

*Qtech-Sol Professional Development Center LLC*

3 Executive Drive, Suite 320  
Somerset, New Jersey 08873



**Private Vocational School**  
**School Catalog**  
**2016**

**06.03.2016**

**Signatory Page / Person**

<b>APPROVED BY</b>				
By signing this section, the individual below agrees that he/she has reviewed and approved this functional document described in this School Catalog document. The signature below represents the approval of this document for execution and acceptance by Qtech Solutions Inc management for approval of proposed PVS - School Qtech-Sol Professional Development Center (Training division of Qtech Solutions Inc., NJ) to be presented to State of NJ / DOL for approval process.				
<b>Role</b>	<b>Title, Department</b>	<b>Name</b>	<b>Document</b>	<b>Date</b>
Director	TRAINING DIVISION	Umachandran Thumbavanam	School Catalog for Qtech-Sol Professional Development Center	11-MAY-2012
Director	TRAINING DIVISION	Chandra Nate	School Catalog for Qtech-Sol Professional Development Center	2-MAY-2013
Director	TRAINING DIVISION	Chandra Nate	School Catalog for Qtech-Sol Professional Development Center	10-JULY-2014
Director	TRAINING DIVISION	Chandra Nate	School Catalog for Qtech-Sol Professional Development Center	28-FEB-2015
Director	TRAINING DIVISION	Chandra Nate	School Catalog for Qtech-Sol Professional Development Center	23-MAY-2015
Director	TRAINING DIVISION	Chandra Nate	School Catalog for Qtech-Sol Professional Development Center	03-JUN-2016

<b>INITIAL PREPARED BY</b>				
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<b>Role</b>	<b>Title, Department</b>	<b>Name</b>	<b>Document</b>	<b>Date</b>
Marketing Analyst	TRAINING DIVISION	Magdalena Oleksiewicz	School Catalog for Qtech-Sol Professional Development Center	01-MAY-2012

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<b>Role</b>	<b>Title, Department</b>	<b>Name</b>	<b>Document</b>	<b>Date</b>
Marketing Manager	TRAINING DIVISION	Magdalena Oleksiewicz	School Catalog for Qtech-Sol Professional Development Center	25-APRIL-2013
Director	TRAINING DIVISION	Chandra Nate	School Catalog for Qtech-Sol Professional Development Center	18-FEB-2015

**Revision History**

<b>Rev. #</b>	<b>Date</b>	<b>Author</b>	<b>Description</b>
1.0	25-APRIL-2013	Magdalena Oleksiewicz	Draft Template Document Submitted for PVS Renewal Package
2.0	8-MAY-2013	Magdalena Oleksiewicz	Corrections to Refund Policy in 16.1, p.19 (Reimbursement Scale) in Accordance to Per NJAC, chap. 41, p. 11
3.0	18-JUNE-2014	Krishna Mahida	Up dated Section 1. Administrators and Staff
4.0	10-JULY-2014	Chandra Nate	Updated Section 12.1 Refund Policy
5.0	28-FEB-2015	Chandra Nate	Updated Location Address Pages 5, 7 & 23
6.0	23-MAY-2015	Chandra Nate	Updated Item 1, 4 and 16
7.0	03-JUN-2016	Chandra Nate	Updated Sections 3, 4, 5, 6, 7, 9, 12, 13, 17 and 21

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## 1. Administrators and Staff

### Administration / Student Advisement

Chandra Nate [chandranate@qtech-solutions.com](mailto:chandranate@qtech-solutions.com)  
Program Director

Meena Ramachandran [meenar@qtech-solutions.com](mailto:meenar@qtech-solutions.com)  
Administrative Officer

### Technical Web Support

Subba Rao [subba.rao@qtechelearncenter.com](mailto:subba.rao@qtechelearncenter.com)

### Subject Matter Expert (Delivery & Evaluation)

Chandra Nate [chandra.nate@qtechelearncenter.com](mailto:chandra.nate@qtechelearncenter.com)  
Jigna Parekh [jigna.parekh@qtechelearncenter.com](mailto:jigna.parekh@qtechelearncenter.com)  
Chintan patel [chintan.patel@qtechelearncenter.com](mailto:chintan.patel@qtechelearncenter.com)

### Business Analyst (Planning & Strategy)

Shahnaz Ruby (Finance) [shahnaz.ruby@qtechelearncenter.com](mailto:shahnaz.ruby@qtechelearncenter.com)

### Research Analyst (New Products)

Chandra Nate [chandra.nate@qtechelearncenter.com](mailto:chandra.nate@qtechelearncenter.com)  
Swanandi Tare [swanandi.t@qtechelearncenter.com](mailto:swanandi.t@qtechelearncenter.com)

### Product Technical Writer (Content Matter Experts)

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Abhishek Thummanapally [abhishek.t@qtechelearncenter.com](mailto:abhishek.t@qtechelearncenter.com)

### LMS System Administration

Kalyan Vempaty [kalyan.vempaty@qtechelearncenter.com](mailto:kalyan.vempaty@qtechelearncenter.com)

Attendance staff is available Monday through Friday from 9:30 a.m. to 5:00 p.m. EST.

Updated on 06.03.2016

## 2. School Calendar

The following holidays will be observed by the school and classes will not be held.

