P R O G R A M M E PROJECT REPORT (PPR)

POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS

(OPEN AND DISTANCE LEARNING MODE)

School of Open And Distance Learning

JAMIA HAMDARD

(Deemed University)

Hamdard Nagar, New Delhi-110062

Jamia Hamdard

Late Janaab Hakeem Abdul Hameed sb, the founder of Jamia Hamdard, had a vision to develop Jamia Hamdard into an institution of excellence imparting modern professional education with special emphasis on Unani medicine and Islamic studies. Today, it has evolved into an excellent centre of higher learning, fulfilling the objective of the *wakf,* which has been funding the University ever since its inception.

As a mark of tribute and thanks to the Almighty Allah for bestowing his guiding spirit to its founder and his associates, Jamia Hamdard adopted a seal inscribed with the following

"He *(The Prophet may peace be upon him)*
Instructs them in the Book and Wisdom"

Ever since the inception of Jamia Hamdard, this holy verse (*ayat*) has been a source of inspiration and guidance for all those associated with its management and administration. As an Islamic charity, *wakf* has played the vital financial role in the making of Jamia Hamdard. He (PBUH) preached his followers that

"Wisdom is (like) the lost animal of a believer
wherever he finds it, catches hold of it"

Inspired by the Holy Qur'an and exhorted by the Prophet (PBHU), Muslims became the torch-bearers of knowledge and civilization in the medieval period, but are lagging behind in present times. Late Hakeem Abdul Hameed Sahib wisely chose education and pursuit of knowledge as his prime objective when he decided to convert *Hamdard Dawakhana* into a *wakf*, a charity dedicated to fulfilling educational and health care needs of Indian Muslims. Hamdard (*wakf*) continues to provide generous grant to the university for building, equipments and salaries of staff and other development activities.

Jamia Hamdard was inaugurated by late Shri Rajiv Gandhi, the then Prime Minister of India, on August 01, 1989. In his impressive speech, the Prime Minister applauded the efforts of Hakeem Abdul Hameed Sahib in setting up institutions of higher learning, which were emerging in the form of a "Deemed to be University." He said, "This will enable (the Muslim) minority to go forward and thus help India to march forward."

The University offers professional courses, which equip the students to get placements in the highly competitive job market. On the basis of the record of performance of the University and quality of infrastructure including staff, the university has been accredited by NAAC in category 'A' of Indian Universities.

Hamdard is among top 18 universities of India and ranked 1st in the field of Pharmacy and its medical college is ranked 15th by the Govt. of India (HIRF- 2019 ranking) Jamia Hamdard is recommended as an "Institute of Eminence" by the Empowered Expert Committee of MHRD.

Mission & Objective

The Study programme aims to provide contemporary education and training to meet the challenges of the evolving global scenario and changing environment in business administration. The objective of the project is to help the students develop ability to apply multi- disciplinary concepts, tools and technique to sole organizational problem.

Jamia Hamdard Mission and Goal in relevance of the programme

Jamia Hamdard's study programmes under ODL are selective and customized to meet the learning requirements of knowledge seekers as well as to ensure that they learn at their own pace and convenience. Within the financial means of University, due care has been taken to keep the cost of education low, so that educationally backward sections can take advantage of University's programmes through ODL mode. This goal in view, the SODL of Jamia Hamdard has made concerted efforts to offer professional and job oriented courses with regular updates of curricula and study material and introduction of tools of Information Technology.

Targeted Group

The distance education has potential to reach to unreached and even marginalized and excluded group of the society such as tribal populations and Muslims women. Jamia Hamdard, SODL programme provides an opportunity to students for acquiring new knowledge and skills that are needed for their development. Jamia Hamdard being in education for a long time has taken initiatives to offer an opportunity to those students who are unable to get on campus education and those who have limited access to educational resources. ODL programme of Jamia Hamdard also envisage to provide an opportunity to girls from Muslim community, who by and large have been left out by the national education endeavors.

Faculty of SPER

A College of Pharmacy with diploma curse was established in 1972, which was affiliated to the Delhi Board of Technical Education. In 1973, B.Pharm. course was started under Delhi University. In 1982, M.Pharm. in Pharmacognosy was started. From 1986 M. pharm programme in all the four disciplines an simultaneously a Ph.D. Programme in all the disciplines was started. Earlier the intake for B.Pharma was 40, which was enhanced to 60 with the approval of AICTE in 1996. From 1997, self financing B.Pharm. course was started with 60 seats. In collaboration with Ranbaxy Laboratories, department of Pharmaceutical Medicine was started in 1999 for Ph.D. programme in this discipline. It is a unique programme of its own kind in our country.

