Parul® University | NAAC GRADE A++

Centre for Distance and Online Education.

DIPLOMA PROGRAM IN REGULATORY AFFAIRS

Program Code:
2275932

Course Duration:
1 Year

Course Fees:
Rs. 25,000/- & $450
For Indian and International Candidates

PARUL UNIVERSITY

Parul University is an intellectual and a creative quest for all its stakeholders viz. Indian and International Students, Parents, Alumni, Faculties, Industry & Academic partners as well as society at large. We believe in proliferating our efforts towards quality education and environment. Every year we advance our targets to make headway to our scholarly endeavors.

Our University brings to everyone the best of all worlds. Be it its ethics, global exposure, contemporary educational practices, innovation and growth, PU outshines in all of these. We aim to make successful academic pursuits through entrepreneurship, research, modernization and partnerships with educationally inclined organizations, thus enhancing our position as the finest education destination.

We have been pioneers in accepting various interdisciplinary programs and have included them to our ideal and promising higher education curriculum. Starting with this decade it's our collective effort to empower more youth towards the pursuit to continuously learn, enhance skills, generate better employment opportunities and become competent entrepreneurs. For this very purpose, we are initiating a plurality of short term courses.

CENTRE FOR CONTINUING EDUCATION & ONLINE LEARNING

In this present day world, each year creates a generation gap which leads to change in the demand of job skills by the employers. Parul University has embarked on filling this gap by enlightening students and working professionals with the most updated skill based education and to transform them into adept industry professionals and talented entrepreneurs.

Parul University is introducing multiple programs under Centre for Continuing Education & Online Learning which are developed as per industry requirements and in compliance with the changing market needs.

DUAL DEGREE PROGRAM - LETS YOU EARN TWO CREDENTIALS IN DISTINCT DOMAINS

With the ever increasing knowledge and skills in today's competitive world, Parul University's Dual Degree opportunities allow you to pursue two degrees at the same time. Pursuing dual degrees will provide you with the most competitive advantage, and will give you diverse knowledge in multiple fields and disciplines. Undergraduate and Postgraduate students can undergo two degree programs in distinct fields. All programs offered by Parul University under Dual Degree are designed in line with NEP 2020 and guidelines suggested by University Grants Commission (UGC).

Surprising Benefits of Graduating with a Dual Degree

- Enhancing Employability and Entrepreneurship Skills
- Increase in Knowledge Base
- Diverse Career Options
- Enhancement of Multi-disciplinary Talent
- Saving of Time and Money

PREAMBLE

One Year Diploma Program in Regulatory Affairs is designed to equip professionals and students with a comprehensive understanding of regulatory frameworks governing pharmaceuticals, biotechnology, medical devices, and healthcare products. With the increasing globalization in healthcare sector, regulatory compliance has become a critical aspect of product development, approval, and commercialization. This program provides an in-depth exploration of international regulatory guidelines, including those set by USFDA, EMA, CDSCO, ICH, WHO, and other global regulatory bodies. It covers key aspects such as drug development, clinical trial regulations, dossier preparation, quality assurance, and post-market surveillance. The curriculum integrates theoretical knowledge with practical case studies to enhance analytical and decision-making skills in regulatory affairs. The program offers flexibility for working professionals, academicians, and fresh graduates aspiring to build a career in regulatory compliance with a multidisciplinary approach, fostering expertise in both scientific and legal aspects of regulatory affairs. Upon successful completion, graduates will be well-prepared for careers in pharmaceutical industries, healthcare organizations, regulatory agencies, and consultancy firms, contributing to the seamless regulatory approval and market access of healthcare products worldwide.