### Observed Holidays:

- New Year Observed Day
- Martin Luther's King Day
- President's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- Christmas Eve
- Christmas Day

## 3. Class Schedule

Normal Business hours is from 9:30 A.M. EST until 5:00 P.M. EST from Monday to Friday.

Class schedule includes 45 days of online access to the material supported with 10 WebEx sessions (2 hours each) and faculty student interactive sessions provided to those who need additional assistance during their learning curve (2 hours each). Option is provided to student to attend the Class session On-Site at QPDC.

Faculty student query interactive sessions are provided per appointment to those who need additional assistance. The assistance is given per appointment in person during office hours, via email, phone call or via Skype.

### (A) For Blended Class-room program (BIP) - online access with WebEx sessions

- ✓ The schedule of WebEx classes varies by batch. Minimum of 7 students is required to initiate WebEx classes.
- ✓ Students are informed about WebEx class schedule as soon as batch of min of 7 students are enrolled.
- ✓ 10 WebEx classes are scheduled within 45 days of the training program
- ✓ Make-up WebEx session is available to students in case they missed the class and they will attend in the next batch schedule.
- ✓ Qtech may cancel or reschedule a training course if the number of participants is less than 7, or if an instructor is incapacitated through illness, or for other reasons of a serious nature

- ✓ Due to non-availability of faculty alternative day will be provided

### **(B) Advanced Learning programs (Internship program) - 15 Hours (Optional)**

Student will have opportunity to enroll into Advanced learnings sessions as Internship. This program is conducted for 15 Hours as WebEx Sessions focusing on role based learnings as project management activities. During this Internship case projects are provided for student to apply their learning as real-time. During Internship, the students are subject to deliver various project related exercises and will attend 5 WebEx sessions. All Exercises must be submitted via email. Due to changing and challenging job market scenario, the Students are provided with additional details per current findings and learnings required to meet the job market.

### **(C) Post Training Assistance Program - 10 Hours (Optional)**

Additional minimum 5 days (10 hours) of post training support is provided to students:

The post training support is conducted for the period of minimum 5 business days (10 hours), which includes:

- ✓ Resume writing
- ✓ Interview tips as guidelines
- ✓ Narrative preparation
- ✓ 2 Mock interviews

## **4 Registration Requirements**

Students/Trainees may register for courses up to one week (5 business days) prior to the start of Classes. Students must register online at <http://www.qtechelearncenter.com> and take a survey describing their Educational background, experience level, Work Permit Status in USA and reason for taking the course.

Other documents required:

- Copy of Identification (one of the following: current drivers license, birth certificate, passport, or Green Card permanent resident card)
- Most updated resume
- Copy of Bachelor/Master degree
- Completed Application form
- Passport Photograph (1)
- Print out of online registration (established at: <http://www.qtechelearncenter.com>)

- Personal essay (50-100 words statement explaining the reason why candidates has chosen our program and his/her thoughts about further career path)
- Proof of payment for registration and tuition fees. We accept credit card payments and personal checks payable to: “Qtech-Sol Professional Development Center LLC, NJ”.

All documents must be submitted in person to the HR Department, faxed at (888) 532-0210 or send by mail to the following address:

**Qtech-Sol Professional Developments Center LLC**

**Human Resources**

**3 Executive Drive, Suite 320**

**Somerset, New Jersey 08873**

## **5. School Policies**

### **5.1 Entrance Requirements**

Every student/trainee must:

1. Be at least twenty-one (21) years of age on or before the first day of class.
  2. Hold minimum of Bachelor degree.
- If the student is interested in enrolling in Drug Safety/ Pharmacovigilance Associate (DSA/ PVA) the following educational background is advised:
    - ✓ Pharmaceutical Chemistry
    - ✓ Public Health/Medicine
    - ✓ Pharmaceutical Management
    - ✓ Clinical Research
    - ✓ Biotechnology
    - ✓ Master of Public Administration
    - ✓ Pharmacy
    - ✓ Pharmaceutical Engineering
    - ✓ Pharmacology/Toxicology
    - ✓ Pharmaceutical Business
    - ✓ Industrial Pharmacy
    - ✓ Industrial Chemistry



- If the student is interested in enrolling in Clinical Research Associate / Coordinator (CRA/CRC) the following educational background is advised:
  - ✓ Pharmaceutical Chemistry
  - ✓ Pharmaceutical Engineering
  - ✓ Public Health/Medicine
  - ✓ Clinical Data Management
  - ✓ Biomedical Engineering
  - ✓ Chemical and Materials Engineering
  - ✓ Biology
  - ✓ Biological Science
  - ✓ Biotechnology
  - ✓ Nursing
  - ✓ Master of Public Administration
  - ✓ Chemistry
  - ✓ Biochemistry
  - ✓ Pharmacy
  - ✓ Pharmacology/Toxicology
  - ✓ Pharmaceutical Business
  - ✓ Industrial Pharmacy
  - ✓ Industrial Chemistry
  
- If the student is interested in enrolling in Clinical Research Data Management (CDM) the following educational background is advised:
  - ✓ Pharmaceutical Chemistry
  - ✓ Pharmaceutical Engineering
  - ✓ Public Health/Medicine
  - ✓ Clinical Data Management
  - ✓ Biomedical Engineering
  - ✓ Chemical and Materials Engineering
  - ✓ Biology
  - ✓ Biological Science

- ✓ Biotechnology
- ✓ Nursing
- ✓ Master of Public Administration
- ✓ Chemistry
- ✓ Biochemistry
- ✓ Pharmacy
- ✓ Pharmacology/Toxicology
- ✓ Pharmaceutical Business
- ✓ Industrial Pharmacy
- ✓ Industrial Chemistry

The above recommendations in regards to educational backgrounds are strongly advised but not limited to. In the circumstances the candidate who applies for the training presents different educational background, the management will review student's resume and will suggest alternative career path.

