Proposed Syllabus for
Department of Regulatory Affairs
National Institute of Pharmaceutical Education and Research
(NIPER- R)
Bijnor-Sisendi Road, Sarojini Nagar,
Near CRPF Base Camp, Lucknow (U.P.) – 226002

M.S. (Pharm.) Regulatory Affairs

Course number	Name of the course	Credits
Semester I		
RA-510	Good Regulatory Practices	02
RA-520	Regulatory Aspects of Drugs, Biologicals and Medical Devices	02
PE-540	Regulatory Consideration for Pharm Development	01
GE-520	Fundamentals of Intellectual Property (IP) & Technology Management	01
RT-550	Introduction to Regulatory Toxicology	02
GE-510	Biostatistics	02
LG-510	Regulatory Aspects of Herbals and Biologicals - Lab	03
GE-511	Seminar	01
Total credits		14
Semester II		
RA-610	Documentation and Regulatory Writing	02
RA-620	Clinical Research Regulations	02
RA-630	Documentation and Regulatory Writing – (Lab)	02
RA-640	Mini Project	02
PA-630	Stability Testing	01
PC-611	Pharmacological Screening and Assays	01
RT-650	Good Regulatory Practice in Regulatory Toxicology	02
RT-660	Bioethics	01
LS-610	Regulatory Aspects of Drug Formulations and Medical Devices	02
GE-611	Seminar	01
Total credits		16
Semester III		
TH-598	Synopsis	05
TH-599	Presentation	3
Total credits		**08**
Semester IV		
TH-698	Thesis	09
TH-699	Defense of Thesis	03
Total credits		12
Grand Credits (Semester I to IV)		**50**

RA-510: Good Regulatory Practices
Proposed Number of Credits: 02

Unit Number	Detail of content	Contact hours
1	**Introduction to good regulatory practices (GRP) and its importance, Coverage of GRP** **Good Manufacturing Practices (GMP):** GMP principles focusing on US cGMP regulations outlined in Part 210 and Part 211, EC principles of GMP (Directive 91/356/EEC), WHO cGMP guidelines, GAMP-5, and IMDRF guidance documents. Quality systems in GMP. Schedule M. Data integrity	**8**
2	**Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises, and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards. New Drug Approval Guidelines in India. Audit systems	**4**
3	**Clinical Research Related Guidelines:** Good Clinical Practice Guidelines (ICH GCP E6), Indian GCP Guidelines, ICMR Ethical Guidelines for Biomedical Research, CDSCO guidelines.	**6**
4	**Good Laboratory Practices (GLP):** Introduction to GLP, USFDA GLP Regulations, controlling the GLP inspection process, documentation, audit, goals of Laboratory Quality Audit, audit tools, and the future of GLP regulations along with relevant ISO and QCI Standards.	**6**
5	**Good Automated Laboratory Practices (GALP):** Introduction to GALP, principles, requirements, SOPs, training documentation, 21 CFR Part 11 compliance, general checklists, spreadsheets used in GLP, software evaluation checklists. Relevant ISO and QCI standards. Management of laboratory standards. Deviation management in GLP. Computer system validation	**6**
6	**Quality Management Systems:** Overview of ICH Q9 and Q10. Concept of Quality, Total Quality Management, Six Sigma concept, Out of Specifications (OOS) and out of trend (OOT), Deviations, change control. Validation: Types of validation, Types of qualification, Validation master plan (VMP).	**6**

Bibliography

1. Weinberg S. (Ed.). (2007). Good Laboratory Practice Regulations, NY: Marcel Dekker, (4th ed.). CRC Press.
2. Sharp J. (2004). Good Pharmaceutical Manufacturing Practice: Rationale and Compliance (1st ed.). CRC Press.
3. Willig SH, Stoker JR, Stockdale JM. (2008). Pharmaceutical Manufacturing Handbook, Regulations and Quality by. Wiley-Interscience, A John Wiley and Sons, Inc., Publications.

