GREAT ONLINE TRAINING

PV & CDM

FULL COURSE

Course Features

Name of the Course	Pharmacovigilance & CDM full course
Duration	60 Days / 1Hr per day
Training Days	Monday to Friday(EST)
Course Materials	Projects, Videos, Books
Realtime Project Data	Life Time Access

GREAT ONLINE TRAINING

About Us.

Great online training is the best e-learning platform which is providing the top quality online courses at affordable prices. Our online training courses are provided by qualified and professional trainers. We offer self-paced online training course to job professionals to learn at their flexible time and from their gadgets. Our instructor-led training is also provided by professional trainers who are available 24/7 to candidates in training period to guide.

In 10 years of experience we trained over 0.25 million candidates. Our team has the ability to identify the skills and tasks that the emerging market requires and examine the weaknesses or gaps as well as determine what steps can be taken to elevate your capabilities. Our team has the ability to identify the skills and tasks that the emerging market requires and examine the weaknesses or gaps as well as determine what steps can be taken to elevate your capabilities.

ENROLL TO INSTRUCTOR LED TRAINING

GREAT ONLINE TRAINING

About

Pharmacovigilance & CDM course.

Our Pharmacovigilance & Cdm course covers the essentials of drug safety. Learn about adverse event reporting, signal detection, risk management, and regulatory aspects. Master the tools and practices required in real-world pharmacovigilance scenarios. Step into a safer future in pharma today.

Course Features:

- Unlimited training Attempts
- Daily Class Recordings
- 24/7 support
- Resume & Interview Preparation

Training Modes:

- Self-paced training
- Instructor-led training

Candidate Requirements:

- Need to have some basic knowledge Requirment on computer
- Person with Gud internet connectivity
- laptop

Who are Eligible:

- Any Graduates
- PHD candidates
- Graduates
- Programming enthusiasts
- Technical leads

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About

PV & CDM course.

Training Course Includes:

Pharmacovigilance Training
✓Daily class recordings
✓Pharmacovigilance Material
✓Real-time Project
✓Life Time Access to Course
✓Pharmacovigilance Project
✓Pharmacovigilance Job Support
✓Resume
✓Mock Interview
✓Clinical research and data base
✓Oracle clinical database
✓Various phases of clinical trails
✓INDA and NDA applications
✓ICH-GCP guidelines
✓CRF annotation
✓In Oracle clinical database subsystems, programs, projects, regions,
✓ creation of intervals and events, investigator site records and
✓assignments and more functions
✓In RDC data entry process, discrepancy management and CRFS.

Certification Details:

- After successful completion of training course industry recognized certification will be provided to candidates.

GREAT ONLINE TRAINING

Professional Team

Meet Our Trainers.

Ramya

Pharmacovigilance Trainer

A magazine is a periodical publication, which can either be printed or published digitally. It is issued regularly, usually every week or every month, and it contains a variety of content. This can include articles, stories, photographs, and advertisements. To create your own, choose a topic that interests you.

Chandrakala

CDM Trainer

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Course Curriculum

PV

- Day 1: Overview of pharmacovigilance
- Day 2: Brief about drug discovery, development and clinical trials
- Day 3: Terms and definitions in Pharmacovigilance - as per ICH E2A, CIOMS and GVP guidelines
- Day 4: Pharmacovigilance process flow
- Day 5-14: Pharmacovigilance Regulatory Requirements
- Day 15-26: ICSR processing
- Day 27-31: Aggregate Reporting
- Day 32-33: Signal Management
- Day 34-35: Vaccine pharmacovigilance
- Day 36: Device Pharmacovigilance
- Day 37: Herbavigilance
- Day 38: Medicine Safety plans (RMP and REMS)
- Day 39-40: Pharmacovigilance Inspections and Audits
- Day 41-46: ARGUS training and Case scenarios

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Course Curriculum
CDM

Module1: Clinical Research and CDM

- Introduction To Oracle Clinical Database
- Introduction To Clinical Research And CDM
- Different Phases Of Clinical Trials
- INDA, NDA Applications
- ICH-GCP Guidelines
- Responsibilities Of Clinical Trial Team
- Protocol And Informed Consent Forms
- Clinical Data Management Process And Life Cycle
- Data Management Plan
- Case Report Forms, Types Of CRFs
- Designing Of CRFs
- CRF Annotation
- Data Capture Methods And EDC
- Data Entry – First Pass And Second Pass Entry
- Edit Check Specifications
- Data Validation Procedures
- Discrepancy Management
- Data Clarification Forms (DCFs)
- Database Locking And Freezing
- Data Coding And Medical Dictionaries
- SAE Reconciliation

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Course Curriculum
CDM

Module2: Oracle Clinical Database

- Introduction To Oracle Clinical Database
- Introduction To OC Window
- Subsystems In OC
- Defining Programs And Projects
- Defining Organization Units
- Defining Regions
- Defining Planned Studies
- Easy Study Design
- Creating Intervals
- Creating Events
- Creating Investigator, Site Records And Assignments
- Creating Patient Positions And Assignments
- Creating Questions
- Creating Question Groups
- Creating And Maintaining DVG's
- Creating DCM's, DCI's & DCI Books
- Test A Study
- Test Data Entry
- Initial Login
- Key Changes
- First Pass Entry

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Course Curriculum CDM

Module2: Oracle Clinical Database

- Second Pass Entry
- Comparison Reconciliation
- Update
- Browse
- Patient Enrollment
- Data Validation(Batch Validation)
- Discrepancy Management
- Data Clarification Forms (DCFs)
- Locking And Freezing

Module3: RDC (Remote Data Capture)

- DATA ENTRY IN RDC
- DISCREPANCY MANAGEMENT IN RDC
- CRFS IN RDC

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For Live Training

To Enroll for Free Demo Session Please Visit Our Website
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Thank You !