

Qtech-Sol Professional Development Center

Training Division of Qtech Solutions Inc.

**208-2250, Boundary Road, Burnaby,
British Columbia, V5M3Z3, Canada**



Private Career School (PCS) **School Catalog** **2020**

Dated: 03.03.2020

Signatory Page / Person

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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. (Business Name: Qtech-Sol Professional Development Center) for Program registration with Private Training Institution Branch (PTIB), Ministry of Advanced Education, BC, Canada.

| Role | Title, Department | Name | Document | Date |
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| Program Director | TRAINING DIVISION | Chandra, Nate | School Catalog Qtech Canada | 02-AUG-2019 |

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| Administrative Officer | TRAINING DIVISION | Veera Venkata Visweswarulu, Guthula | School Catalog Qtech Canada | 23-JULY-2019 |

INITIAL PREPARED BY

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| Training Coordinator | TRAINING DIVISION | Swanandi Tare | School Catalog Qtech Canada | 20-JULY-2019 |

Revision History

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| 1.0 | 20-JULY-2019 | Swanandi Tare | Initial Document for PTIB Program Registration |
| 2.0 | 24-FEB-2020 | Chandra Nate | Added Sections 6.3 and 6.4 Modified Class A and Class-B Program Listing - Section 19 and 20 |
| 3.0 | 03-MAR-2020 | Chandra Nate | Removed Class-B programs classification from details Section 20 |

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1. Administrator Contact

Chandra Nate
Program Director

chandranate@qtech-solutions.ca
732-770-4100 Ext 202 (NJ, USA)
604-757-7733 Ext 501 (BC, CANADA)

Human Resources

Email to hrs@qtech-solutions.com

Attendance staff is available Monday through Friday from 8:30 a.m. to 5:00 p.m. PST

2. School Calendar

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

Observed Holidays:

- New year
- Good Friday
- Easter
- Victoria Day / National Patriots Day
- Canada Day
- British Columbia Day
- Labor Day
- Thanksgiving
- Remembrance Day
- Christmas
- Boxing Day

3. Office Hours and Program Delivery Types

3.1 Office Hours

Normal Business hours is from **8.30 A.M. until 5:00 P.M. PST** from Monday through Friday.

3.2 Program Delivery Type and Services

The programs offered are distance learning, along with faculty interactive online sessions provided based on type of delivery method enrolled. The Program is offered as distance learning – Self Paced Program and queries are addressed via email and phone. Exercise solutions is made available in LMS to refer.

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

A. Self-Paced Online Training with Email Support

- This is Self-Paced Pure Online Program (SIP) - Learn from Home at your own pace.
- Student Enrolls Online, pays fee by card - Online Shopping Cart / or Check.
- Material accessed thru Internet from Qtech Custom LMS (Along with Start-End Dates).
- Will complete the Online Training program as Self-Paced.
- Program Schedule is provided describing (Days / Hours), along with lesson deliveries to be submitted on daily basis (Mon through Fri).
- Submissions are monitored and evaluated for scoring.
- Queries are addressed via Email and Phone.
- Feedback is provided via email; Solutions to exercises are made available online for reference and understanding.
- Student takes Online Final Exam
- Certificate and Transcript emailed.
- Student enrolls for Post Training Assistance for Resume, Narrative and Mock Session (15 Days)
- List of open jobs available /job leads are shared with candidate for 30 days after training completion.



B. Advanced Learnings

Selected Student will have the opportunity to enroll into Advanced learning sessions as Training as Internship Program. This program is conducted for 15 Days focusing on role based learnings per industry standards. During this program advanced case studies as projects are provided to students to apply their learning. During this program, the students will have to deliver tasks on various projects and will attend multiple WebEx Online sessions to understand the hypothesis, the tasks and delivery objectives. All Exercises are submitted via email. Due to changing and challenging job market scenario, the Students are provided with current findings and industry learnings needed to meet the job market.

C. Post Training Assistance Program

Each Student enrolled into the program, will have opportunity to participate in post training assistance program, This program is offered for a period of 5 business days (15 hours), which includes:

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

D. Student Support

All subject matter queries are emailed to academic_support@qtech-solutions.com

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 www.qtech-solutions.ca

Other documents required:

- Copy of Identification (one of the following: current driver license, passport, or permanent resident card) for Identity Verification.
- Most updated resume
- Copy of Degree Certificate (Bachelor/Master's degree)
- Completed Enrollment Form / Online Application form
- Optional - Personal essay (50-100 words statement explaining the reason why the candidate has chosen our program and his/her thoughts about further career path)
- Proof of payment for registration and tuition fees. We accept payments via Secured Shopping Cart by Credit Card (OR) Personal checks payable to: "Qtech Solutions Inc.
- All documents will be submitted to Human Resources, via email to qpdc@qtech-solutions.ca or hrrs@qtech-solutions.com / By fax at (888) 532-0210 / By mail to the following address:

QTECH SOLUTIONS INC.
208-2250 Boundary Road,
Burnaby, BC V5M3Z3, Canada

5. Program Admission Requirements

5.1 Education Qualification

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 or Associate degree.

5.1.1 Education Requirement - Clinical Research Project Mgmt. & Trial Monitoring (CRPM)

If the student is interested in enrolling in [Clinical Research Project Management and Trial Monitoring Training \(CRPM\)](#) the following educational background is advised:

Recommended: An Associate / Bachelor's degree in Medicine, Nursing, Pharmacy, Public health Biology, Biochemistry, Biotechnology, Chemistry, Clinical Research, Biomedical engineering, Public health, Pharmacology, or toxicology, Medical Device & Technology, Psychology, Sociology and Healthcare Administration.