4. Berry IR, Martin RP. (Eds.). (2008). The Pharmaceutical Regulatory Process (2nd ed.). CRC Press.
5. Pisano DJ, Mantus DS. (Eds.). (2008). FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics (2nd ed.). CRC Press.
6. Sharp J. (2004). Good Pharmaceutical Manufacturing Practice: Rationale and Compliance (1st ed.). CRC Press.
7. Singer DC, Stefan RI, Van Staden JF. (2005). Laboratory Auditing for Quality and Regulatory Compliance (1st ed.). Taylor & Francis Publisher.
8. Anderson M. (2002). GLP Essentials: A Concise Guide to Good Laboratory Practice, 2nd Ed., CRC Press.

RA-520: Regulatory Aspects of Drugs, Biologicals and Medical Devices
Proposed Number of Credits: 02

Unit Number	Detail of content	Contact hours
1	Organizational structure and functions of FDA and EMA. Regulatory framework of ROW countries Code of Federal Regulations; Federal, Food, Drug and Cosmetic Act (FFDCA), Manufacturing, packaging, and labelling requirements for drugs and biologicals in regulated markets. Regulatory requirements for the approval and registration of API (including orphan drugs) and their products (single as well as fixed dose combinations), biologics and novel formulations/therapies; Registration of generic drugs (including their BA-BE assessments)	**6**
2	Regulations for clinical studies: Investigator brochure, Conducting clinical trials. Role of institutional review board/ ethics committees, informed consent process, study process, pharmacovigilance and monitoring of safety. Post approval regulatory affairs: Nonclinical development; CTD formats; Dossier preparation; Liaison between the industry and regulatory agencies.	**6**
3	Brief overview of ICH guidelines (Q, S, E, M) in context to API/product development. Marketing authorization procedure in USA and EU; Mutual recognition procedure. Regulatory considerations for manufacturing, packaging, distribution and labelling of pharmaceuticals and biologicals.	**6**
4	Introduction to biologics and biosimilars, different biologic products, difference between biologic and small molecular drugs/products. Bio-similarity assessment Laws, regulations, and guidelines for the development of biosimilar/biologic and approval of biologics and biosimilars (IND, PMA, BLA, NDA). Pre-clinical and clinical development.	**6**

	Principles for the development, manufacturing, distribution, commercialization of biologics in USA, EU and India; Post-marketing surveillance and pharmacovigilance on biologics, Case studies.	
5	Medical devices in diagnosis and therapeutics: Definition, classification, global nomenclatures, essential principles and life cycle of medical devices. Drug-device combination and other hybrids History of medical device regulation and regulatory approval of medical devices in US and European markets. Role of International Medical Device Regulators Forum (IMDRF). Existing regulations on registration of medical devices in India. An overview of chemical tests on medical device components	**6**
6	Good clinical practice in context to the investigation of medical devices; Safety and risks; Quality management system for medical devices, ISO 13485 International and national standards for medical devices; Future of medical devices in India Assessment of quality, effectiveness and risks; Reporting of adverse events; Post-marketing surveillance	**6**

Bibliography

1. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry and Robert P. Martin
2. Guidebook for drug regulatory submissions by Sandy Weinberg, John Wiley & Sons
3. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
4. Preparation and maintenance of the IND application in eCTD Format by William K. Sietsema
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second edition by Douglas J. Pisano and David S. Mantus
6. Biological Drug Products: Development and Strategies; Wei Wang and Manmohan Singh; By Wiley, 2013
7. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization by the Department of Biotechnology, CDSCO, Ministry of Health and Family Welfare, Govt. of India
8. www.ema.europa.eu
9. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, Second Edition by John J. Tobin and Gary Walsh
10. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen
11. Medical Device Regulations: Global overview and guiding principles, World Health Organization.
12. Quality System Information - Guidance documents released by regulatory agencies
13. Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products, Douglas J. Ball, Daniel L. Norwood, Cheryl L. M. Stults and Lee M. Nagao
14. Indian regulations on registration of medical devices.