Post Graduate Diploma in DRUG Regulatory Affairs through Open and Distance Mode (Course Code 654)

Apart from the full time regular courses, the department of Pharmaceutics has decided to offer this PGDDRA programme through open and distance mode for those students who

are not able to afford the expenses of education or who have not been able to make it to the courses offered by the universities and colleges in traditional mode. However, our endeavor is to provide best quality education, keeping with the traditions of Jamia Hamdard.

Objective

The major objective of this course is to provide an interdisciplinary knowledge of pharmacy and law as applicable in the field of Pharmaceutical regulation at National and International levels. The course prepares the students to pursue career in pharmaceutical industry, drug licensing and control authorities, and export-import agencies dealing with the Pharmaceuticals.

The Course

Highlights of the course are described in the following table:

a.	Name of the course	Post Graduate Diploma in DRUG Regulatory Affairs (PGDDRA)
b.	Nature	Open and Distance Mode
c.	Duration	Minimum: 1 year (2 Semesters of Six months each) Maximum: 2 years
d.	Medium of Instruction and Examinations	English
e.	Eligibility Criteria Educational Requirements	B.Pharm or other Graduates in Medical Sciences, or Graduate in any stream with 1 years experience in Pharma industry, Clinical Research, Regulatory affair and IPR.
f.	Commencement of the course	January / July. Twice in a year
h.	Mode of Admission	As per the norms prescribed by Jamia Hamdard from time to time.
i.	Period of Completion (Span Period)	Not more than 02 years
j.	Fees	Rs. 10,000/- per semester

<u>The Curriculum</u>

Highlights of the curriculum of Post Graduate Diploma in Drug Regulatory Affairs

a.	Total number of Semesters and Examinations	(02 Minimum) While the teaching/counseling of the courses will be done on the Semester

		pattern, the examinations will be held only once a year along with any backlogs or improvement papers.
b.	Total Theory Papers	08 Nos. (100 marks each)
c.	Theory Papers/Semester	08 Nos. (100 Marks each)
d.	Counseling Hours for theory papers	30 hours per theory paper of 4 credits each
e.	Attendance	Attendance not compulsory

- Modes of curriculum transaction include teaching/counseling at the Study Centres, assignments, tests, presentations, participation in relevant events and regularity.

Course Structure

Course structure that guides the teaching and associated assessment of PGDDRA programme is described semester-wise in the following tables:

Semesterwise Distribution of Courses in Post Graduate Diploma in Drug Regulatory Affairs (PGDDRA)

1st Semester				
S. No.	Subject Code	Name of the Paper	Credits	Total
01	PGDRAD 101	An Introduction to Pharmaceutical Drug Regulatory Affairs	4	100
02	PGDRAD 102	General Pharmaceutical Laws and Guidelines	4	100
03	PGDRAD 103	Drug regulatory Affairs in India	4	100
04	PGDRAD 104	Information and Quality Management	4	100
2nd Semester				
S. No.	Subject Code	Name of the Paper	Credits	Total
01	PGDRAD 201	Chemical, Pharmaceutical and biological aspects of Regulatory documentation	4	100
02	PGDRAD 202	Clinical Trials and Health care policies	4	100
03	PGDRAD 203	International licensing	4	100

04	PGDRAD 204	Regulatory considerations in controlled Drug delivery and future aspects of Biopharmaceuticals	4	100

Duration of the Programme
(Minimum-1 Years, Maximum-2 Years)

To fulfill the degree requirements for acquiring the PGDDRA, a students may clear all the subjects in one year. If a student fails to clear all the requirement of subjects in a year, he/she may be permitted to stretch it over a period of another 1 year. In case the student is still unable to pass all the subjects of PGDDRA, programme in 2 years, the student may be permitted to stretch it for another year. In such cases, the student has to seek readmission as per 'Re-Admission' rules and pay the requisite fee.

Admission

a. A candidate, aspiring for admission to PGDDRA programme, shall have to apply in the prescribed application form that is complete in all respects, on or before the last date of submission.
b. The Admission committee shall display/publish the list of candidates who are declared eligible for admission, after the due approval of the competent authority.
c. Eligible candidates shall have to complete the prescribed formalities, for completion of admission, within the stipulate period of time; otherwise they will forfeit the right to admission.

Semester Teaching and Annual Examination

For the purpose of teaching and counseling, academic year shall consist of two Academic Semesters. Examinations of papers of both the semesters will be held at the end of academic year. Format for conducting examinations of papers, after the conclusion of two semesters, are presented in the following table:

a.	Mode (Theory Papers)	Written only
b.	Duration (Theory Paper)	03 Hours
c.	Examiners (Theory Paper)	Paper setters and evaluators to be decided by the University for each paper from time to time.

