



**INFORMATION BROCHURE
CERTIFICATE COURSE ON
REGULATORY AFFAIRS**



ONLINE



Course name : Certificate Course on Regulatory Affairs

The Certificate Course on Regulatory Affairs has been developed by industry experts to provide a thorough understanding of the regulatory landscape and its functional areas. With the ever-evolving global regulatory environment, the course ensures comprehensive coverage of regulations governing pharmaceuticals, medical devices, and healthcare products. Participants will gain insights into the latest industry standards, regulatory requirements, and compliance strategies critical to advancing their careers.

The regulatory affairs sector is continuously growing, offering recession-proof, high-demand career opportunities. However, it is a dynamic and challenging field where only well-trained professionals can truly succeed. At Pharmatrendz, we focus on preparing aspiring regulatory professionals with the skills and knowledge needed to navigate this fast-paced industry confidently.

Eligibility

Any Graduation/ B.tech/ B.Sc. in Microbiology/ Life Sciences/ Botany/ Zoology/ Food Science/ Food Technology/ BE/ B.Pharm/ MBBS/ BDS/ BHMS/ BUMS/ BAMS or any other discipline. Diploma holders are eligible for our Executive Diploma, Industry Certificate, and Certificate Programmes.

Course fee : 20000

Duration : 3 months

Mode : Online

Days of Classes –

- Batch 1- Mon, Wed, Fri
- Batch 2 – Tue, Thu, Sat
- Weekend Batch – Sat & Sun

Subjects to be covered

- **Module 1:** Basic Terminologies
- **Module 2 :** Introduction To Clinical Research
- **Module 3 :** Introduction To Regulatory Affairs
- **Module 4 :** Documentation Of Drug, Medical Device, Biologics And
- **Module 5 :** Regulatory Filing In US, Europe, India, Japan, Canada And Australia
- **Module 6 :** ECTD Submission
- **Module 7 :** Intellectual Property Rights
- **Module 8 :** Privacy And Confidentiality
- **Module 9 :** Career In Regulatory Affairs

Course Deliverables

- Comprehensive study materials aligned with current industry standards, provided in hard copies for all modules.
- Assignments for each module to ensure continuous evaluation and personalized guidance.
- Interactive live sessions and online classes covering all key topics, designed for flexibility.
- Weekend online classes, with additional doubt-clearing sessions before assessments.
- Expert faculty ensures that all course content is easily understandable.
- Rigorous assessments to enhance competencies, leading to practical application in regulatory roles.
- Feedback is collected at the end of each module to improve learning outcomes.
- All sessions will be delivered in English.

Examination & Certification

To complete the course, participants must pass all assigned assessments, which include module-wise assignments and a final online exam. Upon successful completion, participants will receive certification from Pharmatrendz. Both online and regular modes of learning are available, with comprehensive study materials and self-assessment assignments provided by the institute.

Career with Placement Assistance

Pharmatrendz offers placement assistance through partnerships with numerous organizations. Our robust placement cell, staffed with senior HR professionals and talent acquisition experts, actively promotes participants' employability. By maintaining strong industry connections, the placement cell works to match participants with suitable career opportunities in the regulatory sector.

Future career prospects of Training in Regulatory Affairs

Professional training in regulatory affairs opens the door to a wide range of career opportunities in the pharmaceutical, biotech, and medical device sectors. A certification in regulatory affairs not only enhances the credentials of those already in the industry but also provides newcomers with the knowledge and confidence needed to thrive. This course covers vital areas such as drug and medical device regulations, quality assurance, compliance, and global regulatory frameworks. Graduates will be well-positioned to pursue roles in drug development, clinical trials, regulatory submissions, quality control, and post-marketing surveillance, among other areas. For professionals looking to transition within their current organization, the course also provides the skills necessary for lateral movement into different departments.



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