# Certificate Program in
# Drug Regulatory Affairs

PHYSIS
LEARNING ACADEMY

# About This Course

The regulatory affairs industry in India is poised for rapid growth which is associated with flamboyant salaries. There are 120+ pharma companies having structured regulatory affairs department in India. Due to the entry of MNCs in India, it is expected a requirement of 30,000 competent and trained workforce in next 5 years.

This self-paced certificate program will provide you a comprehensive training on scientific, practical, ethical and technical concepts of the drug regulatory affairs in compliance with regulatory guidelines. CPDRA is a 6 months course and covers all the essential topics of DRA in 5 major modules covering 300+ topics. Each module is well explained in detail with the help of illustrations, examples, and flowcharts.

# Course Highights

- Mode of Learning: Online/ Distance
- Course Timings: Self-paced
- Course Duration: 6 Months
- Total Efforts: 60 Hours Approximately
- Assessment: Online Single Exam at the End of the Course
- Award: Certificate of Completion and a Grade Card
- Course Access: Lifetime

Please visit our website physislearningacademy.com for information regarding course fee and current batch

# Learning Objectives

At the end of the course, you should be able to learn about the:

- Concepts and processes involved in drug regulatory affairs
- Global regulatory framework of DRA
- Global medical device regulation
- Applicable regulatory requirement and ICH guidelines
- Knowledge & skills required to start career in DRA domain

# Course Curriculum

- Module 1: Introduction to Drug Regulatory Affairs (Evolution, Scope and Role of DRA)
- Module 2: Regulatory Authorities (USFDA, Canadian, EU, CDSCO, ICH, WHO)
- Module 3: Regulatory Requirements in Pharmaceutical (Drug Product Lifecycle – Development, Regulatory Submission, Regulatory Compliance etc.)
- Module 4: Medical Device Regulation (Definition and Classification, Steps in Development, Product Lifecycle)
- Module 5: Applicable ICH Guidelines in DRA (Q1A, Q1B, Q1C, Q1D, Q1E, Q1F, Q2, Q3, Q6, Q7)
- Assessment and Evaluation through Exam

# Who Should Enroll?

- Health-science students/ working professionals (Pharmacy, Life-Science, Medicine, AYUSH, Dental, Nursing, Physiotherapy, Ph.D. etc.) who are looking to gain knowledge & start their career in the drug regulatory profile.
- Fresher, newly appointed and experienced DRA personnel.

# Testimonials

4.4

Average Rating

★★★★½

Course has covered all latest concepts on DRA which are of great need for any professional into this industry.

Neeraj Poddar

Simple and easy to understand course modules are of great help.

Akhilesh Maheshwari

A good course for all the fresher in regulatory affairs.

Ashish Khaitan

Enrolled in DRA and Pharmacovigilance course. Both courses are very good in terms of course content and flow of information.

Vedant Puri

# How This Works?

Upon enrollment, the course participants will get the  login details or course material via post before the start of batch via email.

Upon receipt of course content, the participant can read or log in to take the course modules anytime and from any device.

After reading all the course modules, the course participant is required to attempt and submit an exam.

Upon evaluation of exam, the certificate of completion will be issued to all the successful participants of the batch.

# Contact Us

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