## 5.2 Attendance Requirements

QPDC's online courses are delivered via the Qtech LMS (Learning Management System), using internet connection and Microsoft Suite.

The participation in WebEx class sessions requires prior download of WebEx application. The invitation and instructions for WebEx installation will be sent prior to the WebEx class. Speakers and microphone or a headset is required for the purpose of discussions and being able to talk with the instructor during the class via voice.

During the WebEx sessions, the attendance will be taken by faculties. Local Students are requested to attend the session On-Site at QPDC Location in Somerset, NJ.

HR Department of Qtech-Sol Professional Development Center will keep records of student's attendance on file. Records will be available for the review per student's request.

In regards to WebEx classes, this school requires students to be in attendance for 100% percent of the training in order to guarantee the effectiveness of the program and maintain the appropriate learning curve.

Absenteeism for the WebEx class sessions may cause discrepancy of learning curve and failure of final exam.

### 5.3 Leave of Absence

Students will be granted a leave of absence for WebEx classes upon request. The following guidelines must be adhered to:

1. The request for a leave of absence for WebEx class must be submitted to the Director in writing via email to Human Resources at [helpdesk@qtechelearncenter.com](mailto:helpdesk@qtechelearncenter.com) or at [info@qtech-solutions.com](mailto:info@qtech-solutions.com).
2. The request must have the date that the student will begin the leave of absence and the expected date of return to WebEx classes as well as the reason of absence.
3. HR department will direct the request to the program Director, who will consider the reason of student's leave of absence and schedule a "make up" WebEx session with the next available batch.
4. On the occasion if there is no available spot in any upcoming batches, student will need to make up material covered in WebEx class on his/her own.
5. Leave of absence will be honored within the student's Enrollment Agreement contract and will not extend beyond the contract.

Note: Each individual situation will be handled privately. The school will make every effort to help students meet their educational goals. Leave of absences that extend beyond the original contract may be subject to additional tuition costs. Students should be prepared to make up WebEx lessons missed prior to re-entry into the program.

### 5.4 Missed Lessons (WebEx Classes)

Hours lost due to missing WebEx class will be recorded as absences. Students are responsible for making up class work and assignments. Missed WebEx lessons must be made-up in order to follow effective learning curve.

### 5.5 Make-up Work

In order for students/trainees to meet their educational goals they must follow instructions in all aspects of the program. WebEx lessons missed due to absences or a leave of absence need to be made up.

It is advised that the students/trainees make up missed WebEx classes and assignments as soon as possible in order to continue effective learning path. Please refer to "Leave of Absence" for written request and procedure for "make up" WebEx classes.

Students should complete missed assignments which will always be available online. In case student needs to clarify which assignments were covered during missed WebEx session, he/she has to communicate with the instructor or administrator to get missed assignments.

Students who do not take advantage of the school's make-up policy may be affected by discrepancy of learning curve. When applicable, should the student request to wait until the missed WebEx lesson is offered in another batch. However, the student needs to be aware that this may change their completion date. The student will need permission from the Program Director for a change in completion date and may result in a contract amendment.

## 5.6 Tardiness

Developing good work ethics is an important part of the WebEx training at Qtech-Sol Professional Developing Center. Students arriving late for WebEx classes are interrupting the instructor and other students. Thus, it is strongly recommended to have online access and be prepared for WebEx session at least 5 minutes before the start of the WebEx class.

The roster will be provided to the faculty, who will record student attendance in WebEx session by date.

It is the responsibility of the student to make up missed assignments.

## 6 Code of conduct

### 6.1 Introduction and purpose

All individuals enrolled and attended training programs of Qtech-Sol Professional Development Center are expected to know and follow the Qtech-Sol Professional Development Center's Student Code of Conduct. The Student Code of Conduct is established to foster and protect the core missions of the Qtech-Sol Professional Development Center as the private vocational school.

The core mission Qtech-Sol Professional Development Center is to provide the best-in-class job oriented career development class-room and online training programs in Clinical Research, Pharmacovigilance-Drug Safety, Data management using SAS and Business analysis programs. We are primarily engaged in offering an array of short duration courses and seminars towards professional development. The Training's are provided to individuals and corporate through employers training programs. Our courses are customized and modified to meet the job market. Our Instructions is provided thru our custom-built Learning Management System as distance-learning (Online) and On-site. The training provided has simulation methods and client settings required for student online learning.

Our PLACEMENT division offers Internship and support to client by providing resources to meet cost efficiency, time saving, and commitment towards hiring solutions to various companies in pharmaceutical, healthcare, and financial segments. QPDC is an equal opportunity employer.

The Qtech-Sol Professional Development Center upholds a core set of values which include: (1) quality through continuous improvement, (2) continuous individual development, (3) teamwork and 'doing what's right'.