Annual Examinations

Examinations of all the papers will be held only once in a year at the end of both of the semester. Students will be required to fill up an examination form that will be made available at Jamia Hamdard. The University would send admit-cards to all the eligible

students. Examination fee of Rs. 2,000 will be charged. Admit cards will be issued for examination in the papers for which the student had registered. The decision about the Examination Centres will be the prerogative of the University.

Provision for Unsuccessful Candidates:

Candidates who fail in one or more subject(s) will have to reappear for supplementary examination, which will be conducted along with the term end examination of the subsequent batch.

A student will have to clear all courses in maximum period of two years after admission. After the expiry of this period the learners will have to seek fresh admission.

Award if Division of Successful Candidates:

The candidate will be declared successful on securing 50% marks in each subjects and will be placed in the division in accordance with the following categories on the basis of aggregate marks obtained in all the subjects:

Less than 50%	Fail
50% or above but less than 60% marks	2nd Division
60% or above	1st Division
75% or above	Distinction

DETAIL SYLLABUS OF POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS

PGDRAD 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.

PGDRAD 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.

PGDRAD 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.

PGDRAD 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

PGDRAD 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.

PGDRAD 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.

PGDRAD 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.

PGDRAD 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**

Students' Support Services

The coordinators of the respective Courses would display a copy of such important circulars/ notifications on the notice board for the benefit of all the students. Therefore, it is important for all the students to keep in regular touch with the Study Centers so as to get advance information about assignments, submission schedule, examination forms, list of students admitted to particular examination, declaration of results, etc.

Supply of Study Material

One book per course will be supplied to the students as study material. However, the fast pace of computer industry necessitates that students must read some other reference materials. Studying the supplied printed material alone may not be sufficient for the knowledge of the subject. Therefore, it is strongly recommended that the students take the help of other reference materials/ websites for the preparation of their assignments and other examinations.

Counseling Sessions

In distance education, face -to-face contact between the learners and their teachers/ counselors is relatively less and, therefore, is an important activity. The purpose of such a contact is to answer some of the questions and clarify the doubts, which may not be possible through any other means of communication. It also intends to provide an opportunity to meet the fellow students. There are academic counselors at the Study Centers to provide

counselling and guidance to the students in the courses that they have chosen for study. These sessions will be held at the Study Centers during week ends **(Saturdays and Sundays)**

It may be noted that the counseling sessions would be very different from the classroom teaching or lectures. Counsellors will not be delivering lectures as in conventional teaching. They will try to help the students to overcome difficulties, which they face while studying for the Programme. In these sessions, they must try to resolve their subject-based difficulties and any other related problems.

Before the students go to attend the counselling sessions, they are expected to go through the course materials supplied to them and make a plan of the points to be discussed. Unless they have gone through the Units, they may not find much to be discussed with course counsellors.

COST SHEET OF POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS

SEMESTER - WISE COST / BENEFIT STRUCTURE

Recurring Expenses (A)	
Number of Courses	8
Number of Counseling Sessions	10
Cost Per Counselling Session	Rs.1000.00/hour/Session
Cost Per Course – Counselling Charges	8,000-12,000
Total cost of Counseling Sessions for 8 courses	49,000
Administrative Expenditure per Semester	20,000/month
Total Administrative Expenditure / Semester	1,20,000
Total Recurring Expenses (A)	**2,16,000**
Fixed Cost (B) Study Material Development	
Course Development /Course	65,000
Course Development for 8 courses (Writing/editing/vetting Cost)	5,20,000
Total Courses writing for 3year	1,73,333
Total Cost for SLM per student (including course writing and printing)	**2783**

TOTAL COST PGDPRA DISTANCE (PROGRAM)

All Sessions Counselling (A*4 Semester)	3,20,000 - 3,84,000
Office Expenditure	4,80,000
Total Recurring Expenses (A)	**8,64,000**
Total cost of counseling class per student	**8,640**
Cost of one semester Per Student	**11,423**

PROPOSED FEE STRUCTURE

Expected Admissions per semester	100
Fees per semester / per student	10,000

Total Revenue in one Semester	**10,00,000**

MODE OF PROGRAM

Admission in a year	Two Batches
First Admission	Jan- June
Second Admission	July-Dec

