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LIVE ONLINE CLASS

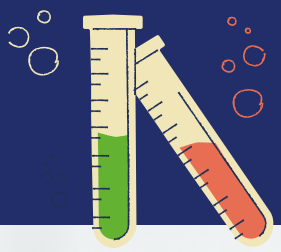
CERTIFICATION IN ADVANCED REGULATORY AFFAIRS

EXCLUSIVE COURSES FOR LIFE SCIENCE AND PHARMA GRADUATES

THE GLOBAL CLINICAL TRIALS MARKET SIZE IS EXPECTED TO REACH USD 69.8 BILLION BY 2027.

BANGALORE CLINICAL RESEARCH INSTITUTE

CERTIFICATION IN ADVANCED REGULATORY AFFAIRS



Unit-1: Introduction to PV Regulations

- Overview of Pharmacovigilance – Importance of safety monitoring.
- Overview of all Pharmacovigilance Regulations.
- Regulatory guidelines and laws governing Pharmacovigilance across Globe.

Unit 2: Global Pharmacovigilance Regulations

ICH Efficacy Guidelines for medicine safety

- E2A
- E2B
- E2C
- E2D
- E2E
- E2F

CIOMS Working Group and Contributions in Pharmacovigilance

- CIOMS 1
- CIOMS 2
- CIOMS 3
- CIOMS 4
- CIOMS 5
- CIOMS 6
- CIOMS 7
- CIOMS 8
- CIOMS 9

Unit 3: Global Pharmacovigilance Regulations

Regulatory Requirements in USA – FDA Perspective

- What, When, How to Report
- Submission Methods

Regulatory Requirements in Europe – EMA Perspective and Regulation

- What, When, How to Report
- Submission Methods

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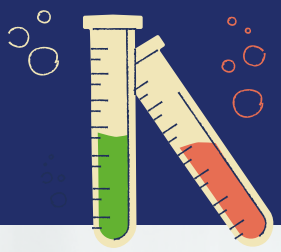

Regulatory system in India (National Pharmacovigilance Program and centres)

- What, When, How to Report
- Submission Methods

Unit 4: Regulatory Screening & Activities in Industry (Practical Aspects)

- Industry method of Regulatory site screening and searches
- Identification of safety reports
- Identification of safety updates and changes
- Identification of labeling changes
- Extended EudraVigilance medicinal product dictionary
- Company Core Data Sheet Preparation

Target Audience:
The target audience for this course would be Candidates interested in the Regulatory domain of Pharmacovigilance, including freshers and experienced candidates.

Note:
The course requires candidates to be familiar with clinical trial fundamentals. There will be a brief discussion in class about pharmacovigilance. We Recommend joining our Certification in Pharmacovigilance & Basic of Regulatory Affairs course to have a better hold on Pharmacovigilance and Regulatory Affairs.

Course Duration :
one Month Monday-Friday Live Online Classes

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