Program Name: Diploma in Regulatory Affairs

Program Type: Diploma

Program Duration: 1 Year

For Whom: individuals with 10+2 education or relevant education in science stream

Program Fees: The program fee is Rs. 25,000/- for Indian Candidates and $450 for International Candidates

PROGRAM HIGHLIGHTS

- **Comprehensive Curriculum:** Covers key aspects of drug development, clinical trials, dossier preparation, quality assurance, and post-market surveillance.
- **Global Regulatory Frameworks:** In-depth study of regulations by USFDA, EMA, CDSCO, ICH, WHO, TGA, MHRA, and other international regulatory agencies.
- **Multidisciplinary Approach:** Multidisciplinary expertise in both scientific and legal aspects of regulatory affairs.
- **Industry-Relevant Case Studies:** Practical insights through real-world regulatory filings, compliance strategies, and risk management.
- **Professionals-Led Training:** Learn from industry professionals, regulatory experts, and academic scholars with extensive experience.
- **Career-Focused Learning:** Designed for working professionals, fresh graduates, and mid-career professionals aiming for regulatory roles in pharmaceuticals, biotechnology, medical devices, and healthcare industries.
- **Capstone Project & Certification:** Hands-on project-based learning with a certification recognized by regulatory bodies and industry leaders.

CAREER OPPORTUNITIES

Graduates of this program will be well-equipped for diverse roles in the pharmaceutical, biotechnology, medical devices, cosmetics, and healthcare industries, as well as regulatory agencies and consultancy firms. Career opportunities include:

01. Regulatory Affairs Associate/Executive
02. Regulatory Affairs Specialist
03. Regulatory Compliance Officer
04. Regulatory Affairs Manager
05. Quality Assurance (QA) Specialist
06. Quality Control (QC) Analyst
07. Pharmacovigilance Associate
08. Clinical Research Associate (CRA)
09. Medical Writer (Regulatory & Scientific Writing)
10. Drug Safety Specialist
11. CMC (Chemistry, Manufacturing & Controls) Regulatory Specialist
12. Formulation & Regulatory Scientist
13. Drug Inspector/Regulatory Officer
14. Regulatory Policy Analyst
15. Regulatory Consultant
16. Freelance Regulatory Writer
17. Regulatory Affairs Business Development Manager
18. Market Access Specialist

PROGRAM OBJECTIVES AND OUTCOMES

Program Objectives	Program Outcomes
Define regulatory requirements for clinical research, drug safety monitoring, and adverse event reporting.	List essential processes, documentation and reports for regulatory submissions.
Recognize need of international regulatory guidelines, including USFDA, EMA, CDSCO, ICH, WHO, TGA, and MHRA.	Identify global regulatory systems and their norms.
Demonstrate dossier preparation, regulatory submissions, post-market surveillance, and compliance strategies for ensuring product safety and efficacy.	Implement industry standards for compliance.
Analyze regulatory strategies for international product approvals, pricing, and reimbursement policies.	Organize product approvals and market access.
Evaluate quality control, GMP, GLP (Good Laboratory Practices), and GDP (Good Distribution Practices) for regulatory compliance.	Justify the ethical practices and legal implications of regulatory compliance in healthcare product development, drug safety and clinical trials.
Develop expertise in regulatory writing, technical documentation, and electronic submission processes (eCTD and NeeS).	Construct ethical and legal workforce to maintain quality and risk standards.

COURSE CURRICULUM:

Semester – I					
Sr. No.	Subject Name	Teaching Scheme (Contact hrs/week)			Credit Assigned
		Theory	Practical/Tutorial	Total	
1	Fundamentals of Regulatory Affairs	4	0	4	4
2	Pharmaceutical Law and Ethics	4	0	4	4
3	Regulatory Strategy and Planning	4	0	4	4
4	Global Regulatory Frameworks	4	0	4	4
5	Clinical Trials and Regulatory Compliance	4	0	4	4
				TOTAL	**20**

Semester – II					
Sr. No.	Name of the Paper	Teaching Scheme (Contact hrs/week)			Credit Assigned
		Theory	Practical/Tutorial	Total	
1	Medical Devices and In Vitro Diagnostics	4	0	4	4
2	Advanced Regulatory Affairs	4	0	4	4
3	Regulatory Writing and Communication	4	0	4	4
4	Regulatory Inspection and Audit	4	0	4	4
5	Project	0	8	8	4
				TOTAL	**20**