ANDHRA UNIVERSITY

AU COLLEGE OF PHARMACEUTICAL SCIENCES

MASTER OF PHARMACY

Regulations and Syllabus Four semester pattern

With effect from 2013-14

1. General Regulations:

1.1 The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

The candidate must have passed the B.Pharm. degree examination of this University or B.Pharm. degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2 The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus mentioned in the Annexures – I & II.

1.3 The subjects of specializations for Master of Pharmacy Course shall be as follows:

I. Pharmaceutical Analysis and Quality Assurance

II. Pharmaceutical Chemistry

III. Pharmaceutical Technology

IV. Pharmaceutical Biotechnology

V. Pharmacology

VI. Pharmacognosy and Phytochemistry

VII. Pharmaceutical Management and Regulatory Affairs

VIII. Pharmaceutical Analysis and Quality Control

IX. Pharmaceutics

X. Industrial Pharmacy

XI. Pharmacy Practice

1.4 Every candidate shall put the attendance for not less than 75% of the total number of working days in each semester to be eligible to sit for the semester end examination. If a student represents the University officially at games, sports or other officially organized extra-curricular activities, it will be deemed that he/she has attended the college on the days he/she is absent for this purpose.

2. Regulations for Evaluation:

2.1 Evaluation of performance of all candidates who pursue the above courses shall be as per the scheme of examination enclosed. The course shall be on the basis of the semester end examinations. In theory, 20% of the marks are earmarked for sessional (internal; there have to be two examinations of each theory and consider the average marks of two examinations) examination and 80% marks are earmarked for the semester end examination. In practical, 20% of the marks are earmarked for continuous evaluation and record, and 80% are earmarked for the semester end examination. The marks certificate issued to the candidate by the University shall show separately the sessional marks in practicals and the semester end examination marks.

2.2 Regulations concerning semester-end examinations of the first two semesters:

a) There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be

double valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done jointly by two examiners, one external and one internal.

b) In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

c) If the disparity between the marks awarded by the both the examiners is 20% or less, the average mark shall be taken as the marks awarded in the paper. If the disparity happens to be more than 20, reference to a third examiner will be made whose valuation shall be final.

3. Results:

3.1 A candidate shall be declared to have passed the examination held at the end of each semester if obtains not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce and 50% in the aggregate of all examinations including internal assessment marks in practical.

3.2 A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

3.3 A candidate who fails to secure 50% of marks on the aggregate but secures 50% or more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

3.4 Candidates who secure not less than 70% of the total marks including the sessional marks in practicals in all the examinations of the four semesters taken together shall be declared to have passed in First Class with Distinction. Candidates who secure not less than 60% shall be declared to have passed in First Class. All the remaining successful candidates shall be declared to have passed in Second Class (50%). However, any candidate who has not passed all the papers relating to an examination of any semester at First appearance shall not be declared to have passed in First Class with Distinction nor eligible for the award of any medals or prizes and is not eligible to receive a rank certificate.

4. M. Pharm. III & IV Semester Evaluation Pattern:

4.1 Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected research topic will be done by the research guide and external examiner within the college.

4.2 A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

4.3 The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external

examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

4.4 A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

5. Guidelines for writing the thesis

The thesis should have the following pages in order:

5.1 Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.

5.2 The inner title page containing the same details on white background.

5.3 Certificate from the Head of the institution

5.4 Certificate from the Research Director

5.5 Certificate from the ethical committees for approval of study, if any

5.6 Declaration by the student

5.7 Acknowledgements

5.8 Index highlighting chapter titles and sections titles

5.9 Index for tables, figures and plates, if any

5.10 Abbreviations and symbols

5.11Materials used in the investigation with their procurement details like name of the company, batch number etc.

5.12 Equipment used in the study with the model number and other details

5.13 The thesis should contain the following chapters:

a) Aim and objectives of the investigation

b) Introduction and literature survey

c) Description: Methods and Materials, etc.

d) Experimental work

e) Results and discussion

f) Summary and conclusions

g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

The thesis should be typed in a suitable font like times new roman, bookman old style in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

6. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

6.1 The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

6.2 The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

6.3 The recognised M.Pharm guides are not eligible to guide more than 6 students in one academic year including joint guidance.

7. Regulations for pursuing M.Pharm III and IV Semester project

7.1 Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

7.2 All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

7.3 No code names or numbers are allowed to be written in the thesis for the materials used in the project.

III. PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS (Drug Regulatory Affairs as per new regulations w.e.f 2018 – 2019 admitted batch)

Course no: 7101 Bio Statistics Common For All Specializations
(Paper common for all specialisations)

Tests of significance: Testing hypotheses- principle and applications of Z, t-, F-ratio and chi-square tests in pharmaceutical and medical research.