5.1.2 Education Requirement - Drug Safety-Pharmacovigilance Data Management (DSPM)

If the student is interested in enrolling in [Drug Safety- Pharmacovigilance Data Management Training \(DSPM\)](#) the following educational background is advised:

Recommended: Minimum a bachelor's degree in medicine, Nursing (RN), Pharm D, Public Health, Pharmaceutical and Industrial Chemistry.

5.1.3 Education Requirement - Clinical Trial SAS Data Analysis and Reporting (CDAR)

If the student is interested in enrolling in [Clinical Trial SAS Data Analysis and Reporting Training \(CDAR\)](#) the following educational background is advised:

Recommended: An Associate or Bachelor's degree in Statistics, Biostatistics, Biotechnology, Economics, Computer Science, Engineering, Cognitive Science, Data Science, Machine Learning (ML), Artificial Intelligence (AI), Mathematics.

The student must have SAS 9.x software in their PC for practice and submissions.

5.1.4 Education Requirement - Clinical Research Data Management (CDMT)

If the student is interested in enrolling in [Clinical Data Management Training \(CDMT\)](#) the following educational background is advised:

Recommended: An Associate or bachelor's degree in medicine, Nursing, Pharmacy, Public health Biology, Biochemistry, Biomedical engineering, Biotechnology, Chemistry, Clinical Research, Public health, Pharmacology, or toxicology, Medical Device & Technology, Psychology, Sociology and Healthcare Administration.

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

5.2 English Proficiency Evaluation

Below is Qtech targeted student segments based on Canadian residential status, and English proficiency score need for admission.

- International Student
- National Student (English spoken)
- Permanent Resident (PR)
- Citizen (English Spoken)

Qtech programs is delivered in ENGLISH. English is ONE of the prime language used for global clinical trials and pharmacovigilance reporting and communication, by most pharmaceutical and research organizations, performing clinical trials and/or pharmacovigilance operations. Keeping in view of Qtech targeted student segments, below is the English proficiency level required to participate in our clinical science programs.

- **International Student**
Most universities enroll students who are proficient in English. They evaluate using ONE of the following exams to qualify them for admission. Such as IETLS and TOFEL. The Average IETLS required for admission by most colleges is between 5.0 and 7.5. The TOEFL score range is 0-120. The average IBT test score required for top 15 Canadian Universities is 88. Qtech expects Average IETLS score between 5.0 and 7.5 (or) TOFEL score between 70-80. Henceforth majority International Student automatically qualified for admission into Qtech programs.

Qtech Offers programs that meet medicine as one of the prime education requirements. Students enrolled with universities for medicine or related medical science programs are usually evaluated for admission based on their MCAT score. The MCAT total score ranges between 472-528, with 500 as the average score.

Qtech expects Average IETLS score between 5.0 and 7.5 (or) TOFEL score between 70-80. We expect majority of the International Student, automatically qualified for admission into Qtech programs. Student with Average MCAT score 500 and above is eligible for Qtech Programs.

- **National Student (English spoken)**

Majority of Students native to Canada are versed with English and French, since in their schooling have undergone English as one of the prime lessons, have already achieved the set required benchmark. Henceforth we do not find any issue enrolling them into Qtech program. Those not versed with English and more proficient in Other Language, must produce an IETLS English Language test result score between 5.0 and 7.5.

- **Permanent Resident (PR)**

For Admission into as PR Status into Canada, the Canadian immigration requires candidate to submit a language proficiency test results from one of the authorized organizations. They accept certificates issued from two authorized test providers in English, the International English Language Testing System (IELTS) and the Canadian English Language Proficiency Index Program (CELPIP). Most Candidates applying for PR receive an average IELTS score between 5.0 and 7.5 to meet the requirements. English proficiency of Candidates applying for PR, with their prime residence from Middle East (Dubai, UAE, and surrounding Countries) are usually validated off CEPIP certification with score varying between 0-12.

Qtech expects an IETLS English Language test result score between 5.0 and 7.5, (or) CEPIP score above 5 on Average. Most PRs will automatically qualify for Qtech Programs upon entry as PR into Canada.

- **Citizen (English Spoken)**

Candidates versed in English (speaking, reading, and writing) are ONLY admitted into Qtech Programs. During our counselling step, we converse in English and explain the basic requirements to participate along with qualifying education background and English proficiency needed. Our

marketing advertisements is posted in English and we usually expect leads from those who can understand English as posted in our Advertisement. For those whose prime language is French or other native, must produce an IETLS English Language test result score with between 5.0 and 7.5 or related certificate.

5.3 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 sessions requires prior download of WebEx application. The invitation and instructions for WebEx / Online sessions (SBP Model) will be sent prior to the class. Speakers and microphone or a headset are required for the purpose of discussions and being able to talk with the instructor during the class.
- During the WebEx /Online sessions (SBP Model) the attendance will be taken by faculties.
- 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.
- Regarding WebEx / Online sessions (SBP Model), the 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 / Online sessions (SBP Model) may cause discrepancy of learning curve and failure of final exam.

5.4 Leave of Absence

Students will be granted a leave of absence for WebEx / Online class Online sessions (SBP Model) upon request. The following guidelines must be adhered to:

1. The request for a leave of absence for WebEx / Online class Online sessions (SBP Model) must be submitted to the HR associate in writing or via email to qpdc@qtech-solutions.ca
2. The request must have the date that the student will begin the leave of absence and the expected date of return to WebEx / Online classes Online sessions (SBP Model) 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 / Online session Online sessions (SBP Model) 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 using recorded WebEx session (if available) or use the book binder material.
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 / Online lessons Online sessions (SBP Model) missed prior to re-entry into the program.

