Jamia Hamdard

School of Open and Distance Learning

DETAIL SYLLABUS OF POST GRADUATE DIPLOMA IN PHARMACEUTICAL REGULATORY AFFAIRS

PGPRAD 101 AN INTRODUCTION TO PHARMACEUTICAL DRUG REGULATORY AFFAIRS

S. No.	Topics

1. Introduction to general aspects

Definition of drug regulatory affairs (DRA); Drug development process; Trade names; Documentation of study reports; Literature searching methodology; Regulatory and scientific product information sources; Competitive intelligence; Advertisement; Pricing; Pharmacovigilance; Labelling; Intellectual property.

2. Responsibilities of Regulatory affairs professional

Professional Ethics; Professional qualifications; Scientific and regulatory advice; Adequate assessment aspects; CO-ordination between Regulatory authority and Pharmaceutical industry.

3. Regulatory Affairs Department in Pharmaceutical industry

Structure and functioning of regulatory affairs departments in pharmaceutical industry; Co-ordination of regulatory affair department with other departments within the industry, Co-ordination of regulatory affair department with drug registration authorities.

4. Pharmaceutical Marketing

Marketing ethics; Marketing setup and Hierarchy in pharmaceutical industry; Trends in pharmaceutical markets in other countries; Block buster molecules and products; Marketing strategies of pharmaceutical companies

5. Marketing authorization

Formal aspects of marketing authorization in major markets; Measures for maintaining authorization and Life cycle management

6. Good Regulatory Practices (GRP)

Definition; GRP and pharmaceutical industry; Quality and quantity of data; Authenticity of data; Data integrity; Dossier structure; Obligatory and optional studies; Development and registration strategy; Role of GRP after registration of pharmaceuticals; GRP with regard to licensing authorities and supervisory bodies.

7. Introduction to Drug Substance Regulation

Drug Master files, closed part and open part of DMF, ASMF, EDQM, CEP, SMFetc; Structure elucidation of drug substances; Chemical Process development (lab scale, pilot scale and commercial scale); Analytical techniques-HPLC, TLC, UV, IR, NMR, XRD, Mass, GC, LC-MS, GC-MS, HPTLC, Potentiometry, etc.; IND submission.

PGPRAD 102 GENERAL PHARMACEUTICAL LAWS AND GUIDELINES

S. No.	Topics

1. U.S. Federal Food & Drugs Laws that affect Drug product, Design, Manufacture and Distribution

- Impact of the Food and Drug laws-Historical perspective, Functions and Organization of the federal Food & Drug Administration (FDA).
- Laws Governing evaluation of Drug Products, Investigational New Drug (IND), Claimed Investigational exemption for a new drug, Drug Efficacy study
- Law covering preparation and distribution of existing products
  a) Current Good Manufacturing Practices (cGMP)
  b) The FDA Recall system
  c) Tamper-Resistant Packaging.

2. A brief introduction to Other U.S. agencies involved in dealing with Pharmaceutical Products

- Occupational Safety and Health Administration (OSHA)
- Maximum Allowable Costs (MAC)/Laws involving the cost of drug distribution and selection including MAC.

3. Environmental Protection Agency (EPA)

General aspects; EPA Dockets (Electronic Public Dockets); Major Environmental Laws; Regulations and Proposed rules (Federal Register-Environmental documents and Federal register database); EPA regulatory planning; Code of Federal Regulations Database.

4. ICH Guidelines

- ICH global cooperation-General information.
- Quality topics (Stability testing of drug substance and drug product, Validation, Impurity testing drug substance and drug product, Elemental impurity, ICH Q6A and Q6B). Different types of specifications.
- Safety topics (Carcinogenicity testing, Genotoxicity testing, Toxickinetics, Pharmacokinetics, Toxicity testing, Reproductive toxicity, Pharmacological studies)
- Efficacy topics (Clinical safety, Clinical study reports, Dose-response studies, Good clinical Practices, Clinical Evaluation)
- Multidisciplinary-Electronic standards for Transmission of regulatory information
- MedDRA (Medical Dictionary for Regulatory Activities)

5. WHO Guidelines

Essential drugs and Medicines policy; Counterfeit drugs Guidelines; Effective drug regulation; Regulatory assessment of medicinal products for use in self medication; WHO model system for SIAMED (Computer assisted drug registration); National regulatory Policy; Review of ICDRA (International Conference on Drug regulatory Authorities); Who Certification Scheme on the Quality of Pharmaceutical products moving in the International Commerce; Exchange of Drug Regulatory information; Pharmaco-vigilance activities; WHO International Drug monitoring.

6. Patents and Other Intellectual property rights in Drug Delivery

- Patents-Patentability requirements, Patent Term and Provisional application, Patent procedure and its Implications to inventors, Infringement, Patents Cooperation Treatise (PCT).
- Trade Secrets, Copyright and Trademarks.
- Exploiting Intellectual Property Rights.