Analysis of Variance: 1-way, 2-way and 3-way classification.

Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD- their applications and analysis of data; Factorial Experiments- Principles and applications; Probit analysis-Dose-effect relationships, calculation of LD_{50}, ED_{50}

Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.

Course no 7102: Pharmaceutical Organization and Production 75hrs. **agement**

UNIT I : Meaning and Evolution of Management; Planning, Organizing, Staffing, Directing, Co- Ordinating, Reporting & Budgeting (POSDCORB), functions of management with reference to pharmaceutical management.

Introduction to budgeting, budgetary control, types of budgets, entrepreneurship development, types of entrepreneurs & characteristics of entrepreneurs.

UNIT II : Understanding Organization: Types of organization structures; line, line & staff & matrix organizational structure. Resistance to change;

Authority & Responsibility; Organizational conflicts, Organizational Communication system. Theory –X, Theory –Y and theory-Z. Motivational Aspects, Maslow's hierarchy of needs, Hedge Berg two factor theory, group dynamics.

UNIT III: Personnel management: Recruitment & selection, training & development, compensation, transfer, promotion, demotion policies, job evaluation, performance appraisal, industrial relations, grievance handling, stress management. Handling strikes, gheraos, arbitration and negotiations, enforcement of discipline, lay off and discharge.

UNIT IV: Role of personnel manager: Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. -Stress management.

UNIT V: Operational Management: Nature and scope of production management: Types of manufacturing systems – batch production and selection: Process planning: Aggregate planning and Master production scheduling: Project management – project planning, scheduling Programme Evaluation Review Technique (PERT) and Critical Path Method (CPM) use.

UNIT VI : Materials Management: An introduction to materials management. Material requirement Purchase management, Inventory control, Material handling: Vendor selection Make or buy decision Negotiation: Cost – reduction techniques – Standardization codification and variety reduction: waste management: Value analysis.

UNIT VII: Formulation and Production Management: Locating production and service facilities - layout planning and analysis. Material handling for various pharmaceutical products, service facilities and preventive maintenance in pharmaceutical companies- group and individual replacement.

Introduction to automation requirements: supervisory control and data acquisition (SCADA) and programmable logic controller (PLC) based process controls.

UNIT VIII : Introduction to accounting, book keeping, Systems of accounting, journal, ledger, trial balance and final accounts. Study of computer based systems for accounting with examples.

List of Books recommended :

1. The theory and practice of Industrial Pharmacy Leon Lachman, Ph.D., Lachamn Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates Inc. Consultant Services, Livingstom, New Jersey, Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc Ridgefield Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400017.1987.

2. Pharmaceutical Dosage Forms and Drug Delivery Systems Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G. Popovich , Ph.d., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia, London. 1990.

3. Selected Topics in Industrial Pharmacy, Dr. N. Udupa, 1992, II Edition Varghese Publishing House, Bombay.

4. Admn. E.E. and Ebert RJ: Production and Operations Management, 6th Edition, New Delhi, Prentice Hall of India 1995.

5. Chunawalla and Patel: Production and Operations Management, Himalaya Publishing House.

6. Gopalakrishnan.P and Sudarshan M Hand Book Materials Management New Delhi Prentice Hall of India. 1994.

7. Dutta A.K. Integrated Materials Management New Delhi PhI1986.

8. Buffa E.S. and Sareen: Modern Production Management, New York, John Wiley 2002.

9. Koonz, Weihrich and Aryasri: “Principles of Management”, Tata Mc Graw Hill.

10. Daft : “The Era of Management “,Cengage Learning, New Delhi.

11. K.Aswathappa: “Organizational Behavior – Text, Cases and games”, Himalaya Publishing House, New Delhi,2008,

12. Aswathappa K: “Production and Operation Management”, Himalaya Publishing House, Mumbai.

13. R.Panneerselvam:”Productions and operations Management”,PHI Learning private limited,New Delhi,2009.

Reference Books :

1. Modern Pharmaceutics, Second Edition, Revised & Expand (Volume40) Edited by Gilbert S. Banker, University of Minnesota, Minneapoils, Minnesota; Chistopher T. Rhodes, University of Rhode Island, Kingston, 1990 Marcel Dekker Inc., 270 Madison Avenue, New York 10016.

2. GMP for Pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.

3. I.P.., B.P., U.S.P. International Pharmacopoeia.

Journals:

Journals related to National and International status to cover the syllabus.