5.5 Missed Lessons (WebEx / Online Classes)

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

5.6 Make-up Work

- In order for students/trainees to meet their educational goals they must follow instructions in all aspects of the program. WebEx / Online 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 / Online 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 / Online classes.
- Students should complete missed assignments which will always be available online. In case a student needs to clarify which assignments were covered during missed WebEx / Online session, he/she must 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. Sometimes students insist on waiting until the missed WebEx / Online 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.

5.7 Tardiness

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

The roster will be provided to the faculty, who will record student attendance in WebEx / Online 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 of Qtech-Sol Professional Development Center is **to provide the best-in-class job oriented career development Elearning training courses and programs in Clinical Research, Drug Safety-Pharmacovigilance, 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.**

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 honestly and without integrity in the training course of Qtech.
5. Acting without care and diligence in the course material.
6. Disobey confidentiality 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 / Online training sessions (SBP Model) 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 the class session begins,
 - Participation and responsibility. Training attendance is the responsibility of participants.

6.3 Fair and Respectful Treatment Policy

Qtech Solutions Inc. is committed to ensuring that its learning environment promotes the respectful and fair treatment of all students. **Although we are Online Training providers, while on Qtech Solutions Inc premises or during activities or events hosted by the School, following activities are prohibited:**

Bullying

Bullying is a form of harassment and is when a person or group of people misuse power in a relationship to repeatedly and intentionally harm others. The outcome is the victim feels distressed, less powerful or helpless and there is a risk to their wellbeing.

Bullying can be overt (obvious) such as physical, verbal, or cyber harassment, or covert (hidden) such as social exclusion or intimidation. Examples of bullying behavior include: unfair and excessive criticism; excluding someone from a group (including online or in person); ignoring a person's point of view; constantly changing or setting unrealistic targets for a person; undervaluing the efforts of a person; intentionally and repeatedly hurting a person physically; stalking a person; taking advantage of any power over someone else.

Bullying is not mutual arguments, disagreements or dislikes.

Qtech Solutions Inc. does not tolerate any form of harassment and students who believe they are subject to harassment should initially discuss their concerns with the perpetrator if appropriate and safe to do so or discuss their concerns with School staff. Students can also lodge a complaint.

It must be also highlighted that harassment is not legitimate comment or advice (including negative comment or feedback) from others, such as genuine assessment feedback. School staff at the Institute are responsible for undertaking assessment of students' work and making a judgement about their attained knowledge and competency in a subject. They are also expected to provide academic guidance and advice to students to complement their assessment and may have to instruct them about academic policy, processes and timeline provisions. In itself, the act – including repeated acts – of correcting students or pointing out inadequacies of performance does not constitute harassment or bullying in an educational environment.

Similarly, invoking unsatisfactory performance procedures or misconduct procedures, or applying student progress procedures, academic integrity procedures or assessment due dates do not in themselves constitute harassment or bullying of students.

Harassment

Harassment is perceived or actual unwelcomed conduct that humiliates, offends, or intimidates people. Harassment is bullying conduct that is neither appropriate nor relevant to a situation. This includes words, as well as acts, pictures, and images that create a hostile or threatening atmosphere. Behaviors that can be considered harassment include: verbal abuse; offensive gestures; ignoring or segregating a person or group.

The effect of harassment is to make a person feel insulted, offended, intimidated and unable to perform a task effectively or, ultimately safely.

Sexual Harassment

Sexual harassment is unwanted or unwelcome sexual behavior, whether verbal, physical or electronically communicated which makes a person feel offended, humiliated or intimidated. Behaviors that can be considered sexual harassment include: staring or leering; unnecessary familiarity, such as deliberately brushing up against a person or unwelcome touching; suggestive comments or jokes; insults or taunts of a sexual nature; intrusive questions or statements about a student's personal life; displaying screen savers of a sexual nature; sending sexually explicit emails or text messages; inappropriate advances on social networking sites; accessing sexually explicit internet sites; requests for sex or repeated unwanted requests to go out on dates; behavior that may also be considered to be an offence under criminal law, such as physical assault, indecent exposure, sexual assault, stalking or obscene communications.

Sexual harassment is not interaction, flirtation or friendship which is mutual or consensual. It is not mutual attraction or friendship.

Discrimination

Discrimination in student education occurs when a student is denied a benefit, or the equal opportunity outlined above, or treated less favorably than another student, on the grounds of a personal characteristic or attributes (e.g. race, gender, religion, disability etc.).

Discrimination can be either direct or indirect. Direct discrimination occurs when unlawful distinctions are made between individual students and student groups based on any of the discriminatory grounds. Indirect discrimination occurs when a seemingly harmless policy, rule or practice has a discriminatory effect on an individual student or student group.

The following discriminatory grounds: age; breastfeeding; career status; family responsibilities; impairment/disability (past, present or future); industrial activity; lawful political belief or activity; lawful religious belief or activity; lawful sexual activity; marital status; parental status; physical features; pregnancy or potential pregnancy; race, color, nationality, ethnic or national origin; sex; personal association with a person identified by reference to one of the above attributes.

Equal Opportunity

Equal opportunity in student education is a principle of non-discrimination which emphasizes that opportunities in education should be freely and equally available to all students irrespective of their personal characteristics or attributes which are unrelated to their ability, performance, knowledge, skill or competence (e.g. race, gender, religion, disability etc.).

Responsibility

It is the School's responsibility to ensure that unlawful discrimination and harassment does not occur. If it does occur, the allegation will be investigated in a sympathetic, fair, confidential and in a timely manner according to the Respectful and Fair Treatment of Students Complaint Procedure.

If a student informs the School of allegations of harassment or discrimination that involves persons who are not staff members or students of the Institute, the Institute will consider the appropriateness of the Institute's intervening or assisting. The decision to intervene or assist will be made by Manager.

The Institute will take all reasonable steps ensure there is no retaliation towards students who have voiced a discrimination or harassment complaint.