Total Admission in a Year	200
Total Revenue	**40,00,000**

List of Academic Counselors for PGDPRA Programme

S No	Name of the Academic Counsellor	Designation
1.	Dr. Mohammad Ahmed Khan,	Assistant Professor
2.	Mr. Adil Ahmad,	Assistant Professor
3.	Dr. Rabea Parveen	Assistant Professor
4.	Mr. Usman Mansoori	Assistant Professor
5.	Dr. Sarwar Beg	Assistant Professor
6.	Mr. Umair Naqvi	Assistant Professor
7.	Dr. Ruhi Ali	Assistant Professor
8.	Miss Farah Deeba	Assistant Professor
9.	Dr. Javed Khan	Assistant Professor
10.	Dr. Mohd. Ashif Khan	Assistant Professor
11.	Dr. Ibrahhem Hussain	Assistant Professor
12.	Md. Asif Iqbal	Assistant Professor
13.	Mr. Imran Ahmad	Assistant Professor
14.	Dr. Aamir Mirza	Assistant Professor

FEEDBACK OF THE ODL LEARNERS TO MONITOR QUALITY OF STUDENT SUPPORT SERVICES PROVIDED TO THE LEARNERS

We are obtaining a feedback from you for improving quality of the academic programmes we offer and also to improve the quality of student support services provided to you at Jamia Hamdard. We request you to please provide the following information related to your studies at Jamia Hamdard in the ODL Programme. The feedback given by you would help us in improving quality of academic programmes on offer and the student support services.

The filled – in feedback form may be submitted to the undersigned by post / in – person at the School of Open and Distance Learning, First Floor, Hamdard Convention Centre, Jamia Hamdard, New Delhi – 110 062. Scanned copy of the filled – in feedback form can also be sent to me at sodl@jamiahamdard.ac.in.

ACADEMIC SESSION: _____

S No	Feedback Questions	Answers & Remarks
1	Your Name	
2	Your Programme	
3	Your Enrollment Number	
4	Year of Study: Mention – I, II, III, IV, V, VI Semester / 1st, 2nd , 3rd Year	
5	Your Mobile Number:	
6	Your Email ID	
7	Are you in service / employed? Mention – Yes / No	
8	Have you received your Identity Card in time? Mention - Yes / No	
8	Have you received your study material? Mention - Yes / No	
10	Have you received your study material in time? Mention - Yes / No	
11	Have you gone through your study material thoroughly? Mention - Yes / No:	
12	How do you rate quality of the study material? Mention - Excellent / Good / Poor:	
13	Did you attend the Induction Meeting? Mention – yes / No	

14	Have you attended the counselling session? Mention - Yes / No:	
15	If yes, how many counselling sessions you have attended? Mention the number:	
16	Are the counselling sessions conducted as per the schedule? Mention - Yes / No	
17	How do you rate quality of the counselling sessions conducted? Mention - Excellent / Good / Poor:	
18	Have you attended the practical sessions? Mention - Yes / No, if applicable:	
19	How many practical sessions you have attended? Mention number, if applicable:	
20	Are the practical sessions conducted as per the schedule? Mention - Yes / No	
21	How do you rate quality of the practical sessions conducted? Mention - Excellent / Good / Poor	
22	How do you rate ambiance and physical upkeep of the class rooms / laboratories where your counselling / practical sessions were held? Mention - Excellent / Good / Poor	
23	Have you submitted Assignments / Projects? Mention - Yes / No	
24	Are you satisfied with the evaluation of your Assignments / Projects? Mention - Yes / No	
25	Are you receiving feedback from your academic counsellors on your assignment responses? Mention – Yes / No	
26	Have you availed Library Services of Jamia Hamdard? Mention - Yes / No	
27	If No, then why? (You may add additional sheet, if required)	

28	If Yes, how do you rate the quality of library services at Jamia Hamdard? Mention - Excellent / Good / Poor	
29	Have you appeared in the examinations conducted by SODL, Jamia Hamdard? Mention - Yes / No	
30	If Yes, mention the quality of conduct of the examinations. Mention - Excellent / Good / Poor	
31	Are you satisfied with evaluation of your examination papers? Mention - Yes / No	
32	If No, mention reason thereof! Attach additional sheet if required.	
33	Are you getting result in time? Mention - Yes / No	
34	Are you receiving your mark sheets in time? Mention - Yes / No	
35	Are your grievances redressed satisfactorily at SODL? Mention Yes / No	
36	Are your emails responded at SODL in a reasonable time? Mention - Yes / No	
37	How do you rate the quality of responses given to your emails / grievances at SODL? Mention - Excellent / Good / Poor	
38	Have you visited SODL for queries / redress of your grievances? Mention - Yes / No	
39	Are you satisfied with the responses given to you at SODL? Mention - Yes / No	
40	How do you rate the quality of responses given to you at SODL? Mention - Excellent / Good / Poor	
41	How frequently do you visit website of Jamia Hamdard www.jamiahamdard.edu to check for updated information about your studies? Mention – Regularly / Frequently / Never	
42	How do you rate the information given on the website about your studies at Jamia Hamdard?	

