



QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses



Drug Safety- Pharmacovigilance Data Management (DSPM)

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 DATA MANAGEMENT

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

BASICS OF DRUG SAFETY

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

ROLE BASED PROJECTS

1. Medical Record Extraction
2. Adverse Events Case Processing
3. CIOMS Line Listing
4. Case processing and FDA Reporting for Medical Devices
5. Revision of SOP Quality Control Procedure
6. SAE Reconciliation
7. PSUR - Periodic Safety Update Reporting
8. Triage
9. Data Entry
10. Signal Detection
11. Labeling Edit check
12. Quality Control Procedure
13. Resolution of queries of pending cases
14. SUSAR – Suspected Unexpected Serious Adverse Reaction

ADVANCED DRUG SAFETY TOPICS

1. Introduction to MedDRA
2. MedDRA Coding Guidelines
3. AE Causality assessments
4. ICSR Medical Causality assessment
5. Risk Management Plan (RMP)
6. Introduction to Risk Management Plan (REMS)
7. ARGUS Tool Safety End-User Training
8. Product Technical Complaints (PTC)
9. Corrective and Preventative Actions (CAPAs)
10. Overview of Aggregate Reporting (PSUR/ PBRER)
11. Overview of Aggregate Reporting - PADER
12. Overview of Aggregate Reporting - PRAC / DSUR



Responsibilities Senior Drug Safety / Medical Reviewer

- 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 Nursing (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**



Contact Information

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