15. Scientific journals

PE 540 – Regulatory considerations for Pharmaceutical Development - II
(1 Credit)

1. International regulatory trends in pharmaceutical industry.
2. Role of regulatory affairs department in pharmaceutical organization: regulatory audits, interactions with various other departments, single point contact with regulatory agencies.
3. Types of regulatory filings for pharmaceutical products: goals of regulatory registration procedures investigational new drug applications, introduction to various type of regulatory filings.
4. New drug applications: stages involved in NDA, different phases of clinical trials, purpose of IND, types, and categories of IND applications information to be given in IND applications.
5. Chemistry, manufacturing, and control (CMC)information in NDA: information related to drug substance like manufacturing process, specifications, description of tests methods. Information related to drug product: description of method of manufacturing, specifications, and acceptable limits. Information related to placebo.
6. Hybrid NDA: a difference from NDA, historical background, literature-based hybrid NDAs and other sources of information for hybrid NDA, examples of types of products considered under hybrid NDA.
7. Abbreviated New Drug applications (ANDAs): historical developments leading to creation of ANDA process, Hatch Waxman Act, patent term restoration, criteria for patent term extension, various types of Hatch Waxman Exclusivities, concept of therapeutic equivalence, ANDA review process.
8. Paragraph IV certification ANDAs: different ANDA patent certification options, Medicare Modernization Act, implications of this act on 30 months stay period and 180-day exclusivity, triggering and forfeiture of 180-day exclusivity, shared exclusivity.
9. ANDA with suitability petition: case studies of drug products considered appropriate for filing under suitability petition.

GE 520 - Fundamentals of Intellectual Property (IP) and Technology Management
(1 Credit)

1. Intellectual property: Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property-patents, copyrights, trademark; Factors effecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
2. Trade related aspects of intellectual property rights: Intellectual property and international trade; Concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures), and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.
3. Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS: Filing of a patent application; Precautions before patenting-disclosures / nondisclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search

requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications provisional, non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attomeys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists-University / organizational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brouchers, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multimedia works; Trademarks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.

4. Technology development / transfer / commercialization related aspects: Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialization and commercialization-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personal; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalization of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies-antiretroviral drugs and others.

5. Funding sources for commercialization of technology: Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT, CCMB, IMTECH, and NIPER. Documentation and related aspects.

6. Ethics and values in IP: IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social, and environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies.

1. **Recommended books:**
2. Law Relating to Intellectual Property by B.L. Wadhera
3. IPR Handbook for Pharma Students and Researchers by P.Bansal
4. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012)
5. Patent Agent Examination by Sheetal Chopra and Akash Taneja
6. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan
7. Making Breakthrough Innovation Happen by Porus Munshi

8. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson
9. Legal Drafting for the Layman by Nabhi Kumar Jain
10. How to Write and Publish a Scientific Paper by Rober A Day
11. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V. Chandrachud
12. Biomedical Research- From Ideation to Publication by G. Jagadeesh and others

RT 550 - Introduction to Regulatory Toxicology
(2 Credits)

1. Drug discovery and development: Drug Laws, Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Organization for Economic Co-operation and Development (OECD), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), Central Drugs Standard Control Organization (CDSCO).
2. New Drugs and Clinical Trials Rules, 2019: Salient features including definitions, Ethics Committees (EC), registration of clinical studies and biomedical and health research, academic clinical trials, and role of ECs in compensation.
3. Overview of guidelines: OECD Guidelines for the Testing of Chemicals (Section 4 - Health Effects), ICH guidelines (ICH Q3A to ICH Q3D, ICH S1 to ICH S12, ICH M3, ICH M4, ICH M7), ISO 10993 guidelines brief overview, Introduction to ISO 10993 standards that govern biocompatibility and toxicity testing of medical devices, Medical Devices Rules, 2017 – CDSCO, Guidelines on Umbilical Cord Blood Banking, Guidelines for Stem Cell Research, Framework for the Regulation of Regenerative Medicine - stem cell and exosome based therapeutics.
4. Drug discovery and registration: Regulatory affairs, WTO, patent regime, accreditation, and harmonization process.
5. Threshold limitations: Hormesis and dose-response relationship, lower dose extrapolation.
6. Concepts in Risk assessment: Threshold, Determining the Point of departure (i.e., NOAEL, NOEL, LOAEL, LOEL, BMD, LD50, TD50, TTC, MABEL), MTD, Biocompatibility, Margin of safety, Margin of exposure, Weight-of-Evidence (WOE) Approach, Clinical risk/benefit analysis.
7. Animal to human dose extrapolation: NOAEL determination, human equivalent dose calculation, appropriate species selection and application of Uncertainty/Safety factors.
8. Flow chart: "Case by Case" basis in non-clinical development and its influences on safety assessment, usefulness and limitations Models and bioassay: Methods in toxicity testing, dose-response characterization.
9. Regulations of human pharmaceuticals: FDA approval pathways and preclinical safety evaluation of biotechnology-derived pharmaceuticals.
10. Influence of new technologies: Discovery development gap, future of drug safety.