Course no 7103: Pharmaceutical Organization and Production Management Practical

1. Organization/ Business case presentations.

2. Survey of market research to collect information regarding management of a given disease and/or disorder.

3. Group discussions and case studies based on theory.

4. Layouts for production of API and Pharmaceutical formulations (Tablets, capsules, ophthalmic, parenteral and other formulations)

5. Preparation of trial balance, preparation of final accounts, inventory measurement methods

Course no 7104: Indian Drug Regulatory Affairs - Theory **75 hrs.**

Unit I : A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts / Laws (with latest amendments)

- Package commodities act
- Competition council of India
- Right to information act
- National Pharmaceutical Pricing Authority (NPPA) – Power to fix the maximum sale prices of bulk drugs specified in the First Schedule, calculation of retail price of formulation, power to revise price of bulk drugs and formulations, display of prices of non-scheduled formulations and price list thereof. Study of different forms to be used for submission of these approvals.

Unit II : Introduction to IPRs : Intellectual property (IP) versus conventional property. Introduction to 8 different IP mechanisms – patents, industrial designs, and layout designs, plant varieties, geographical indications, copyright, trademark, trade secrets; their characteristics, properties. usefulness of patents for researchers. Factors affecting choice of IP protection; penalties for violation / infringement. IPRs vs. Regulatory affairs- similarities and differences.

Patenting in India : Development of IP law in India. Patent legislation and introduction to current IP laws in India. Amendments in Indian Patent laws and their significance; Requirement for patenting- novelty, inventive step (non obviousness) and industrial application (utility). Patent specification & claims, patent infringement. Procedure for filing patent in India- provisional, complete, divisional, additional and conventional patent applications; forms and fee. Prior art search and sources of patent information – free and paid databases. Patent analysis and land-scaping. Patent Search Maps. Infringement analysis. Concepts of Patent writing in India. Patent cooperation treaty (PCT) route of filing for International patents.

Unit III : Schedule M, M1, M2 & U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production of Active Pharmaceutical Ingredients (APIs), other raw materials (including packaging materials) used in drugs
& cosmetics.

Unit IV : Schedule M, M1, M2 &U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production aspects of various drugs

& cosmetic formulations (solid, parenteral and semi solid preparations).

Pilot plant scale- up techniques: Pharmaceutical pilot plant, pilot plant design, case studies for above preparations. Basic requirements for design of product, facility, equipment selection and personnel.

Unit V: Schedule M, M1, M2 &U general requirements and special provisions DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to quality control & quality assurance aspects of various drugs & cosmetic formulations (solid, parentaral and semi solid preparations).

Unit VI : General requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal

provisions related to marketing of various drugs & cosmetic formulations (solid, parentaral and semi solid preparation). Introduction to uniform code of marketing practices for the Indian pharmaceutical industry (UCPMP).

Unit VI : Indian Good Clinical Practices guidelines: National regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Schedule Y of Indian Drugs and Cosmetics Act 1940, Role of Regulatory affairs in Developing clinical trial protocols, Clinical phase, Preclinical Phase, Manufacturing phase and Marketing Phase.

Unit VII : Hierarchy and working flow of DCGA in India. Regulations and documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Unit VIII : WHO certification, Trademarks and copyrights. National Accreditation Board for testing and Calibration Laboratory (NABL) certification and accreditation procedure. The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000.

Recommended books:

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.

2. Pharmaceutical Jurisprudence, G.K. Jani.

3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin

4. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh.

5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus

6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.

7. Pharmaceutical Patent Law – John R. Thomas.

8. Original laws published by Govt. of India.

9. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.

10. Laws of Drugs in India by Hussain.

11. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.

7105: Indian Drug Regulatory Affairs Practical

1. Testing of glass, rubber, plastic & metal packaging materials and preparing document for submission for approval.

2. Stability testing of an API, a pharmaceutical excipient, pharmaceutical dosage forms (solid, parenteral & semi solid) as per regulatory requirements and preparing required documents for submission

3. Quality control testing of finished product (solid, parenteral & semi solid dosage forms) as per Indian Pharmacopoeial requirements and preparing required documents for submission.

4. Patent writing for a given modification in the composition of a dosage form
(minimum of 2 protocols).

5. Preparation of documents for submitting a patent file through Patent cooperation treaty (PCT) route.

6. Preparation of Dossiers to be submitted to the CDSCO/DCGA for a solid/parenteral/ semi solid dosage forms.

Course no: 7207 Modern Analytical Techniques (Paper common for all Specialisations)

A study of the principals, instrumentation and applications in pharmaceutical research of the following

Chromatography: HPLC and GC

Spectroscopy: IR, FTIR, NMR, Mass spectrometry,
^{13}CNMR,

Differential thermal analysis (DTA), Differential scanning calorimetry, X-ray diffraction analysis, Radiometric techniques.