PGPRAD 103 DRUG REGULATORY AFFAIRS IN INDIA

S. No.	Topics

1. **Drug policy in India (1986)**

Definition; Main objectives of the drug policy, 1986; Industrial licensing-import and economic policies; Research and Development in drug industry; Investment-New industrial policy, bulk drug growth in public sector units; Export of medicinal substances; Bulk drug production by the use of recombinant DNA technology; Proposal for the set up of National Drug Authority for specific objectives and functioning.

2. Pharmaceutical pricing policies

Economic considerations; Liberalization; Price control; Maximum Allowable Post Manufacturing Expenses (MAPE); Pricing mechanisms; National Health Programs (Category-I drugs) and others (category-II drugs); National pharmaceutical pricing authority (NPPA); Drug price control order (DPCO); Indian patent act 1970 and DPCO; Formulations; Essential commodities act in regard to pricing mechanism; Ceiling pricing; Drug price equalization account (DPEA).

3. Quality control and rational Use of drugs

Objectives; Bio-laboratories-Central and State drug testing drug laboratories; Screening of irrational or harmful drugs; Adverse drug reaction monitoring centers; Good manufacturing practices (GMP); Licensing of large volume parenterals, sera, vaccines and whole human blood and blood products.

4. Study of the major acts/laws enforced

1. The Drugs and Cosmetics Act, 1940 and rules 1945 with latest amendments
2. The Prevention of Food Adulteration act and rules, 1954 with latest amendments
3. The Drugs and Magic remedies (Objectionable Advertisement) Act 1954 and Rule 1955
4. The Narcotics and Psychotropic substances Act and Rules 1985
5. The Poisons Act
6. The Insecticides Act

5. Pharmaceutical sector in India

Introduction; Key Indian companies; Production-Bulk drug and formulation; Domestic demand and exports, chemicals and pharmaceuticals Export promotion council (CHEMEXCIL), Export promotion cell; Imports-Open General License (OGL), Special Import License (SIL); Research and Development-future projections, academic research institutes (CSIR and NIPER), Corporate R&D projects, Rifampicin and Penicillin G policies; Post WTO Developments-in licensing alliances, co marketing alliances, generic market, Outsourcing,

6. Structure and functions of CDSCO

Functions; Organizational setup; legal basis; GMP certifications; Licensing; licensing renewals.

7. State Drug control authorities

8. Schedule Y

9. Other aspects of drug regulation in India

Indian Pharmacopoeias, Standard terms, Detailing of drug substance and products; summary of product characteristics (SPCs), SPCs of comparable products, chemical and pharmaceutical data (quality), Toxicological and Pharmacological documentation (pre-clinical) data.

PGPRAD 104 INFORMATION AND QUALITY MANAGEMENT

S. No.	Topics

1. Basic structure of different types of Dossiers.

e.g., IND, NDA, ANDA, BLA etc.

2. Data Transfer and databases

Use of computers; Local networking; Spreadsheets preparation; Overview of database; Internet as a source of Pharmaceutical information; Impact of digital technology in pharmaceutical industry

3. Industrial documentation

Documentation and information management in Pharmaceutical industry; ICH M2; ICH M4; Electronic submission;

3. Document Management in Pharmaceutical Industry

Document Organization/Notice to applicants; Addition in documentation; Paper versus electronic; Work Organization for paper/electronic documentation; Documentation management system-structure, function, authenticity, File formats, Electronic application for marketing authorization, application of software systems in documentations; International aspects of electronic authorization-International reviewer forum, ICH.

4. Quality Management Systems

Quality Management Guidelines in relation to pharmaceutical industry; ICH Q9.

5. Quality assurance in Development and Production

Pre-formulation studies; Development process of medicinal products; ICH Q8; pre-approval inspection; production; Testing; Quality assurance in production; Production hygiene.

6. Quality assurance in packaging

Different types of packaging systems; Fault evaluation and fault consequences; product-package compatibility; Stability of product; Packaging selection and critical development.

7. Process quality control

Sterile and Non sterile dosage forms

8. GMP audits

GMP audits by authorities like FDA, ANVISA, EMA etc.

9. ISO certifications

10. Post approval changes and handling deficiencies

11. Other parameters

Data Integrity issues, especially in Indian context
Requirements of supervisory authorities for quality assurance systems
International agreements-ICH, PIC
Legislature requirements in Quality of the Product

PGPRAD 201 CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL ASPECTS OF REGULATORY DOCUMENTATION

S. No.	Topics

1. Raw materials and finished pharmaceutical products

Raw materials; Reference standards; Change of Specification during development and after authorization; Batch tests and analysis certificates.

2. Development and Production documentation

Pharmacopeial monographs; Suitability of drug substances; Batch conformity; Product development-pre-formulation, formulation development, containers and closure suitability, production formulas, methods of production and specifications; process validation; Analytical methods validation, In- house Test methods, Pharmacopeial methods, cross validation and method transfer.

