POST GRADUATE DIPLOMA IN REGULATORY AFFAIRS (PGDRA)

- The aim of this program is to provide complete understanding for the Clinical Research and Regulatory Affairs in Pharmacy and Clinical Research process and to provide practical know-how to the participants.

- Since there has been an ever-increasing public and government interest in the safety and efficacy of pharmaceutical and medical device products. This interest has been accompanied by a growing number of regulations that regulatory agencies, such as the Food and Drug Administration, DCGI, ANVISA, WHO, MHRA, EMEA and many more have imposed upon the healthcare product industries. This increase in the stringent regulatory requirements for pharmaceutical and medical device products demands a career in Regulatory Affairs and unfolds a vista full of opportunities for the trained professionals.

- This program include Pharma Regulation Practices and Procedure, Essential Documents for Regulatory Approval Process like Master Formula Record, Master Formula Card, Material Safety Data Sheet and Drug Master File, Pharma Patents, IPR and Regulation, Clinical Trials different Regulation, Pharma Regulatory Regime in USA, EU, ANVISA and Indi, BABE Submissions to different regulatory, Indian Regulatory-Import and Export of Drugs in India, Operations in Clinical Trial, Quality Assurance and Regulation, Product Registration for Regulated Markets and Regulatory Companies for Pharma and allied products.

Duration: Six Months-Part Time

Prospects: Candidates can perform and cater to different profiles like Clinical Research Coordinator, Clinical Research Associate, Regulatory Affairs Executive, Regulatory Affairs-Assistant Manager, Regulatory Affairs Manager

Eligibility: Graduates and Post Graduates in Pharmacy, M.Sc./B.Sc. (Microbiology, Chemistry, Botany, Zoology, Biochemistry, Biotechnology, Life Science), MBBS, BAMS, BHMS, BDS, Physiotherapy, Para-Medical, BPNA, GNM, B.Sc. (Nursing)

Certificate: Certified by Gujarat University (B++/83.1% NAAC Accredited)

Fee: INR 30,000/-

Program Modules:

Chapter 1 Introduction

Chapter 2 Essential Documents for Regulatory Approval Process

Chapter 3 Good Manufacturing Process Guideline

Chapter 4 Basic about Clinical Research

Chapter 5 Various Countries and Its Regulatory Agency

Chapter 6 Clinical Trial Application Requirements

Chapter 7 Regulatory Approaches in India

Chapter 8 ICH Guidelines

Chapter 9 Bioavailability and Bioequivalence Studies

Chapter 10 Guidelines of Bioavailability/Bioequivalence Studies

Chapter 11 Code of Federal Regulations

Chapter 12 Regulatory Submissions

Chapter 13 Introduction and Purpose of Periodic Safety Update Report

Chapter 14 Intellectual Property Rights

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