All staff have a role and obligation to take reasonable steps to ensure that the educational environment at the School is free from discrimination and harassment for students. All staff at the School have a responsibility to take appropriate action if concerns about discrimination and harassment are brought to their attention by a student or are personally witnessed.

Staff must ensure they do not engage in discriminatory or harassing behavior towards students themselves and there can be no retaliation against anyone for making a discrimination or harassment complaint. Any staff member found to be engaging in such behavior may be subject to consequential disciplinary action both by the School and through legal avenues (cost to be adhered by the staff in question).

Students

The School requires all students to behave responsibly by complying with this policy and to report unacceptable behavior to staff.

All students must ensure they do not engage in discriminatory or harassing behavior towards other students or staff members and may be subject to consequential disciplinary action both by the School and legal avenues.

If under any circumstances, a prohibited activity occurs, the following outlines the process for addressing the activity:

The Manager meets with the accused student to discuss the issue. Based on the meeting any of the following may be done:

- The School closes the file and informs all parties involved if it decides that the student did not commit the prohibited act. OR
- The School may let the student continue classes pending further investigation. OR
- The student may be given a written warning regarding the conduct. OR
- The student can face immediate suspension or expulsion

6.4 Sexual Misconduct Policy

I. General Policy Statement

Qtech Solutions Inc. is committed to promoting and maintaining a safe and respectful environment as Private Career School. The School will not tolerate sexual harassment, sexual violence, domestic violence, dating violence, or stalking (collectively “Sexual Misconduct”) regardless of the sex or marital status of the parties involved. This policy prohibits Sexual Misconduct perpetrated by or against School employees (including all faculty, staff, administrative employees, and student employees), School students, visitors to the School (such as independent contractors, vendors, visiting lecturers, camp participants, and visiting students), and other participants in School programs and activities on premises and in off-premises areas controlled by the School.

This policy establishes a process whereby an individual who believes he or she has been subjected to Sexual Misconduct (“Complainant”) may report to the School. The School will take prompt and appropriate steps to stop Sexual Misconduct, prevent its recurrence, and address its effects by

- educating members at the premises about this policy and applicable laws.
- promptly addressing and resolving reports of Sexual Misconduct in accordance with this policy.
- protecting the rights of all parties involved in a complaint.
- providing support and assistance to the parties involved in a report of Sexual Misconduct; and
- imposing appropriate discipline against those who have engaged in Sexual Misconduct.

Any person who violates this policy may be subject to discipline up to and including termination of employment, suspension, dismissal, and a ban from premises, depending on the circumstances and the severity of the violation and the violator’s status as an employee, student, or visitor.

II. Prohibited Conduct

Sexual Misconduct includes a range of unwelcome and unwanted sexual conduct, including verbal and physical sexual harassment, sexual assault, and other forms of sexual violence, each of which is a form

of prohibited sex discrimination. Domestic violence, dating violence, and stalking are also considered Sexual Misconduct under this policy.

A. Consent

Consent is a voluntary agreement to engage in sexual activity and is determined by all the relevant facts and circumstances. Consent cannot be given by someone who lacks capacity to consent (e.g., because of age, disability, unconsciousness, or use of drugs or alcohol). Consent is invalid where it is given under coercion, force, or threats.

B. Sexual Harassment

Sexual harassment is unwelcome and unwanted conduct of a sexual nature, whether verbal, nonverbal, or physical, and can include unwelcome sexual advances, requests for sexual favors, and other conduct of a sexual nature. Conduct is unwelcome and unwanted if the individual toward whom it is directed did not request or invite it and regarded the conduct as undesirable or offensive. A wide variety of sexual conduct may constitute sexual harassment, including, but not limited to, the following:

- Sexually suggestive or sexually offensive joking, flirting, or comments
- Unwelcome and intentional touching
- Sexually oriented verbal abuse or threats
- Sexually oriented comments about an individual's body
- Displaying objects or pictures that are sexual in nature
- Sending sexually explicit or offensive communications (e.g., text messages, emails, social media messages or posts)
- Sexual exploitation
- Voyeurism

Quid pro quo sexual harassment—when submission to or rejection of the unwelcome sexual conduct is used as a basis for employment decisions affecting an employee, or when a teacher or other employee conditions an educational decision or benefit on a student's submission to unwelcome sexual conduct.

Hostile environment sexual harassment—when the unwelcome and unwanted sexual conduct is so severe or pervasive that it alters the conditions of an employee's employment and creates a hostile, intimidating, or abusive working or educational environment or it denies or limits a student's or employee's ability to participate in or benefit from the School's programs or activities.

To avoid the possibility or appearance of quid pro quo sexual harassment, employees and students should avoid dating, romantic, or amorous relationships where a power differential exists. Examples of such relationships include, but are not limited to, a professor or teaching assistant involved in a relationship with his or her student, or a supervisor involved in a relationship with a subordinate employee. If such a relationship exists and both parties want to continue the relationship, the

supervisor(s) of both parties must be informed of the relationship, must document the disclosure of the relationship, and must confirm with each of the parties independently that the relationship is voluntary and not unwelcome to either party. However, as a general rule, dating, romantic, or amorous relationships should not be entered into or continued while one individual in the relationship has the power to either reward or penalize the other in work or in school.

III. Reporting Incidents

Duty of Report

Most School employees have a duty under this policy to report Sexual Misconduct, and everyone is encouraged to voluntarily report incidents of Sexual Misconduct to the School Administrator.

1. Responsible Employees

A dean, director, department chair, professor, coach, or any other School employee in a teaching, managerial, or supervisory role ("Responsible Employee") who, while in that role, becomes aware of or reasonably suspects any incidents of Sexual Misconduct must promptly report all relevant information to the School Administrator. A Responsible Employee who receives a report of Sexual Misconduct should inform the reporting individual that the employee must report the incident, and the employee should then promptly make the report to the School Administrator. Responsible Employees with information regarding an incident of Sexual Misconduct who fail to report relevant information or to cooperate in an investigation may be subject to disciplinary action.