## 6.2 Code of conduct

The following conduct is unacceptable and will not be tolerated:

1. All types of proven dishonesty, including cheating, plagiarism, knowingly furnishing false information to the institution, forgery and alteration or use of institution documents of identification with intent to defraud.
2. Intentional disruption or obstruction of teaching, research, administration, disciplinary proceedings, public meetings and programs, or other school activities.
3. Failure to comply with directions of institutional officials acting in the performance of their duties.
4. Behaving without honesty and without integrity in the training course of Qtech.
5. Acting without care and diligence in the course material.
6. Disobey confidentiality about of the given training material. In this case restrictions include, but are not limited to sharing log in user ID with other participants or other individuals not attending the training program, and printing material that is restricted for download and secured for copyrights purposes.
7. Giving false or misleading information in response to a request for information that is made for admission purposes in connection with the training program.
8. Improper use of:
  - Inside information, or
  - The instructor's duties, status, power or authority in order to gain, or seek to gain, a benefit or advantage for the employee or for any other person;
9. Disobey instructions and training rules, such as:
  - Full attendance in WebEx training sessions necessary for students' success and to achieve the maximum possible benefits from their educational experience,
  - Punctuality and following the deadlines. Trainees must be available online at scheduled time with the appropriate materials, ready to work at the designated time that class session begins,

- Participation and responsibility. Training attendance is the responsibility of participants.

## 7 Conditions for Dismissal

Students may be dismissed from the school for the following reasons:

1. Not adhering to the school's rules, regulations, policies and code of conduct, in particular:
  - Breaching of intellectual property and copyright laws
  - Unreasonable using insults, gestures, or abusive words directed to the instructors or management representatives during WebEx sessions
  - Distributing course material to other individuals
  - Sharing course material for financial gain
2. Missing WebEx session classes
3. Not meeting financial responsibilities to the school

The school director will notify the student in writing or via email should it become necessary to dismiss the student, followed by informing the department and student by email. The dismissal letter will contain the date and the reason for dismissal.

## 8 Re-entry Policy

Students that have been dismissed from the school and are requesting re-entry must put the request in writing to the Program Director.

In cases where the student was dismissed for excessive absences or financial concerns it may be not possible to re-enter within the same course batch. However students can request for alternative available schedule for cover up classes in another batch.

In cases where the student was dismissed due to unacceptable conduct the student may have to meet with Executive Review Panel before re-entering the school. The Executive Review Panel consists with Program Director and General Manager. The decision of the Executive Review Panel is final and the student will receive a letter within five business days from the Program Director stating the decision of the panel.

## 9 Credit for Previous Training

There is no credit and no Certificate of Completion given for previously completed training.

## 10 Student Complaint/Appeal Process

Students who have a complaint or who would like to appeal a dismissal must request in writing an appointment for an interview with the Program Director. The written request should include the following information:

1. Student's full name, last four digits of their social security number , and current address
2. A statement of the concern including dates, times, instructors, and if applicable, other students involved
3. Date of complaint letter and signature of the student
4. Three dates in which the student would be available for a meeting with the Program Director. These dates should be within 10 business days of the complaint.

The Program Director will notify the student in writing of the appointment date in which the concerns or appeal will be addressed. Every effort will be made to bring an amicable closure to the concern. Should it be necessary, a panel of instructors will hear the concerns and will be asked to assist in bringing a resolution to concerns and/or appeals.

The student will be notified in writing within five business days of the outcome of the meetings. The decision of the Program Director is final.

Should the contract be cancelled by either the student or the school the date on the complaint letter will be used as the date to calculate any refund in accordance with the school's refund policy (see: section "Refund Policy").

## 11 Grading System

The New Q-LMS (Qtech Learning Manangement System) is designed to provides program learnings of lesson with multiple check-points for ease control and smooth delivery . The learnings deliveries provided for each lesson are:

1. Presentation with Voice-Over (Narrative Explanation)
2. Lesson Reading material as Chapters
3. Quiz for Praticce (15 Objective Questions)
4. Quiz for Test (10 Objective Questions)
5. Short based Questions - 3 per each lesson
6. Related Exercises as Case Scenarios

The Student must attend the Webex sessions, read thru the presnetations, lesson material and attempt the Praticce Quiz and Quiz Test. Students must complete all Quiz Tests, Short Based Questions and related exercises. The Exercises submitted are reviewed and feedbacks is provided via email. The Quiz tests are evaluated as part of Grading process.



At the end of the training, a trainee is obligated to take a final exam that is strictly related to the course material that was studied during the training program. One point is given per fully corrected given answer.

The Quiz Tests and Final exam, tests the knowledge, and understanding of all material covered during the training. An Aggregate score between all Quiz Tests and Final Exam is taken into consideration. A minimum of 75% Aggregate score is required for issuance of final certificate score and transcript.

The final score obtained is indicated in the Certificate of Completion with the "Pass" grade. Students who delivered 74% score or lower will receive "Fail" grade on the Certificate of Completion. In this case the second attempt exam will be provided per student's request.

### 11.1 Minimum grade requirements

Minimum score of 75% is required to achieve a Certificate of Completion.

GRADE	SCORE RECEIVED
PASS	75% - 100%
FAIL	0% - 74%
INCOMPLETE	(No Certificate Issued)

### 11.2 Incomplete Grades

Incomplete grades are given when a student is unable to complete a course because of illness or other serious problems. An incomplete grade may also be given when through negligence or procrastination students fail to turn in work or take examinations. A student who misses a final examination must contact the Program Director within seven (7) business days of the examination to arrange for a make-up examination. If the student does not make arrangement to take missed examinations then a failure grade will be given.

