"If we don't change, we don't grow...If we don't grow, we aren't really living." -Gail Sheehy

The Global Institute of Regulatory Affairs (GIRA) is a change that will help you begin & grow your career in Pharma Industry. GIRA through its industrial expertise offers quality educational programs in the field of Regulatory Affairs. It offers both Full time and part time courses this flexibility ensures prior commitments are taken care of and at the same time skills are added to their CVs. GIRA is a division of PPC which is primarily involved in RA consulting for the past 20 years. RA is a very dynamic field it keeps on evolving to the next level, each time you are faced with a new challenge.

GIRA is promoted directly by MR. Rajkumar Gupta MD of Perfect Pharmaceutical Consultants Pvt Ltd (PPC). He is the founder of the company and has more than 30 years of industrial experience. He has been honored with the GOLD STAR in 1996. He has written various books and articles.

Psychology at GIRA

"Tell me and I'll forget; show me and I may remember; involve me and I'll understand."

People at GIRA believe only theoretical knowledge is no good, Practical application is very important, hence special importance is given to practical aspect of education. With the combination of technology and well experienced faculty measures are taken to see communication is bilateral and knowledge is understood in a practical way.

Vision Statement

GIRA vision is to become to world leader in Regulatory Affairs certification.

Mission Statement

GIRA has a sole aim of bridging Skilled Manpower Gap in Pharmaceutical Industry by providing them with highly trained and qualified personal to manage their regulatory and clinical trial affairs

Course Content

I. The Aims & Structure of Regulation

- ✓ Purpose & principle of Regulations
- ✓ The Legal Framework for Regulations
- ✓ Guidance Document on Regulatory Affairs

II. Regulatory Strategy

- ✓ Basic Regulatory Strategy
- ✓ Quality Assurance System
- ✓ US FDA & ICH
- ✓ EDQM/EMEA
- ✓ MHRA (UK)
- ✓ WHO

III. Marketing Authorization

- ✓ The Concept of CTD Application
- ✓ CTD Module 1- Admin Details
- ✓ CTD Module 2 – Summaries
- ✓ CTD Module 3 – Drug Substance Part & Product Part
- ✓ CTD Module 4 – Non Clinical Study
- ✓ CTD Module 5- Clinical Trials

IV. Non Clinical Study Reports

- ✓ Non- Clinical Study Objectives & Timings
- ✓ Pharmacological Studies
- ✓ Bioavailability and Bioequivalence
- ✓ Toxicology Studies

V. Clinical Trials

- ✓ Clinical Trials
- ✓ Clinical Trial Design
- ✓ Good Clinical Practice
- ✓ The Sponsor
- ✓ The Investigator
- ✓ The Trial Protocol
- ✓ Competent Authority Clinical Trial Application
- ✓ Amendments to Clinical Trials
- ✓ Monitoring of Trials
- ✓ Trial Master File

VI. Submission and Review Process

- ✓ DMF filing procedure for USFDA
- ✓ EDQM and MHRA submissions (EDMF, Certificate of Suitability)
- ✓ National Authorizations (DCGI Submission)
- ✓ WHO Submissions
- ✓ ANDA submissions
- ✓ Review of DMF/Dossier
- ✓ Regulatory Audits

VII. Good Manufacturing Practice (GMP)

- ✓ Essential of GMP Requirements
- ✓ Validation

Click Here To Ask Queries??

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