Responsible Employees who receive the information as part of a confidential communication in the context of a professional or otherwise privileged relationship (e.g., the Responsible Employee was the reporting person's physician, therapist, lawyer, ecclesiastical leader, or spouse) do not have a reporting obligation. Note that this exception to mandatory reporting for these privileged communications is different from the confidentiality given to School-designated confidential sources of support, described below.

2. Timing

Reports of Sexual Misconduct should be made to the School Administrator as soon as possible. If Sexual Misconduct occurred more than four years before the report is made, the School may decline to investigate the report. However, counseling, advocacy, and support are available to Complainants regardless of when they make a report.

3. Confidential Sources of Support

Many victims of Sexual Misconduct experience stress and may find it helpful to talk in a supportive, confidential context. The School provides confidential on-premises resources where someone may discuss the situation even if he or she is not sure about reporting the incident to the School Administrator or law enforcement.

IV. Complaint Resolution Procedures

The following procedures are designed to provide for the prompt and equitable investigation and resolution of allegations of Sexual Misconduct perpetrated by or against School employees, students, or premises visitors. Additionally, these procedures will be conducted by officials who do not have a conflict of interest or bias for or against the parties and who receive annual training on the issues related to sexual harassment, domestic violence, dating violence, sexual assault, and stalking and how to conduct an investigation that protects the safety of the parties involved and promotes accountability.

A. Informal Resolution

Whenever it is reasonably possible and safe to do so, and all parties voluntarily agree, a Complainant and the person alleged to be responsible for the misconduct (“Respondent”) may attempt to resolve the issue privately. After a complaint has been opened for investigation, informal resolution may occur only after all parties have received a full disclosure of the allegations and their options for formal resolution. The goal of informal resolution is to conclude the matter to the satisfaction of both parties quickly and confidentially. Either party may enlist the assistance of the School Administrator or a deputy School Administrator in this effort. If satisfactory resolution is not reached after such informal efforts, the Complainant or Respondent may forgo the informal resolution process or discontinue it at any time and address the concern using the formal resolution process described below. Additionally, if the School Administrator believes informal resolution is not appropriate or is potentially unsafe, he or she may require formal resolution.

B. Formal Resolution

A formal resolution process may be initiated by submitting a Report to the School Administrator. Anyone can submit a Report under this policy; however, the submission of such a Report does not prevent the Complainant from subsequently pursuing informal resolution with the Respondent in appropriate circumstances.

1. Preliminary Assessment

Upon receiving a Report, the School Administrator will promptly perform a preliminary assessment based on the allegations to determine whether the Report reasonably alleges violations of the Sexual Misconduct Policy. If the Report contains allegations for which the Office has authority, the School Administrator will seek the Complainant’s consent to conduct an investigation. Note that if the Complainant asks the School not to pursue an investigation, the School may not be able to honor this request if doing so would prevent the School from meeting its obligations and responsibilities as indicated throughout this policy. If the Report does not contain allegations of Sexual Misconduct for which the Office has authority, the School Administrator will inform the Complainant that no investigation of the Report will be conducted.

2. Selection of the Investigator

If a preliminary assessment warrants an investigation, the School Administrator will select a qualified employee to promptly investigate the allegations in the Report (“Investigator”). Generally, a deputy School Administrator will serve as the Investigator. The School Administrator will consider conflicts of interest, time constraints, and other relevant factors in selecting an Investigator.

The Complainant and the Respondent may each raise issues regarding bias or a potential conflict of interest of Investigators or others involved in the resolution process by contacting the School Administrator.

3. Confidentiality

Given the sensitive nature of Sexual Misconduct allegations and the potential for damage to the parties’ personal reputations, all Reports will be investigated as confidentially as is reasonably possible. All participants in the investigation—including the Complainant, the Respondent, the Investigator, and individuals interviewed by the Investigator—should keep the allegations and proceedings confidential and should provide information only to those School and governmental employees who are authorized to investigate the Report or who otherwise have a legitimate need to know. Records kept by the School relating to Sexual Misconduct allegations are not publicly available, but in the event that the School is required to make any records publicly available, any identifying information about the parties will be redacted, to the extent permissible by law, to protect the parties’ confidentiality. Federal law requires the School to publicly disclose statistics about reported incidents of sexual assault, domestic violence, dating violence, and stalking; however, no individual information is maintained or published for purposes of federal reporting.

Notwithstanding the foregoing confidentiality provisions, Complainants and any witnesses who participate in an investigation of Sexual Misconduct should be advised that their confidentiality will be preserved only to the extent it does not interfere with the School’s ability to investigate the Report and take corrective action, and that if the investigation results in court action the School may be legally required to disclose any information it has received.

If a Complainant requests that his or her identity be kept confidential or asks the School not to pursue an investigation, the Complainant should be notified that (a) the School’s ability to investigate and respond to the Report may be limited by such a request, and (b) under some circumstances the School may not be able to honor such a request. The School will take all reasonable steps to investigate and respond to a Report consistent with the Complainant’s request for confidentiality. However, without conducting a full investigation or disclosing the full nature of the Report (including its source) to the Respondent, the School may be unable to impose any discipline, and its corrective actions might be limited to informing the Respondent that allegations of discriminatory behavior have been made against him or her, preserving a record of the discrimination allegation in the Respondent’s employment or student disciplinary file, and pursuing other steps to limit the effects of the alleged Sexual Misconduct and prevent its recurrence, such as training or surveys in the affected area or department.