Recommended Books and Websites:
1. Regulatory Toxicology by Shayne C. Gad Taylor & Francis
2. Principles and Methods of Toxicology by A. Wallace Hayes
3. https://www.fda.gov/regulatory-information/search-fda-guidance-documents
4. https://cdsco.gov.in/
5. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
6. https://www.ich.org/

7. https://www.aami.org/standards/
8. https://www.fda.gov/Medical-Devices
9. https://www.iso.org/standard/68936.html
10. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products
11. https://main.icmr.nic.in/content/draft-guidelines-umbilical-cord-blood-banking-202

GE 510 - Biostatistics
(2 Credits)

1. Statistics: Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.
2. Probability: Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. Sampling: Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. Estimation and Hypothesis Testing: Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student- t and Chi square tests. Sample size and power.
5. Experimental design and analysis of variance: Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. Correlation and regression: Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. Non-parametric tests: Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal Wallis and Friedman two-way ANOVA tests. Spearman rank correlation.
8. Statistical techniques in pharmaceutics: Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

Recommended Books:

1. Fundamentals of Biostatistics by Bernard Rosner
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon
3. Statistical Misconceptions by Huck

LG-510: Regulatory Aspects of Herbal and Biological Products - Lab
Proposed Number of Credits: 03

1. Presentation and assignments on rules, guidelines and Indian standards related to herbal products
2. Case studies on regulatory procedures for herbal and biological products (type of tests/trials, assembling the data, overall content, format, stability requirements, ethical guidelines for pre-clinical and clinical studies, etc.)

GE-511: Seminar
Proposed Number of Credits: 01

1. Introduction, information retrieval systems
2. Writing term papers and reports
3. Organization of scientific material, thesis, dissertation and references
4. Reading research papers and skill in oral presentation

RA-610: Documentation and Regulatory Writing
Proposed Number of Credits: 02

Unit Number	Detail of content	Contact hours
1	Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR). packaging development report, Trade dress, Dissolution method development report, Analytical method development and validation, Genotoxic and nitrosamine risk assessment report, ICH Q8. Relevant guidelines of US-FDA and EU guidelines and differences therein.	**5**
2	Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Product specification. Certificate of Analysis (CoA).	**5**
3	Description of 505(b)(2) terminologies Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). None CTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.	**7**
4	Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits, Auditing strategies, Preparation and conducting audit, Audit analysis, audit report and compliance, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	**6**
5	Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems	**6**

	requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).	
6	Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC] for immediate and modified release dosage forms, Changes Being Affected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labelling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard. ICH Q12	**7**

Bibliography:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

RA-620: Clinical Research Regulations
Proposed Number of Credits: 02

Unit Number	Detail of content	Contact hours
1.	Clinical drug development process: Types of clinical studies, Clinical trial protocol, Phases of clinical trial, Phase 0 studies, Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points), Phase II studies (proof of concept or principle studies to establish efficacy), Phase III studies (Multi ethnicity, multinational, registration studies), Phase IV studies (Post marketing authorization studies; pits and practices)	6
2.	Ethics in clinical research: Historical Perspectives (Nuremberg Code study, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki, Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines, The ethics of randomized clinical trials, The role of placebo in clinical trials, Ethics of clinical research in special population, Institutional Review Board/Independent Ethics Committee/Ethics Committee, Data safety monitoring boards, Responsibilities of sponsor, CRO, and investigator in ethical, Conduct of clinical research, Informed Consent Process (Ethical principles governing informed consent process, Structure and content of Patient Information Sheet and Informed Consent Form, The informed consent process and documentation	6
3.	Regulations governing Clinical Trials India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA) EU: Clinical Research regulations in European Union (EMA)	6
4.	Clinical Research Related Guidelines: Good Clinical Practice Guidelines (ICH GCP E6), Indian GCP Guidelines, ICMR Ethical Guidelines for Biomedical Research, CDSCO guidelines	6
5.	Types and Designs used in Clinical Research Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross-sectional study), Health outcome measures (Clinical & Physiological, Humanistic, and economic)	6
6.	Regulations for the Development and Clinical Trials of Biosimilars and Medical Devices: Biosimilars (Guidelines and Regulations, Development and Quality aspects, Safety and Efficacy, Clinical	6