### 11.3 Exam Failure

#### First Attempt Exam

Score of 74% and lower at the first attempt requires repeating the exam. On the occasion when the trainee do not satisfy the minimum grading requirement and obtain 74% or less, the second exam attempt is given within 10 business days after the first exam. Per trainees' request, the free extended online access to the material is also given for duration of 10 business days. It is the trainees



responsibility to contact administrator at [info@qtech-solutions.com](mailto:info@qtech-solutions.com) about the willingness of writing a second attempt exam and a request of extended online access.

### Second Attempt Exam

Score of 74% and lower at the second attempt results in:

- ✓ receiving “Fail” grade on the final Certificate of Completion, or
- ✓ in case of important reason - a trainee has a right to further communication with Program Director. In this situation a trainee must submit written letter to the Program Director within 3 business days from the date of second attempt exam requesting a meeting and stating the rational reason of his/her failure. Program Director will review trainee’s performance and if applicable will recommend additional training. Additional costs may apply. The final decision is given by Program Director within 5 business days. All such scenarios will be dealt on case to case basis upon request from the student.

## 12 Probation for Failed First Attempt Exam

Students who fail the first attempt exam will need to enter a probation period which is the period between first and second attempt exam. The probation period lasts 10 days. During a probation period it is the trainees responsibility to contact course administrator about the willingness of writing a second attempt exam and a request of extended online access. The second exam attempt is given within 10 business days after the first exam. Per trainees’ request, the extended free online access to the material is also given for duration of 10 calendar days.

Students unable to obtain score of minimum 75% at the second attempt exam will receive a “Fail” grade.

## 13 Student Evaluation Techniques

During the online training program, students are assigned to number of practical projects. The homework material includes but it is not limited to:

- Chapter quizzes and Final Exam
- Practical exercises

Students must answer all quizzes and practical exercises for accurate student evaluation purposes.

For *quizz evaluation*, every assignment is graded by percentage score. The average of all scores along with score of the final exam is counted toward final grade as indicated on the Certificate of Completion.

The *practice evaluation* is completed by faculty after online and WebEx sessions. In this case every assignment is graded based on the following grading:

Grade A: Excellent/Highly Efficient

Grade B: Good/Thorough Understanding

Grade C: Average

Grade D: Poor

Grade F: Fail

The main objective of practical exercises is to provide practical real time documentation and scenarios to the students and professionals and prepare them for a possible job opportunities enabling them to meet the competition.

Practice evaluation is be conducted based on **hypothetical solutions templates** prepared by our highly qualified professionals for each exercise. The hypothetical solutions given do not exclude multible other solutions that can be applied for the exercises. The exercise evaluation by grade is determined by best possible solution given. Students may consult with faulties any other solutions.

The practice evaluation does not influence the final grade, but provides information to the facutly about the student progress. Thus, the grade and the faculty feedback will be kept for the school and record purposes. Practice evaluation may be subject to additional review and consideration, in case the student fails the second attent exam.

## 14 Withdrawal From school

Students must fill out a withdrawal notification and submit it to the school director. This document must contain the student's name, student's SSN, and date of withdrawal. All financial obligations on the part of the school and the student will be calculated using the official withdrawal date. It is the student's responsibility to withdraw officially from the school. Failure to withdraw formally may result in failing grades, breach of contract, dismissal, and additional financial obligations.

## 15 Student Records

Student records will be maintained by the school until the school closes. At that time, records will be forwarded to the New Jersey Department of Labor and Workforce Development. Upon the final exam, students will be given a copy of their records per their request.

The records that the school will maintain are as follows:

1. WebEx class attendance records
2. Financial records
3. The Enrollment Agreement / Registration Form
4. Records of meetings, appeals, requests, etc. (if applicable)

#### 5. A copy of the Certificate of Completion

Student records are maintained by the school HR Department in the student folder and are available for the review by the student at any time. Students are encouraged to submit updates to their records, such as address changes, change of name, etc. All records are private and are handled with confidentiality.

After the final exam, the Certificate of Completion is send to each of student via email. Per request, the hard copy is also send to students within USA. If student wish to send the Certificate oversees, the additional charge of \$50 will apply.

In case student needs a duplicate hard copy of the certificate, the student should contact HR department and fill out the Certificate Duplicate Requisition Form. The additional charge applies for sending certificate duplicate - \$15 fee (for USA delivery) and \$50 fee (outside of USA delivery).

## 16 Refund Policy (For State Funded Programs)

In regards to refund policy Qtech-Sol Professional Development Center will retain the registration fee of \$50 plus a pro-rata portion of the tuition calculated based on procentage of completed couse hours (see sample: 16.1, page 19 "Reimbursement Scale").

Should the student's enrollment be terminated or should the student withdraw for any reason, all refunds will be made according to the following refund schedule.

1. Students who wish to cancel their enrollment in a program or at the school must do so in writing. It is best to hand deliver the withdrawal letter and have a copy signed by the HR associate or mail the letter by Certified Mail.
2. All monies will be refunded (100% refund) if the applicant is not accepted by the school or if the student cancels within three (3) business days after the enrollment agreement is signed by both parties **AND** before online access to the course is given.
3. Cancellation after the third (3rd) business day, but before the first class, will result in a refund of all monies paid, with the exception of the Application Fees.
4. Cancellation after the online access is given, after first WebEx class will result in refund of monies paid based on reimbursement scale provided in 12.1.