The Investigator will consider the following factors in determining whether to disclose the identity of a Complainant or pursue an investigation contrary to the Complainant's request:

- The seriousness of the alleged Sexual Misconduct
- The age or maturity of the Complainant
- The existence of any previous accusations against the alleged violator
- The existence of independent evidence to substantiate the allegations
- In the case of accusations against a student, the rights of the student under the Access to Student Records Policy and Procedures and corresponding federal and state privacy laws or laws mandating disclosure

If the Investigator determines he or she cannot honor a Complainant's request for confidentiality or a Complainant's request to forgo an investigation, the Investigator will inform the Complainant prior to commencing or continuing with an investigation.

4. Investigation

An investigation should be prompt and equitable. The School will, in good faith, attempt to conclude the investigation and resolution within sixty calendar days of the School Administrator receiving a Report. If, as a result of the complexity of a case, unavailability of witnesses, or other extenuating facts and circumstances, the investigation cannot reasonably be concluded within the sixty-day period, the Complainant and the Respondent will be provided with written notice of the delay and the reason for the delay.

5. Investigation Finding(s)

No later than seven calendar days prior to the conclusion of an investigation, the Investigator will inform the parties that the investigation is concluding and ask them to submit any final information not already included in the investigation. The parties will then have three business days to submit additional information.

At the conclusion of the investigation, the Investigator will make findings as to the allegations in the Allegation Sheet and will determine, based on the preponderance of the evidence (i.e., whether it is more likely than not), whether the Respondent has engaged in Sexual Misconduct. The Investigator will provide a written report of the findings of the investigation ("Investigatory Report") to the School Administrator for review. The Investigatory Report will not contain any proposed sanctions. Sanctions will be considered separately, as set forth in Section IV.B.13 below.

The School Administrator will promptly and simultaneously send a copy of the Investigatory Report to the Complainant and the Respondent to their email and residential addresses on file with the School. The Investigatory Report will include a notice of appeal rights and procedures.

6. Appeal of Investigation Finding(s)

Either party may appeal the findings in an Investigatory Report (“Factual Findings Appeal”). If no appeal is filed within the time outlined below, the Investigatory Report becomes final, and its findings and conclusions may not be appealed by either party.

The Factual Findings Appeal should

- be made within ten business days of delivery of the Investigatory Report;
- be in writing, limited to five pages;
- identify which of the grounds, listed below, is the basis for the appeal; and
- be sent to the School Administrator.

7. Resolution and Disciplinary Sanctions

Student Respondents

If a final Investigatory Report or Decision on Factual Findings Appeal determines that a student Respondent has violated the Sexual Misconduct Policy, the School Administrator will provide a copy of the Allegation Sheet, Response, Investigatory Report, Decision on Factual Findings Appeal (if any), and other relevant evidence contained in the file to the School’s Honor Code Office.

All Respondents

If a final Investigatory Report or Decision on Factual Finding Appeal determines that a Respondent has violated the Sexual Misconduct Policy, the School Administrator will convene the Disciplinary Committee within twenty-one calendar days, or as soon as is reasonably possible. The Disciplinary Committee will determine, by majority vote, the appropriate resolution of the Sexual Misconduct, including the imposition of any disciplinary sanctions as provided in the applicable disciplinary policy; however, if there is a conflict between this policy and another School disciplinary policy, this policy governs.

8. Voluntary Withdrawal or Resignation

If a student voluntarily withdraws or an employee resigns from the School prior to the investigation being completed or sanctions and resolutions being determined, the School may nevertheless determine at its discretion to proceed with an investigation of the allegations to establish appropriate conditions for permitting the student to return to the School or for rehiring the employee, and to make appropriate notations on the student’s official School records or the employee’s employment records regarding his or her status at the School. The School may also place a hold on a student’s registration, re-admission, and graduation or on any re-hiring of an employee pending an investigation and resolution of the allegations.

V. Training

The School will seek to make all employees and students familiar with the contents of this policy. All administrators, deans, chairs, directors, managers, and supervisors are responsible to ensure that employees within their areas of stewardship are properly trained on their obligations under this policy and applicable laws.

The School Administrator will develop and oversee training and education programs to promote the awareness of domestic violence, dating violence, sexual assault, stalking, sexual harassment, and sexual violence, including rape. Deputy School Administrators may assist in fulfilling that responsibility. All training sessions and participants should be documented, and those records should be provided to the School Administrator.

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 / Online sessions
 - Distributing course material to other individuals
 - Sharing course material for financial gain
2. Missing WebEx / Online session classes (SBP Model)
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 not be 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 of the 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, as per identity document submitted 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 Management System) is designed to provide lesson learnings with multiple check-points for ease of control and smooth delivery . The learning deliveries provided for each lesson are:

- Presentation with Voice-Over (Narrative Explanation)
- Lesson Reading material as Chapters
- Quiz for Practice (15 Objective Questions)
- Quiz for Test (10 Objective Questions)
- Short based Questions – 3 per lesson
- Related Exercises as Case Scenarios

The Student must attend the WebEx / Online sessions (SBP Model), read through the presentations, lesson material and attempt the Practice Quiz and Quiz Test. Students must complete all Quiz Tests, Short Based Questions and related exercises. The Exercises submitted are reviewed and feedback is provided via email. The Quiz tests are evaluated as part of the 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 correct answer.

The Quiz Tests and Final exam, test 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 upon the student's request.

11.1 Minimum grade requirements

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

| GRADE | SCORE RECEIVED | STATUS |
|-------|----------------|------------|
| PASS | 75% - 100% | COMPLETE |
| FAIL | 0% - 74% | INCOMPLETE |

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

A score of 74% and lower at the first attempt requires repeating the exam. On the occasion when the trainee does not satisfy the minimum grading requirement and obtains 74% or less, the second exam attempt is given within 10 business days after the first exam. Upon the trainee's request, the free extended online access to the material is also given for a duration of 10 business days. It is the trainee's responsibility to contact the HR administrator at hrs@qttech-solutions.com about the willingness of writing a second attempt exam and a request for extended online access.