	Development, Principles for Development of Biosimilars, Data requirements for Preclinical studies and Clinical trial application); Medical Devices (Regulations and Research Phases in the lifespan of a medical devices, Conducting clinical trials on medical devices, Medical devices regulations across the world)	

Bibliography:

1. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes
3. Recent Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2013, 2017.
4. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
5. Ethical Guidelines for Biomedical Research on Human Subjects 2000, 2014, 2017. Indian Council of Medical Research, New Delhi. 4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications
7. Drug Discovery and Clinical Research by SK GUPTA, Jaypee Brothers Mediial Publishers (p) ltd. Second Edition New Delhi

RA-630: Documentation and Regulatory Writing (Lab)
Proposed Number of Credits: 02

1. Presentation and assignments on rules, guidelines and Indian standards on nutraceuticals and phytopharmaceuticals
2. Presentation and assignments on rules, guidelines and Indian standards on OTC products
3. Regulatory procedures for IP on phytopharmaceuticals, cosmeceuticals and nutraceuticals (type of tests, overall content, format, stability tests and other requirements)
4. Guidelines related to the advertising and sale of nutraceuticals and supplements
5. Certification requirements for the manufacturers of nutraceuticals

RA-640: Mini Project
Proposed Number of Credits: 02

1. Assignment on preparation of documents as per guidelines
2. Presentation and assignments on GxP
3. Preparation of SOPs and reports (covering the stability profile, validation, etc.)
4. Preparation of CTD
5. Addressing the warning letters and letter of concerns
6. Corrective and preventive actions, and their documentations
7. Clinical trial procedures
8. Any other topic of industrial interest
9. Industrial visit and report preparation

GE-611 – Seminar
(1 Credit)

Students are expected to deliver a Seminar on the project to be pursued in Semesters Ill & IV. The seminar should include the purpose and basis of the project stating the aims, objectives and probable outcomes, literature review towards the project and method of its execution.

PA 630 – Stability Testing
(1 Credit)

1. Drug development cycles and stability testing: Role and types of stability studies during different stages of drug and product development.
2. Drug stability testing guidelines: International, Regional, and National drug stability guidelines.
3. WHO vs. ICH drug stability testing guidelines: Comparison of different aspects in WHO guideline, and critical comparison with ICH parent guideline Q1A(R2).
4. Specific discussion on following ICH guidelines: Q1B, Q1C, Q1D, Q1E and Q5C.
5. Additional topics:
Stress testing and stability-indicating method development: Role, regulatory aspects, protocols/approaches, practical considerations
Stability testing of phytopharmaceuticals: Regulatory requirements
Stability test equipment: Types of stability chambers (walk-in, stand-alone), design considerations, qualification, and other critical issues.
Stability testing for Shipping & Distribution: Stability testing during transport
Stability testing of drug delivery systems
Recommended Books:

1. ICH (www.ich.org) and WHO (www.who.int) guidelines
2. Pharmaceutical Stress Testing (Predicting Drug Degradation) by Steven Baertschi and Karen Alsante
3. Drug Stability (Principles and Practices) by S. James, Jens ThurØCarstensen
4. Stability-indicating HPLC Methods for Drug Analysis by Quanyun A. Xu, Lawrence A. Trissel
5. Stability of Drugs and Dosage Forms by Sumic Yoshioka, Valentino Stella
6. Physical Pharmacy and Pharmaceutical Sciences by Patrick Sinko, Alfred Martin
7. New Drug Approval Process (Chapter 7) by Richard Guarino
8. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices by Kim Huynh-Ba
9. Stability and Characterization of Protein & Peptide of Drugs by Y. John Wang
10. Peptide and Protein Drug Analysis by Ronald Reid

PC 611 - Pharmacological Screening and Assays
(1 Credit)

1. Role of pharmacology in drug discovery.
2. General principles of pharmacological screening.
3. Animal ethics, regulations for conducting animal experimentation.
4. 3 R’s concept, alternatives to animal experimentations, Organs-on-chips.
5. Pharmacological screening models.