### 16.1 Reimbursement Scale

The right to reimbursement would occur based on Per NJAC, chap. 41, p. 11 as indicated in below.

**The Calculation is made basis of Net 175 Hours (6 Weeks) of each course**

If withdrawal or cancellation occurs:

The School Will Retain

**Within 1st week of the course**

**Registration Fee + 10 % of the tuition**

*(not more than 11% of the course has been completed)*

**Between 2nd or 3rd week of the course**

**Registration Fee + 20 % of the tuition**

*(Between 12% and 16% of Course has been completed)*

**After 3rd week of the course**

**Registration Fee + 45 % of the tuition**

*(Between 17% and 25% of Course has been completed)*

**Between 26% and 50% of the completion of the course - Registration Fee + 75 % of the tuition**

**Between 51% - 100 % of the completion of the course - Registration Fee +100 % of the tuition**

The reimbursement table below is a sample while the percentage course completion depends on WebEx class schedule of the batch.

Week	Day of the Training	Daily Course Hours Completed				% of the Course Completion	Reimbursement Scale	
		Daily Individual Student Study	Faculty Class Webex Session	Faculty Student Query Interactive Session	Completed Total Hours of the DSA Program		% of tuition that will be retained by School	Tuition Amount that will be retained by school ( <u>does not include</u> \$50 non refundable application fee)
1	1	3	2	2	7	4%	10%	\$225.00
	2	3			10	6%	10%	\$225.00
	3	3			13	7%	10%	\$225.00
	4	3			16	9%	10%	\$225.00
	5	3			19	11%	10%	\$225.00
SAT	6	3			22	13%	20%	\$450.00
SUN	7	3			25	14%	20%	\$450.00
2	8	3			28	16%	20%	\$450.00
	9	3			31	18%	45%	\$1,012.50
	10	3			34	19%	45%	\$1,012.50

SAT SUN	11	3			37	21%	45%	\$1,012.50
	12	3	2	2	44	25%	45%	\$1,012.50
	13	3			47	27%	75%	\$1,687.50
	14	3			50	29%	75%	\$1,687.50
3	15	3			53	30%	75%	\$1,687.50
	16	3			56	32%	75%	\$1,687.50
	17	3	2	2	63	36%	75%	\$1,687.50
	18	3			66	38%	75%	\$1,687.50
	19	3			69	39%	75%	\$1,687.50
SAT SUN	20	3			72	41%	75%	\$1,687.50
4	21	3			75	43%	75%	\$1,687.50
	22	3			78	45%	75%	\$1,687.50
	23	3			81	46%	75%	\$1,687.50
	24	3			84	48%	75%	\$1,687.50
SAT SUN	25	3			87	50%	75%	\$1,687.50
	26	3	2	2	94	54%	100%	\$2,250.00
	27	3			97	55%	100%	\$2,250.00
	28	3			100	57%	100%	\$2,250.00
5	29	3			103	59%	100%	\$2,250.00
	30	3			106	61%	100%	\$2,250.00
	31	3			109	62%	100%	\$2,250.00
	32	3			112	64%	100%	\$2,250.00
	33	3	2	2	119	68%	100%	\$2,250.00
SAT SUN	34	3			122	70%	100%	\$2,250.00
6	35	3			125	71%	100%	\$2,250.00
	36	3			128	73%	100%	\$2,250.00
	37	3			131	75%	100%	\$2,250.00
	38	3			134	77%	100%	\$2,250.00
	39	3			137	78%	100%	\$2,250.00
	40	3	2	2	144	82%	100%	\$2,250.00
SAT SUN	41	3			147	84%	100%	\$2,250.00
7	42	3			150	86%	100%	\$2,250.00
	43	3			153	87%	100%	\$2,250.00
	44	3			156	89%	100%	\$2,250.00
	45	3			175	100%	100%	\$2,250.00

Note: Additional 15 hours (Internship) + 10 hours of post training support is provided as an optional services.

- The Additional Learnings as Internship (15 hours) provides students project management related studies to apply their study learnings into documents and processes.
- Post training support (10 Hours) include:
  - ✓ Resume writing
  - ✓ Interview tips as guidelines
  - ✓ Narrative preparation
  - ✓ 2 Moke interview

The 25 additional hours do not influence reimbursement scale.

### 17 Tuition and Additional Costs

Tuition and additional costs for each of the following programs: Drug Safety/ Pharmacovigilance Associate (DSA/PVA), Clinical Research Associate/ Coordinator (CRA/CRC) and Clinical Research Data Management (CDM) Programs are as below:

	BIP (with WebEx)
Base course fee	2,250.00
Admission fee (nonrefundable)	50.00
Course Material Book Binder (Book Binder mailed within 3 Business days) (nonrefundable)	175.00
Test (Exam Fees) - 2 Attempts (nonrefundable)	250.00
<b>Total fee per course</b>	<b>2,725.00</b>

The admission, Book Binder and Exam fees are non refundable. Students will need to meet all financial responsibilities before a Certificate of Completion is issued.

