QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses

Drug Safety Pharmacovigilance Associate (DSAT)

Self-Paced Online Training

Our Mission

Our mission is to provide the best-in-class job oriented certification and skill based courses towards Clinical research, Drug Safety, Pharmacovigilance, Clinical Data Management, Clinical SAS Data Analytics and Healthcare business. We offer Entry-Mid and Senior programs for students and professionals, looking for skills refresh or career advancement

CAREER FOCUSED PROGRAM

(Learning for Job)

Drug Development

The process of drug development is generally divided into to stages: (1) new lead discovery (preclinical research), and (2) new product development (clinical development). Drug Safety Pharmacovigilance Associate can work in Pharmaceuticals, Medical Device, Hospitals and research institutions, such as academic health government agencies and departments, contract research organizations/ centers. Their primary role is to identify safety and risk information, evaluate and report with regulatory authorities.

Overview of the Curriculum

Designed by industry experts for students and young professionals. The training program provides in depth knowledge of roles and responsibilities of Drug Safety / Pharmacovigilance Specialist including theoretical aspect of the field and exposure to variety exercises based on industry requirements.

LIST OF TOPICS:
THEORETICAL ASPECT OF THE FIELD

1. Introduction to Clinical Research
2. Drug Development Process
3. Introduction to Drug Safety / Pharmacovigilance
4. Role of DSA / PVA (Trials)
5. Introduction to Adverse Events
6. ICH-Good Clinical Practice Guidelines
7. Drug Safety Regulation and Guidelines
8. Overview of Clinical Trial Protocol
9. Characteristics of a Case
10. Sources of Individual Case Reports
11. Drug Safety Data Extraction and Pre-Processing
12. SOP Development
13. Communication with Cross Functional Team
14. Understanding 21 CFR Part 11 and HIPAA
15. Basic of Coding in Drug Safety
16. Case Follow up approaches and handling of Cases
17. Clinical Trial Safety Surveillance
18. Phase IV Trials and Pharmacovigilance
19. Case Narratives
20. SAE Reconciliation
21. Drug Safety Database and Software
22. Special Scenarios

This course emphasizes about drug safety and pharmacovigilance along with project management concepts. Contains lessons on Introduction to Clinical Research, Drug Development Process, Introduction to Drug Safety / Pharmacovigilance, Role of DSA / PVA (Trials), Introduction to Adverse Events, ICH-Good Clinical Practice Guidelines, Drug Safety Regulation and Guidelines, Overview of the Clinical Trial Protocol, Characteristics of a Case, Sources of Individual Case Reports (ICSR), Drug Safety Data Extraction and Pre-Processing, SOP Development, Communication with Cross Functional Team, Understanding 21 CFR Part 11 and HIPAA, Basic of Coding in Drug Safety, Case Follow up approaches and handling of Cases, Clinical Trial Safety Surveillance, Phase IV Trials and Pharmacovigilance , Case Narratives, SAE Reconciliation, Drug Safety Database and Software, Reporting under Special Scenarios.

The Main Roles and Responsibilities of Drug Safety / Pharmacovigilance Associate

- ❑ Checking the accuracy and cohesiveness of clinical drug trials adverse event and serious adverse event reports and establishing their priority
- ❑ Preparing and reviewing safety reports, such as DSUR, PSUR/ PBRER, PADER,
- ❑ Responding to product safety inquiries, i.e., originating from regulatory authorities, healthcare professionals, patients
- ❑ Assessing patient eligibility for clinical trials
- ❑ Entering data into safety databases and reporting systems
- ❑ Processing adverse event reports from various sources to ensure compliance with regulations
- ❑ Initiating quality assurance analysis on specific drug cases
- ❑ Reviewing the work of other DSA / PVA.
- ❑ Representing drug safety operations at meetings, presentations, and training programs
- ❑ Preparing comprehensive reviews of adverse or serious-adverse events
- ❑ Identifing potential sources of product litigation
- ❑ Processing case-related information
- ❑ Writing case narratives
- ❑ Ensuring compliance with the MedDRA (Medical Dictionary for Regulatory Activities) coding, retrieval and analysis terminology
- ❑ Performing safety audits for the trial clinical data
- ❑ Contributing to the development and training of staff members

Hiring DSA professionals:

Do You Know…?

- ✓ 99% of the employers choose candidates with **doctor of pharmacy (PharmD)**
- ✓ 80% of the employers choose candidates with **nursing** degree
- ✓ 90% of the employers choose candidates with **medicine** degree
- ✓ 80% of the employers choose candidates with **public health** degree
- ✓ 80% of the employers choose candidates with **pharmaceutical chemistry** degree

Contact Information

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