Second Attempt Exam

A 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 a 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 the trainee's performance and if applicable will recommend additional training. Additional costs may apply. The final decision is given by the Program Director within 5 business days. All such scenarios will be dealt with on a 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 trainee's responsibility to contact the course administrator about the willingness of writing a second attempt exam and a request for extended online access. The second exam attempt is given within 10 business days of the first exam. Upon the trainee's request, the extended free online access to

the material is also given for a duration of 10 calendar days. Students unable to obtain a minimum score of 75% at the second attempt exam will receive a “Fail” grade and stated as Incomplete.

13. Student Evaluation Techniques

During the online training program, students are assigned to a number of practical projects. The homework material includes but 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 quiz 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 / Online 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 possible job opportunities enabling them to meet the competition.

Practice evaluation is to be conducted based on hypothetical solutions templates prepared by our highly qualified professionals for each exercise. The hypothetical solutions given do not exclude multiple 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 faculties any other solutions.

The practice evaluation does not influence the final grade, but provides information to the faculty 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 attempt 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, Identification document 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 Private Training Institution Branch (PTIB), Ministry of Advanced Education, BC. 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 / Online class attendance records (SBP Model)
2. Financial records
3. The Enrollment Agreement / Registration Form and Credentials.
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 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 sent via email to the student. Per request, the hard copy will be mailed to students within CANADA.

In case a 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 FedEx charges apply for sending certificate duplicates - \$35 fee (for USA delivery) and \$125 fee (outside of USA delivery).

16. Grants, Student Loans and Scholarships

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

17. Credit Disclaimer Statement

Qtech-Sol Professional Development Center does not offer college/academic credit courses. We are approved to offer college credits with Rutgers college on Internship programs. QPDC is planning in the near future to have our courses accredited as we grow.

18. Facilities

Qtech-Sol Professional Development Center, training division of Qtech Solutions Inc. has its facilities in United States (At New Jersey), Qtech Canada (At British Columbia) and China Alliance Partner (At Hangzhou).

CANADA FACILITY

Burnaby, BC (corporate office) is located at:

208-2250 Boundary Road,

Burnaby, BC V5M3Z3, Canada

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

Our corporate office in Burnaby, British Columbia is placed on the 2ND floor of the building. We occupy seven (5) spacious rooms, which includes copy room, lunch room, reception, Director and Staff rooms and Store. Outside there's ample parking at the parking lot, available for use. Has clear fire exits and separate restrooms for gender. Elevator to reach the office at 2nd Floor.

19. Programs Offered, Tuition and Additional Costs

Qtech-Sol Professional Development Center (QPDC) offers JOB and TITLE based Career Advancement training programs to Masters, Bachelors, Associate / Undergraduate and Health Science High School (XII Grade) students and working professionals. We primarily focus towards Pharmaceutical and Healthcare Industry. The programs we have designed are not curriculum based, but instead focus on the role performed at industry, imparting student real time expertise required to build career in similar pathways.

19.1 Clinical Research Project Management and Trial Monitoring (CRPM)

The CRPM Distance (Online) training program contains **3 learnings modules** and enrollment is made based on education level, prior learnings gained (or) experience.

Below are the **3 Learning Modules** included in this CRPM program, the lessons included and Schedule.

- Module-1: Clinical Research Associate (CRAT) – 8 Weeks / 160 Hours
- Module-2: Advanced Clinical Research Associate (ACRA) – 4 Weeks / 80 Hours
- Module-3: Clinical Research Additional Lessons (AACR) – 2 Weeks / 40 Hours

FEATURES: The program offers 24/7 online access to course material for duration of 14 Weeks (280 Hours), Self-Paced Online classes, student query interactive session, final exam, and optional job preparation and support (Post Training Assistance).

DESCRIPTION: The course provides a thorough Foundation, Advanced and Project Management related concepts focusing clinical trials, drug development, Study design, Project Management, and Monitoring concepts of Clinical Sciences about roles and responsibilities performed by Clinical Research Associate. The concepts include a protocol development, assessment and reporting of adverse events and explains GCP-ICH guidelines along with other necessary regulatory information. The course emphasizes on understanding of the science and the expectations of initiating, conducting, monitoring, and managing clinical trial related work. This training will develop the technical skills and knowledge pertaining to roles and responsibilities of CRA - In House. Students will get exposure to real time practices pertaining to Case Report forms (CRFs), Trial Master File (TMF), Clinical Trial Protocol, Clinical Trial Budget, and Audit. The course curriculum is designed to give an edge to obtain job opportunity in clinical research field.

After Completing this CRPM program, the student can apply for various job titles based on highest Education Background and Prior experience from Entry thru Senior roles.

Job Titles : Clinical Research Associate, Clinical Program Manager, Clinical Research Coordinator, Trial Regulatory Coordinator, Clinical Research Specialist, Clinical Project Manager, Clinical Research Manager, Clinical Trial Management Associate, Clinical Study Manager, Clinical Project Manager, Clinical Trial Assistant, Clinical Documentation Assistant.