## 18 Grants, Student Loans and Scholarships

Qtech-Sol Professional Development Center does not award grants or scholarships.

## 19 Credit Disclaimer Statement

Qtech-Sol Professional Development Center does not offer college/academic credit courses. Qtech Qtech-Sol Professional Development Center is not approved to offer college credits. Qtech-Sol Professional Development Center is New Jersey State approved private vocational school.

However, QPDC is planning in the near future to have our courses accredited.

## 20 Facilities

Qtech-Sol Professional Development Center, training division of Qtech Solutions Inc. has its facilities in U.S.A. and India.

### U.S.A. FACILITIES

**New Jersey (corporate office) is located at:**

3 Executive Drive, Suite 320,  
Somerset, NJ 08873

### INDIA FACILITY

UBN QTECH SOLUTIONS (INDIA) PRIVATE LIMITED.,  
# 16-11-469/27,101 Shalivahana Nagar, Moosarambagh  
Beside State Bank of India, Hyderabad-500036,India

The professional course content preparation and technical support is located in both U.S.A. locations. The software development center is situated in India location.

Our corporate offices in Somerset, New Jersey are placed in four (4) floor building. We occupy seven (4) spacious rooms, one (1) copy room, one (1) lunch room, and reception waiting area. Outside there's ample parking at the parking lot, available for use free of charge.



## 21 Programs Offered

Qtech-Sol Professional Development Center provides professional training programs to undergraduate and graduate students and professionals that primarily are focused towards Pharmaceutical and Healthcare Industry. The programs we have designed are not curriculum based, but instead provide real time experience that a student must know to build career in similar pathways.

### 21.1 Training Programs Offered

#### 1. **PROGRAM: Drug Safety / Pharmacovigilance Associate (DSA / PVA)**

**FEATURES:** Blended Internet Program (BIP), 24/7 online access for duration of 45 days, faculty class WebEx sessions, faculty student query interactive session, final exam, and optional job preparation and support.

**DESCRIPTION:** **Drug Safety / Pharmacovigilance Associate (DSA / PVA) Program** is offered as BIP (Blended Internet Program with WebEx sessions). This is an E-learning program with WebEx sessions packed with power point presentations with voice, course material, quizzes, case scenarios exercises, and final exam. The course is designed to provide real time experience to candidates in order to meet industry requirements. Most candidates who take this program must have a baccalaureate degree in science background such as Biological Science, Pharmacy, Medicine and Nursing. PhramD, RN, and MD are highly preferred backgrounds to have in this field. Upon completion of the training candidates can apply for positions, such as Drug Safety Associate, Clinical Safety Specialist, and Pharmacovigilance Officer and Medical Record Extraction specialist.

In particular, the topics covered in the **Drug Safety / Pharmacovigilance Associate (DSA / PVA)** program are:

1. Introduction to Clinical Research
2. Drug Development Process
3. Introduction to Drug Safety
4. ICH-Good Clinical Practice Guidelines
5. Drug Safety Regulation and Guidelines
6. Clinical Trial Protocol
7. SOP Development
8. Communication with Cross Functional Team
9. Drug Safety Database and Software
10. Understanding 21 CFR Part 11 and HIPAA
11. Role of DSA (Trials)
12. Clinical Trial Safety Surveillance
13. Phase IV Trials and Pharmacovigilance
14. Adverse Events (AE)



15. SAE Reconciliation
16. Characteristics of a Case
17. Sources of Individual Case Reports/Data Elements for Transmission - Individual Case Safety Report (ICSR)
18. Basic of Coding in Drug Safety
19. Case Narratives
20. Case Follow up approaches and handling of Cases
21. Drug Safety Data Extraction and Pre-Processing
22. Special Scenarios

The exercises covered in the **Drug Safety / Pharmacovigilance Associate (DSA/PVA)** Program are:

1. Introduction to Adverse Events
2. Role of DSA
3. Characteristics of Individual Case Safety Report (ICSR)
4. Basics of Coding
5. Medical Record Extraction
6. Triage
7. Case Narratives
8. Drug Safety Database and Software
9. SAE Reconciliation

## **2. PROGRAM: Clinical Research Associate/ Coordinator (CRA/CRC)**

**FEATURES:** Blended Internet Program (BIP), 24/7 online access for duration of 45 days, faculty class WebEx sessions, faculty student query interactive session, final exam, and optional job preparation and support.

**DESCRIPTION:** **Clinical Research Associate/ Coordinator (CRA/CRC)** program is offered as BIP (Blended Internet Program). It is an E-learning program with WebEx sessions packed with power point presentations with voice, course material, quizzes, case scenarios exercises and final exam. The course is designed to provide professional real time experience to candidates in order to meet the industry requirements. Most candidates who take this program must have a baccalaureate degree in science background such as Biological Science, Pharmacy, Pharmaceutical Chemistry, Public Health/Medicine, Biomedical Engineering, Biology, Biotechnology, Nursing, Chemistry, Biochemistry, Pharmacology/Toxicology, and Industrial Pharmacy. Upon completion of the training candidates can apply for positions as Clinical Research Associate, Clinical Monitor, and Clinical Research Coordinator.

