QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses

Drug Safety Assistant (DSAA)

Are you currently working as entry level drug safety associate? Are you ready for career advancement to the higher level of DSA role?

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 Safety Assistant

Designed by industry experts for professionals looking to add new skill set.

LIST OF LESSONS

*** Real time scenario cases are assigned to each topic:**

ROLE BASED PROJECTS - EXCERCISES

- 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
- Characteristics of a Case
- Sources of Individual Case Reports
- 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 ofCases
- Phase IV Trials and Pharmacovigilance
- Clinical Trial Safety Surveillance
- SAE Reconciliation
- Drug Safety Database and Software
- Special Scenarios

HIRING TRENDS

Education Preferred by Employers Hiring for DSA positions:

Doctor of Pharmacy - 99%
Nursing - 75%
Medicine - 50%
Pharmaceutical Science -25%

Role of Drug Safety Assistant

- ❑ 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
- ❑ 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 DSAs
- ❑ Representing drug safety operations at meetings, presentations, and training programs
- ❑ Preparing comprehensive reviews of adverse or serious-adverse events
- ❑ Identifying 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
- ❑ Review and develop Aggregate Reports required for submissions (PSUR, DSUR, PADER etc)

Hiring Drug Safety / Medical Reviewer Professionals:

- ✓ 99% of the employers choose candidates with **Doctor of pharmacy (PharmD)**
- ✓ 80% of the employers choose candidates with Registered N**ursing (RN)**
- ✓ 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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