3. Bioavailability, Bioequivalence and Pharmacokinetics Documentation

Regulatory requirements for bioavailability/bioequivalence for a range of products; Pharmacokinetics in animals-Absorption, distribution, metabolism and excretion; Repeated dose tissue distribution studies; Pharmacokinetics and metabolic studies in the safety evaluation of new Medicinal products.

4. Regulatory backgrounds of Pharmacological/toxicological Documentation

Pre-clinical guidelines; ICH process; GLP; General principles of toxicity studies; Animal ethics and welfare.

5. Pharmacological documentation

Pharmacodynamic effects; ICH guideline for safety pharmacology; Drug Interaction parameters.

7. Documentation of Toxicity Studies

Acute, sub-chronic and Chronic toxicity; Data Evaluation and presentation.

8. Pre-clinical documentation

Significance of Pre-clinical study; Content and structural format; Cross species consideration; Documentation of potential adverse effects in humans.

PGPRAD 202 CLINICAL TRIALS AND HEALTH CARE POLICIES

S. No.	Topics

1. Introduction to clinical trials

Basic principles; Nomenclature; Design (open, single-bline, double-blind); control groups; Requirements; Safety in clinical trials.

2. Ethics and Good Clinical Practices (GCP)

i) E6, E3, DOH etc.

ii) Ethics-background, informed consent, ethical approval process
iii) GCP-documentation, compliance, adverse effects, archiving and audit
iv) Regulatory process in clinical development

3. Clinical Pharmacology

Phase I, II, III and IV studies: background; Pharmacokinetics; ADME studies; Absolute and relative bioavailability; Pharmacogenetics; Population kinetics; Pharmacodynamics.

4. Clinical Trial for other categories of products

Clinical trial guidelines for topicals, Retard dosage forms, combination products, vaccines, immunoglobuins, plasma derived factors and recombinant products.

6. Health Care polices

General introduction; Basics of health care policies; Socio-medical criteria of drug development/evaluation; Health Technology assessment, National and International developments; Pharmacoeconomic, fundamentals-different analysis for burden of illness, cost effectiveness, cost utility and cost benefit; Consequences of European and other international policies on National healthcare policy.

7. Pharmacovigilance

Stage procedures; Post marketing surveillance; Adverse Drug Reactions (ADR) reporting procedures; Pharmacovigilance for traditional medicine; Haemovigilance; Materiovigilance.

PGPRAD 203 INTERNATIONAL LICENSING

S. No.	Topics

1. European Union (EU)

i. Introduction to European procedures-Legal basis and key players, different major European agencies; Scientific advice and other relevant topics of the region.
ii. Different filing procedures in European countries.

2. United States of America (USA)

i. Introduction to US Regulatory system; Organization of USFDA.
ii. Health policy and Insurance system
iii. IND, NDA and ANDA filing procedure in U.S.
iv. Annual reports, supplements, amendments, summary basis or approvals (SBA), renewals, Para IV filings
v. Guidance document of FDA
vi. Cooperation with FDA (Scientific advice/early assess programs)
vii. Biologicals and Devices
viii. EMR (Exclusive Marketing Rights)

3. Australia-New Zealand

MEDSAFE (New Zealand), Trans-Tasman Treaty,
TGA (Therapeutic Goods Administration)-Drug Regulatory affairs system.

4. **Afro-Asian countries-A brief introduction**

ix. Licensing procedures in African Countries.
x. Licensing Procedures in Asian countries-China, Japan, Indonesia, Korea, Malaysia etc.

5. Other markets

LATAM, Canada, CIS, GCC etc.

PGPRAD 204 REGULATORY CONSIDERATIONS IN OTHER DIVERSE CATEGORIES OF PRODUCTS

S .No.	Topics

1. Regulatory consideration in controlled release products

1. Controlled release products (CRP)-Definitions, laws, regulations and guidance
2. Need for clinical and bioavailability studies
3. Requirements to demonstrate safety, efficacy and controlled release
4. Dissolution testing for controlled release drug products
5. Evaluation and application of *in vitro/in vivo* correlations and bioavailability assurance.
6. Pharmacodynamic consideration.

2. Biological/Biosimilar products.

1. Introduction to biopharmaceuticals [biotechnology produced peptide based pharmaceuticals (Bradykinin, Tissue plasminogen activator (t-PA) and Vaccines].
2. Formulation consideration-Pre-formulation, surface adsorption behavior and stability.
3. Pharmacokinetic and analytical considerations
4. Regulatory considerations-
5. Specific standards for identity, purity, potency, stability of peptide based pharmaceuticals.
6. Recombinant DNA technology or hybridoma manufacturing process
7. Regulatory agencies for biopharmaceuticals

3. Cell therapy and regenerative medicine

4. AYUSH products

5. Phytopharmaceuticals

6. Cosmetics

7. Dietary supplements/Neutraceuticals

8. Medical devices

9. 3 DP products