In particular, the topics covered in the **Clinical Research Associate/ Coordinator (CRA/CRC)** program are:

1. Role of CRA In House
2. Drug Discovery Research Process
3. Pre-Clinical Trials
4. Introduction to Clinical Trials.
5. Phase I Clinical Trials
6. Phase II Clinical Trials
7. Phase III Clinical Trials
8. Phase IV Clinical Trials
9. FDA and EMEA Regulations
10. ICH Guidelines for Good Clinical Practice
11. Institutional Review Board (IRB)
12. SOP Development
13. Conducting Multinational Clinical Trials
14. Communication with Cross Functional Team
15. Overview of Clinical Protocol
16. Role of CRA (In-House)
17. Clinical Protocol Design and Development
18. Clinical Trial budget
19. Selection of Investigator
20. Roles and Responsibilities of Investigator
21. Selection of Investigator Site
22. Site Management and Initiation
23. Vendor Management and Selection
24. Case Report Form (CRF) Design and Data Capture
25. Investigator Meetings and Timelines
26. Intro to Adverse Events (AE) Reporting and Classification
27. Trial Master File (TMF)
28. In-House Monitoring and Reporting
29. Informed Consent Preparation
30. Preparing for Internal Audit

The exercises covered in the **Clinical Research Associate/ Coordinator (CRA/CRC)** program are:

1. Introduction To Clinical Trial
2. FDA EMEA Regulations
3. Institutional Review Board (IRB)
4. Protocol Design and Development
5. Clinical Trial Budget
6. Case Report Form (CRF) Design
7. Trial Master File
8. Informed Consent Preparation
9. Audit

10. Investigator Meeting
11. Site Management and Initiation
12. AE Reporting and Classification

### **3. PROGRAM: Clinical Research Data Management (CDM)**

**FEATURES:** Blended Internet Program (BIP), 24/7 online access for duration of 45 days, faculty class WebEx sessions, faculty student query interactive session, final exam and optional job preparation and support.

**DESCRIPTION:** **Clinical Research Data Management (CDM) Program** is offered as BIP (Blended Internet Program). It is an E-learning program with WebEx sessions packed with power point presentations with voice, course material, quizzes, case scenarios exercises and final exam. The course is designed to provide real time experience to candidates in order to meet the industry requirements. Most candidates who take this program must have a baccalaureate degree in Health Information Technology, Life Science, Biological Science, Pharmacy, and Biochemistry with computer skills. Upon completion of the training candidates can apply for positions as Clinical Data Management Specialist, Documentation Specialist, and Clinical Data Coordinator.

In particular, the topics covered in the **Clinical Research Data Management (CDM)** program are:

1. Introduction to Clinical Trials
2. Phase I Clinical Trials
3. Phase II Clinical Trials
4. Phase III Clinical Trials
5. Phase IV Clinical Trials
6. ICH Guidelines for Good Clinical Practice
7. SOP Development
8. Communications : Cross functional
9. Overview of Protocol
10. Foundation Study of Clinical Data Management
11. Good Clinical Data Management Practice (GCDMP)
12. Data Management Plan
13. Clinical Data and Quality Control
14. Clinical Data Management Systems
15. Clinical Data Repositories
16. Loading External Data into the CDM System
17. Exporting Data to Data Management Center
18. Query Management
19. Data Clarification Form (DCF)
20. Patient Diary and Patient Reported Outcome
21. Remote Data Entry

22. Clinical Data Entry - Single/Double Entry, SAE Reconciliation, and Coding of Adverse Events
23. Data Cleaning and Data Validation
24. Case Report Form (CRF) Elements
25. Electronic CRF Design and Data Tracking
26. Types of Reports Generated
27. Database Locking
28. Clinical Data Archiving

The exercises covered in the **Clinical Research Data Management (CDM)** program are:

1. Data Management Plan
2. Query Management
3. Coding of Adverse Events (AE)
4. Data Cleaning and Validation
5. Elements of Case Report Form (CRF)
6. E-CRF Design and Data Tracking
7. SAE Reconciliation
8. Types of Report Generated

## 21.2 Learning Objectives

During the training programs, a trainee develops the following learning objectives:

- ✓ Skill development: Learning and improving skills such as writing, verbal communication, research, organizational, computer, interpersonal, teamwork, presentation, and leadership. It is the development of these skills that often represents the major benefits of an assignment.
- ✓ Broader knowledge: Understanding how government works, as well as how public policy is developed. In addition, this would include knowledge added to existing classroom knowledge, such as the application of theory to practice.
- ✓ Career Awareness: Objectives could include learning about career opportunities, as well as the qualities and training required to obtain those positions.
- ✓ Personal Development: One of the major benefits of QPDC training programs is development of self-confidence, assertiveness, and basic work habits.

## 22 Our Commitment

- Provide best quality of training with high professionalism.
- Focus on delivering sustainable value to our students by employing best qualified instructors and designing the most effective training programs. Our instructors have right skills and experience to help our students, while they continually develop their expertise.

- Continuous internal improvement. On yearly basis to comply with the industry updates and standards, the management of the Qtech-Sol Professional Development Center proactively gathers feedback from their staff and act upon the feedback trends to ensure continuous improvement.
- Proactive external improvement. We proactively gather feedback and testimonials (see: Appendix: Student Feedback Form and Student Testimonials Form) from our students on an ongoing basis after the completion of the training course and act upon the feedback trends.
- Confidentiality. Qtech-Sol Professional Development Center keeps strictly to all agreements about the confidentiality of information. No personal information is ever used without the prior agreement of the trainee.

