



Phistar

Pharma Instinct Skill Training & Research



Pharma Instinct

Adding Value to Innovations & Systems

INTENSIVE COURSE IN REGULATORY AFFAIRS

Eligibility: BDS, BAMS, M. Pharma, B.Pharma, M. Sc./ M.Tech/ B. Sc./ B.Tech. in Biotechnology, Microbiology, Biochemistry, Molecular Biology, Ayurveda, Bioinformatics with good communication skills

Duration: 2 Months Classes

Mode: Online / Offline Available



REGULATORY
AFFAIRS

PROGRAMME MODULES:

MODULE - 1: INTRODUCTION TO GLOBAL REGULATORY AUTHORITIES IN PHARMACEUTICAL INDUSTRIES

- Drug Regulations
- Role of Regulatory Authorities
- Global Pharmaceutical Market
- Regulatory Authorities in Regulated and Semi-regulated (ROW) market

MODULE - 2: DRUG DEVELOPMENT PROCESS

- Pre-Clinical Studies
- Phases of Clinical Trials

MODULE - 3: INTRODUCTION OF GOOD MANUFACTURING PRACTICES

- Introduction of Good Manufacturing Practices

MODULE - 4: DRUG APPROVAL AND REVIEW PROCESS

- Drug approval
- Review process


JOB ROLES IN REGULATORY AFFAIRS FOR FRESHERS:

- Regulatory Affairs Associate
- Regulatory Affairs Coordinator
- Regulatory Affairs Assistant
- Junior Regulatory Affairs Specialist
- Regulatory Affairs Trainee
- Regulatory Compliance Officer

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