for rejection & acceptance of Null Hypothesis, Standard Error

6. **Inferential Statistics - Parametric Test**: 4h
   't' test – Comparison of sample mean with the population mean, Comparison of means of two independent samples, Comparison of two correlated samples
   'Z' test – different applications
   Annova – one way annova: 'F' test

7. **Quality control:**

Introduction, control charts, acceptance sampling and operating characteristic curves, statistical procedures in Assay.Department, establishing in-house limits, some statistical aspects of quality and the "Barr Decision".

8. **Inferential Statistics - Non-parametric test**: 2h
   Chi square test- Testing of goodness of fit, testing of independence, Test of homogeneity; Wilcoxon signed rank test; McNemar test

9. **Computer Applications & Practicals:** 2h
   Introduction of statistical software – SPSS with practical exercises

BOOKS RECOMMENDED:

1. Statistical issues in Drug Development by Stephen Senn, 1997, published by John Wiley and Sons Inc.
2. Practical and Clinical Applications 3rd Edn. Sandord Bolton, 1997 Marcel Dekkar Inc, Newyork.
3. Non parametric statistics for Behavioral Sciences by Sidney Siegel; 1956, McGraw Hills, New Delhi.
4. Design and Analysis of Bioavailability and Bioequivalence Studies – 2nd Edn. By Shein-Chung Chow and Jen-Pei Liu, 2000, Marcel Dekkar Inc, Newyork.
5. Computer Applications and Practicals: Introduction of softwares – SPSS/SAS and practical exercises.

Text Books

1. Pharmaceutical Statistics

MPS1003: BIOLOGICAL STANDARDIZATION & PHARMACOLOGICAL SCREENING (3 Credits)

1. Laboratory Animals 7h.
   a. Commonly used laboratory, transgenic and other genetically prone animal models (viz. nude mice SH rats etc.)
   b. Techniques of blood collection, anesthesia & euthanasia of experiment animals.
   c. Maintenance & breeding of laboratory animals.
   d. Regulation and ethics requirements.
   e. Guidelines & regulatory agencies – CPCSEA, OECD, FDA ICH, FHSA, EPA, EEC, WHO, etc.
   f. Importance of alternative experimental models, its advantages & disadvantages.

2. Principles of Biological Standardization 4h.
   a. Methods of biological assay, principles of biological assays with certain examples as per IP and BP.
   b. Development of new bioassay methods.

3. Immunoassay 5h
   a. General principles of immunoassay, Theoretical basis, Optimization of immunoassay, Heterogenous immunoassay system, Homogenous immuno system.
   b. Production of immunoassay reagent: Introduction, receptors or binders, unlabelled ligands Calibrators, Labelled ligands and receptor, Separation technique, buffers.
   c. Immunoassay Methods Evaluation: Protocol outline, objective & preparation, evaluation of precision, standard tracer, sensitivity, evaluation of accuracy, antibody characteristics, monitoring, reaction conditions, clinical evaluation.

4. Organization of screening for the Pharmacological activity of new substances with emphasis on evaluation using in-vivo, in-vitro, ex-vivo, in-situ, in silico and other possible animal alternative models. 18h.

   a. General Principles & safety pharmacology procedure.
   b. CVS Pharmacology – Antihypertensive, Anti arrhythmics, Vasodilators, disentail.
   c. CNS Pharmacology – behavioral & muscle co-ordination, CNS stimulants, anti-epileptics, Nootropics.
   d. Drugs for Neurodegenerative diseases, like parkinsonism, Alzheimers, multiple sclerosis.
   e. Drugs acting on ANS.
   f. Respiratory Pharmacology – Anti-asthmatics, COPD, Anti-allergic & Mucoactives.
   g. Reproductive Pharmacology – Aphrodisiacs & antifertility agents.
   h. Analgesics, anti-inflammatory & antipyretics.
   i. G.I.T. – Anti-ulcer, anti-emetics, anti-diarrhoeal & laxatives.
   j. Anti-cancer agents.
   k. Metabolic disorders like anti-diabetics, anti-hyperlipidemic, anti-obesity, hepatoprotective.
   l. Models in drug absorption & metabolism.
   m. Immuno Pharmacology – specific (cell & hormonal mediated) & non-specific methods.
   n. Screening of free radical scavenging activity.
   o. Acute, Sub-acute & Chronic toxicity test.

5. Clinical pharmacology and pharmacodynamics: clinical study design, documentation, presentation and interpretation 2h

6. Clinical trials: definition, phase I – IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data, factorial design, guidelines as per Indian and other regulatory authorities. 7h

BOOKS RECOMMENDED :

1. Biological standardization by J.H. Burn, D.J. Finney & L.G. Goodwin.
2. I.P. & B.P.
3. Screening Methods in Pharmacology by R.A. Turner. Vol. I & II Academic Press, New York and London.
4. Evaluation of drug activities by Laurence & Bacherce.
5. Methods in Pharmacology by Arnold Schwartz.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
7. Fundamental of Experimental Pharmacology, by M..N. Ghosh. Scientific Book Agency, Calcutta.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
9. Drug Discovery and evaluation by H.G. Vogel & W.H. Vogel. Springer Verlag, Berlin Heideleberg.
10. Animal Model in Toxicology by Shayne Cox Gad & Christopher P, Chengelis.
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.
13. Handbook of Experimental Pharmacology by S.S. Kulkarni. Vallabh Prakashen, Delhi.
14. Pharmacological Experiments on Intact and Isolated preparations, Edinburgh University Pharmacology Staff, Livingstone.
15. Goodman and Gilman's The Pharmacological basis of Therapeutics – Ninth edition, Editors. A. G. Gilman, J. G. Hardman, L. E. Limbiod, P. B. Melineff, R. W. Rudder, Macmillan Publishing Co. Inc. – Latest edition.
16. Clinical Pharmacotherapecutics, edited by Kamalesh Kohli, Elsevier Publication.