Course no.7208: Quality Assurance and Drug Regulatory Affairs

(Common paper for all specializations)

1. The concepts of quality assurance, GMP, TQM- Principals and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.

2. GMP- A study of Schedule M of Drugs and Cosmetics Act, WHO specifications, US FDA guidelines. The study shall include special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.

3. Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non- sterile areas. Analytical method validation

4. Ware housing for materials and products; complaints and recalls- evaluation of complaints and recall procedures; finished product release-Quality review- Quality audits- Handling of returned goods, recovered materials and reprocessing.

5. Documentation related to Product Development, standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.

6. Regulatory Affairs - Drugs and Cosmetic Act, DPCO, Intellectual Property Right and Patent laws.

7. New Drug Development and Approval Process:

Investigational New Drugs (IND), New Drug Applications (NDA), Supplemental New

Drug Application (SNDA). ICH requirements for registration of Pharmaceuticals

Course no.7209: Pharmaceutical Management Science

75 hrs.

UNIT I : History, growth of Indian Pharmaceutical Industry. Global scenario of Indian pharmaceutical Industry and pharmaceutical market past and present.

UNIT II : Pharmaceutical marketing : Introduction of pharmaceutical marketing, evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented modern concept); market segmentation; concept of marketing mix, role of 7 P's (product, price, promotion, place, physical evidence, process, people) in pharmaceutical marketing management, corporate planning & strategy, pharmaceutical industrial marketing management. pharmaceutical marketing en vironment. E-Pharma marketing.

UNIT III : Supply Chain Management : Scientific purchasing, quality control, problems of productivity, stores organization, location of stores, receiving, inspection of materials, issue from the store, control of stores and stocks, store accounting and records. ABC analysis, VED (Vital, Essential, Desirable), Fast moving, Dormant moving & Obsolete (FDO), Economic Order Quantity (EOQ).

UNIT IV : Product design planning : Selection of product, new product development and product differentiation, pricing, promotion.

Marketing research: definition and importance, Pharmaceutical marketing research techniques, marketing information systems, pharmaceutical market research area.

UNIT V : Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Legal Environment of Business: Need for government regulations; financial regulations, Equity market & SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws -Direct and Indirect.

UNIT VI : Market demands and sales forecasting: major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.Social and legal and ethical issue of pharma marketing, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) code of pharmaceutical marketing practices, pharma guidelines for Direct-to-consumer advertising (DTC advertising) and Organization of Pharmaceutical Producers of India (OPPI) guidelines for Pharmaceutical marketing in India

UNIT VII : Strategic marketing : SWOT Analysis, GAP Analysis, Porter's five- force model, Ansoffs Matrix. Role of customer in marketing, importance of consumer behavior, customer relationship management (CRM). Nature of international marketing, evaluating international marketing, develop international marketing objectives, Formulate product marketing strategies, market entry and overseas distribution system, pricing.

UNIT VIII : Functions of finance management; performance evaluation through ratio analysis & funds flow statement; project preparation, other ethical aspects of Pharmaceutical promotion and advertisement. Effect of Competition Council of India (CCI) on Pharma industry.

References:

1. Phillip Kotler: "Marketing Management", 11/e, Pearson Publishers, New Delhi,
2003

2. K Aswathappa: "Human Resource and Personnel Management", Tata McGraw
Hill, New Delhi, 2007.

3. Aswathappa K: "Production and Operation Management", Himalaya Publishing
House, Mumbai.

4. I.M Pandey: "Financial Management", 9/e, Vikas Publishing, 2004

5. Rajan Saxena: "Marketing Management, 2/edition, Tata McGraw Hill, New
Delhi, 2008.

6. Shashi K Gupta & Sharma, Financial Management, Kalyani Publishers

7. Buffa, Production and Operations management

8. Business Environment, Francis Cherunilam, Himalaya Publications

Course no.7210: International Drug Regulatory Aspects - Theory **75 hrs.**

Unit I: Generic drug product development: Introduction, Hatch-Waxman update, Drug product performance- in vitro, Abbreviated New Drug Application (ANDA) Regulatory Approval Process, paragraph IV drug product application. Bioequivalence and drug product assessment- in vivo, scale- up, post approval changes, post marketing surveillance, outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Formats for marketing authorization submission to WHO, USFDA, EU. Data

privacy Protection, Pharmaceutical Labeling, Advertising and Promotion, Risk Management in regulatory affairs.

