# QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC

Somerset New Jersey USA

Private Vocational School

Training Division of Qtech Solutions Inc.

# ADVANCED Drug Safety Associate Training (ADSA)

## Our Mission

**Our mission is to provide the best-in-class job oriented career development Elearning training courses and programs in clinical research, SAS data management and business analysis for students and institutional professionals requiring a skills refresh – or the development of new skills and experience for job entry, advancement, and placement**

**Are you currently working as entry level drug safety associate?**
**Are you ready for career advancement to the higher level of DSA role?**
**Did you complete basic DSA training, but you wish to add new skill set?**


If your answer is yes to any of the questions above, starting advanced DSA training program might be a right decision. Your job promotion depends on work experience, but also motivation, and possessing advanced skills.

**Trng. Website:** www.qtechelearncenter.com **Email:** qpdc@qtech-solutions.com

# Overview of Advanced Drug Safety Associate Curriculum

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

**LIST OF TOPICS**

*** The real time scenario case is assigned to each topic:**

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

## HIRING TRENDS

### Education Preferred by Employers Hiring for DSA positions:

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

What is the Difference Between **DSA** and **Advanced DSA** Training?

| DSA | ADSA |
|---|---|
| Basic and core topics and exercises | Advanced topics and exercises |
| Certain educational background is strongly recommended to enter the industry | Prior training or relevant experience is required |
| Designed for non experienced individuals to enter into field | Designed for experienced professionals to add new skills set |
| In depth knowledge of roles and responsibilities of DSA + theoretical aspect with projects which help to understand industry requirements | Exposure to diverse DSA exercises, real time documentation + advanced learning supported by practical case scenario tasks and follow up process |

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## The Main Roles and Responsibilities of ADSA

- ❑ Checking the accuracy and ccohesiveness 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
- ❑ 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


**Contact Information**

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