6. Correlations between various animal models and human situations.
7. Correlation between in-vitro and in-vivo screens.
8. Cell- based assay, CaCo-2 cell permeability assay. Single cell gel electrophoresis assay (COMET) assay.
9. Zebrafish model to screen pharmaceutical molecules.
10. Biochemical assays
11. Introduction to cell culture, role of genomic and proteomic techniques in the process of target identification in drug discovery, MALdiToF., microarray.
12. High throughput screening and high content screening, transgenic animal model for drug screening.
13. Specific use of reference drugs
14. Interpretation of results
15. Pharmacogenomics and Personal medicine

Recommended Books/ Journals:

1.Drug Discovery and Evaluation: Pharmacological Assays by Vogel & Vogel
2.CPCSEA guidelines (http://cpcsea.nic.in)
3. Scientific journals in the area of pharmacology

RT 650 - Good Laboratory Practice in Regulatory Toxicology (2 Credits)

1. Good Laboratory Practices (GLP).
2. Organogram, Management, Quality control and Quality Assurance.
3. SOP writing and implementation: GLP Establishment.
4. Historical control data: Importance of the generation of quality data, background lesions, and Use of suitable animal models in toxicity evaluation.
5. Study plans: Study protocols.
6. Master schedule: Responsibility of study directors.
7. Multisite studies and principles investigators responsibility.
8. Reporting of study results.
9. Storage and retention of records and materials.
10. GLP audits and inspections.
11. Cost-benefit comparisons in regulatory setups

Recommended books:

1. Good Laboratory Practice, 2nd Edition, by Jurg P Seiler, Springer
2. WHO/TDR Manual for Good Laboratory Practice, WHO/TDR, Geneva, Switzerland

RT 660 - Bioethics
(1 Credit)

1. Historical perspective of bioethics: Ancient civilizations and the development of Indian, Chinese, Greek ethics, Development of ethics pre- and post-world wars, beliefs, and bioethics.
2. Moral theory and Bioethics: Philosophy and theory of bioethics, moral constrains and dilemmas, autonomy, The Four Principles.
3. Modern research ethics: Codes and guidelines governing biomedical research, regulations, Moral and ethical issues with genetic modifications and uses of iPS cells, development of clinical ethics.
4. Bioethical Issues: Individual rights and treatments, obligations, euthanasia, Disposal of biological Waste.
5. Societal responsibility and ethics: Social pressure, public health vs. individual rights. Public health responsibility vs self-binding.
6. Use of Animals in biomedical research: Guided principles, regulation, procedures etc.
7. Laboratory ethics and behavior: Guided principles and guidelines, internal and external conflicts, data confidentiality, laboratory misconducts, reasons behind misconduct, Quality of outcome vs research fraud, impact of misconduct on society, Protective measures.
8. Publication ethics: Plagiarism, duplication, authorship ethics, reporting and declarations, consequences, Conflicts, etc.,
9. Law and Global health ethics, public health policy: Indian law and its implications on medicine and research, disparity in health care and access to health care, ethical consideration for research in developing countries, ethical Analysis of policies.

Recommended Books:

1. David DeGrazia (Author), A Theory of Bioethics. ISBN no 100901174X
2. Lesley A. Sharp (Author), Animal Ethos: The Morality of Human-Animal Encounters in Experimental Lab Science University of California Press.
3. Simone van der Burg (Editor), Tsjalling Swierstra (Editor). Ethics on the Laboratory Floor. Palgrave Macmillan; 2013th edition.
4. Partha Pratim Ray (Author), A Guide to Research and Publication Ethics, New Delhi Publisher