# QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

**Job Focused Clinical Science Courses**

## Drug Safety Role Based Projects (DSAP)

**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 - Pharmacovigilance
# ROLE BASED PROJECTS

*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

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

This course provides projects and hypothetical tasks as learning to work as DSA or Pharmacovigilance Associate. This is a job and title focused program focusing on Drug Safety and Pharmacovigilance tasks performed during Clinical Trial and Long-Term Phase IV (Post-Marketing Surveillance) studies. This is a job and title focused program. The course emphasizes about Case Registry, Triage, Argus Data Entry (Case Studies, ICSR), QA/QC , Medical Review and Submissions of E2B Safety data with regulatory authorities. The course curriculum is designed to give an edge to obtain job opportunities in the drug safety field with Pharmaceuticals, Biotech, Medical Device, Clinical Research Organizations (CROs) and with Research Clinics.

## 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 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
- ❑ 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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