Unit II: Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, novel therapies, special categories [Over - the - counter (OTC) products, herbal medicines and Homeopathics]. Obtaining New Drug Application (NDA), ways and means of US Registration for foreign drugs, Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), medical devices, Environmental concerns and regulations. 21 Code of Federal Regulations (CFR) Part 11 and LIMS (Laboratory Information Management System).

Unit III: FDA Approval indications and other considerations: Data procession for Global submission, Text and Tabular exposition- Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) format, working with

contract research organization (CRO), industry and FDA liaison, role of European
Commission Competent Authorities and Notified Bodies and USFDA authorities.

Unit IV: Nonclinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigational medicinal product Dossier (IMPD) & Investigator Brochure (IB), new product applications for global pharmaceutical product approvals, US NDA vs. Global CTD Formats, ANDA & Supplemental Abbreviated New Drug Application (SNDA), CTD and eCTD for registration of pharmaceuticals for Human use, combination products & controlled release systems.

Unit V: Centralized procedure for marketing authorization: legal basis – scope. Procedure for submission of application – preauthorization, inspections (GMP inspection) – pre authorization inspection (GCP inspection) – Scientific evaluation of the application – CPMP (Committee for Proprietary Medicinal Products) opinion and follow up action.

Unit VI : Harmonization of regulatory requirements- The International Conference on Harmonization (ICH) process, guidelines to establish quality, safety and efficacy (carcinogenicity studies - need for carcinogenicity studies of pharmaceuticals and testing for carcinogenicity of pharmaceuticals, Genotoxicity- a standard battery for Genotoxicity testing of pharmaceuticals) of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards. Health Insurance Portability and Accountability Act of 1996 (HIPAA)- A new requirement to clinical study process, Code of Federal Regulations (CFR)/ International Conference on Harmonization (ICH) / EU GCP obligations of Investigators, sponsors & monitors.

Unit VII : Stability Testing of New Drug Substances and Products Stability Testing: Photo-stability testing of new drug substances and products, stability testing for new dosage forms, bracketing and matrixing designs for stability testing of new drug substances and products. Evaluation of stability data, impurities in new drug substances, impurities in new drug products, guidelines for residual solvents.

Unit VIII : Quality evaluation and batch release: change control, deviation- (planned and unplanned), corrective action and preventive action (CAPA), Handling of non-conformance, vendor evaluation process, out of specification (OOS), batch reconciliation and finished goods release, market recalls & market complaints.

Joint International Pharmaceutical Excipients Council (IPEC) – Pharmaceutical Quality Group (PQG) Good Manufacturing Practices guidelines for pharmaceutical excipients.

RECOMMENDED BOOKS :

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and
Isader Kaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker
Series,Vol.144

3. The Pharmaceutical Regulatory Process, Second Edition, Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185 Informa Health care Publishers.

4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

6. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.

7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams

8. HIPAA and Human Subjects Research: A Question and Answer Reference
Guide by Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD

9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene

10. Drugs: From Discovery to Approval, Second Edition by Rick Ng

11. New Drug Development: A Regulatory Overview, Eighth Edition by Mark
Mathieu

12. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko

13. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema

14. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan

15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical
Devices by John J. Tobin and Gary Walsh

Course no.7211: International Drug Regulatory Aspects Practical

1. The general stages of drug development from R & D to marketing.

2. List the various types of manufacturer – FDA interactions that can occur during the drug development process.

3. Requirements for registration of ANDA as per ICH CTD/eCTD format.

4. Preparation of documents required for paragraph IV drug product application.

5. The general process by which new molecular entities (NMEs) are identified through pharmaceutical approaches.

6. Types of IND applications and structures of each type.

7. Requirements to complete an IND application and IND review process.

8. Requirements for a new drug application (NDA) & NDA submission process.

9. FDA's review of submitted NDA application/FDA's requirements for changes to an approved NDA

10. Clinical trial protocol preparation / clinical data requirements for approval of controlled release NDA

11. Post NDA approval responsibilities of a sponsor.

12. General study of ICH guidelines with special reference to ICH Q7, Q8, Q9 and
Q10

13. Compliance requirements for bioavailability & bioequivalence studies.

14. Patent challenge/ non infringement case studies.

15. Qualification of disintegration test apparatus/friability test apparatus/dissolution test apparatus

16. Qualification of UV-Vis spectrophotometer.

17. Comparison of D & C Act with that of other regulations such as USFDA, UKMCA, EDQM, South Africa MCC, Brazilian ANVISA, Australian TGA.