	Mention - Excellent / Good / Poor	
43	How frequently do you receive emails alerts from SODL / Programme Coordinators about your studies at Jamia Hamdard? Mention – Regularly / Frequently / Never	
44	How do you rate behavior of teachers of Jamia Hamdard? Mention – Excellent / Good / Poor	
45	How do you rate behavior of staff of Jamia Hamdard? Mention – Excellent / Good / Poor	
46	Are you satisfied studying at Jamia Hamdard? Mention – Yes / No	
47	Will you recommend your friends and relatives to get enrolled for ODL Programmes of Jamia Hamdard? Mention – Yes / No	
48	Would you like to continue your studies at Jamia Hamdard? Mention Yes / No	
49	In which Programme / Course you would like to get enrolled?	
50	Mention the market need – based Programmes / Courses Jamia Hamdard should offer through distance mode	1.
		2.
		3.
		4.
		5.

GENERAL REMARKS AND SUGGESTIONS FOR IMPROVEMENT: (Attach additional sheet, if required)

_____
_____
_____
_____
_____
_____

Date: _____

SIGNATURE OF THE LEARNER

FEEDBACK OF ACADEMIC COUNSELLORS
FOR IMPROVING QUALITY OF THE ODL PROGRAMMES AND THE STUDENT SUPPORT SERVICES

We are obtaining feedback from you to improving the quality of ODL Programmes on offer and also to improve the quality of support services provided to the learners. May I requesting you to kindly provide the following information as your feedback on the academic programme you are associated with at the School of Open and Distance learning, Jamia Hamdard. This feedback would help us for improving quality of the academic programmes and quality of the academic support services provided to learners of your programme.

The filled – in feedback form may please be submitted to the undersigned at the School of Open and Distance Learning, First Floor, Hamdard Convention Centre, Jamia Hamdard, New Delhi – 110 062. Scanned copy of the feedback form can also be sent to me at sodl@jamiahamdard.ac.in.

ACADEMIC SESSION: …….

S No	Feedback Questions	Answers
1	Your Name	
2	Your Programme	
	Courses approved for conducting the academic counselling	1.
		2.
		3.
		4.
		5.
3	Have you received a set of study material? Mention – Yes / No	
4	How many sessions you have conducted in the current academic session. Mention the number	
5	Have you conducted the counselling sessions as per the schedule notified on the website / Notice Board? Mention – Yes / No	
6	How do you rate quality of the study material? Mention – Excellent / Good / Poor	
7	Do you feel syllabus / study material of your Programme needs revision / updating? Mention – Yes / No	
8	Would you like to be a course writer for updating the study material? Mention – Yes / No	

9	Mention the courses / subjects of your choice for wring the study material.	1.
		2.
		3.
		4.
		5.
10	Are learners of your course attending the counselling sessions regularly? Mention – Yes / No	
11	How many learners attend your counselling sessions? Mention an average number.	
12	Do they come prepared for attending the counselling sessions? Mention – Yes / No	
13	Do the learners seek clarifications and participate in discussions during the counselling sessions? Mention – Yes / No	
14	How do you rate participation of the learners during the counselling sessions? Mention – Excellent / Good / Poor	
15	Do the learners approach you on non – counselling days for clarification of their doubts / queries? Mention - Yes / No	
16	Do you evaluate assignments / projects of the learners? Mention – Yes / No	
17	How do you rate quality of the assignments / projects submitted by the learners? Mention – Excellent / Good / Poor	
18	Do you evaluate examination answer books of the learners? Mention – Yes / No	
19	How do you rate quality of response of the learners in their examination papers? Mention – Excellent / Good / Poor	
20	Are you satisfied with the amount of remuneration being paid for conducting the counselling sessions? Mention - Yes / No	

21	Mention the expected amount of remuneration for conducting the counselling sessions	
22	Please suggest new market need – based programmes to offer through distance mode.	1..
		2
		3.
		4.
		5.

23. GENERAL REMARKS AND SUGGESTIONS FOR IMPROVEMENT (Attach additional sheet if required)

_____
_____
_____
_____

Date: _____

SIGNATURE OF THE ACADEMIC COUNSELLOR