The **LESSONS** covered in the CRPM training program are

| CRPM - Clinical Research Project Management and Trial Monitoring | | | | | | | | | | | |
|--|-----------------------------|----------------------------|-------|-------|-------|-------|------|-------|--------|-------|-------|
| MODULE - 1 : CRAT PROGRAM SCHEDULE (Basics of Clinical Research Associate) | | | | | | | | | | | |
| | | Times Allocated in Minutes | | | | | | | | Total | Total |
| Lesson/ Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Drug Discovery and Research | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |

| | Process | | | | | | | | | | |
|----|--|-------|-------|-------|-------|-------|--------|-------|--------|------|------|
| 2 | Pre-Clinical Research | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 3 | Introduction to Clinical Trials | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 60.00 | 90.00 | 290.00 | 4.83 | 1.21 |
| 4 | Role of Clinical Research Associate | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 5 | Phase I Clinical Trials | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 6 | Phase II Clinical Trials | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 7 | Phase III Clinical Trials | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 8 | Phase IV Clinical Trials | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 9 | Good Clinical Practice and ICH Guidelines | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 10 | FDA Regulations | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 |
| 11 | Institutional Review Board (IRB) | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 |
| 12 | Overview of Clinical Protocol | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 13 | Clinical Protocol Design and Development | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 100.00 | 60.00 | 300.00 | 5.00 | 1.25 |
| 14 | SOP Development | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 15 | Case Report Form (CRF) Design | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 |
| 16 | Clinical Trial Budget | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 |
| 17 | Conducting Multinational Clinical Trials | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 18 | Communication-Cross Functional Team | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 19 | CRA / CRC - In House Responsibilities | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 20 | Selection of Investigator | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 21 | Vendor Selection and Management | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 22 | Informed Consent Preparation | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 |
| 23 | Roles and Responsibilities of Investigator | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 24 | Investigator Meetings and Timelines | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 |
| 25 | Selection of Investigator Site | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 26 | Study Initiation | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |
| 27 | In-House Monitoring and | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 |

| | Reporting | | | | | | | | | | | |
|---|---|-------|-------|-------|-------|-------|-------|-------|--------|---------------|------|--|
| 28 | Trial Master File (TMF) | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 | |
| 29 | Introduction- AE Reporting | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 90.00 | 320.00 | 5.33 | 1.33 | |
| 30 | Preparation for Internal Audit | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 31 | Role of CRA Monitoring | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 32 | Subject Recruitment Process and Informed Consent | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 33 | CRF Design and Development Monitoring Perspective | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 34 | Source Documentation, Retention and Compliance | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 35 | Drug Accountability Plan | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 36 | Site Visits | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 37 | Site Monitoring | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 38 | Investigator-Monitor Meetings | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 39 | Understanding Monitoring Worksheets | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 90.00 | 60.00 | 290.00 | 4.83 | 1.21 | |
| 40 | Clinical Trial and Site Audit | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | | 60.00 | 200.00 | 3.33 | 0.83 | |
| 41 | Study Close Out | 45.00 | 40.00 | 20.00 | 15.00 | 20.00 | 85.00 | 60.00 | 285.00 | 4.75 | 1.19 | |
| Final Exam (Two Attempts provided to Pass - Exam 1 and 2) | | | | | | | | 75.00 | 75.00 | 1.25 | 0.31 | |
| NET TOTAL | | | | | | | | | | 160.00 | | |

MODULE - 2 : ACRA PROGRAM SCHEDULE (Advanced Clinical Research Associate)

| | | Times Allocated in Minutes | | | | | | | Total | Total | |
|------------------------|---------------------------------|----------------------------|----|-------|-------|------|--------|--------|--------|-------|------|
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Clinical Trial Budget | 100.00 | | | | | 150.00 | 100.00 | 350.00 | 5.83 | 1.46 |
| 2 | Investigator Selection | 100.00 | | | | | 120.00 | 80.00 | 300.00 | 5.00 | 1.25 |
| 3 | Pre-Study Visit | 100.00 | | | | | 100.00 | 80.00 | 280.00 | 4.67 | 1.17 |
| 4 | Protocol Design and Development | 100.00 | | | | | 150.00 | 100.00 | 350.00 | 5.83 | 1.46 |

| | | | | | | | |
|------------------|--|--------|--------|--------|--------|--------------|------|
| 5 | Informed Consent Preparation | 100.00 | 100.00 | 80.00 | 280.00 | 4.67 | 1.17 |
| 6 | Investigational New Drug (IND) Application | 100.00 | 120.00 | 80.00 | 300.00 | 5.00 | 1.25 |
| 7 | Institutional Review Board (IRB) Regulatory Correspondence | 100.00 | 100.00 | 80.00 | 280.00 | 4.67 | 1.17 |
| 8 | Case Report Form (CRF) | 100.00 | 200.00 | 100.00 | 400.00 | 6.67 | 1.67 |
| 9 | Site Monitoring | 100.00 | 100.00 | 80.00 | 280.00 | 4.67 | 1.17 |
| 10 | Co-Monitoring Visits | 100.00 | 120.00 | 80.00 | 300.00 | 5.00 | 1.25 |
| 11 | Study Initiation Visit | 100.00 | 120.00 | 80.00 | 300.00 | 5.00 | 1.25 |
| 12 | Clinical Trial Management Systems (CTMS) | 100.00 | 200.00 | 100.00 | 400.00 | 6.67 | 1.67 |
| 13 | Trial Master File | 100.00 | 200.00 | 100.00 | 400.00 | 6.67 | 1.67 |
| 14 | Database Lock | 100.00 | 100.00 | 80.00 | 280.00 | 4.67 | 1.17 |
| 15 | Audit and Trial Closeout | 100.00 | 100.00 | 100.00 | 300.00 | 5.00 | 1.25 |
| NET TOTAL | | | | | | 80.00 | |

MODULE - 3 : AACR PROGRAM SCHEDULE (Clinical Research Additional Lessons)

| | | Times Allocated in Minutes | | | | | | | Total | Total | |
|------------------------|--|----------------------------|----|-------|-------|------|------|--------|--------|-------|------|
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Risk Based Monitoring (RBM) | 100.00 | | | | | | 120.00 | 220.00 | 3.67 | 0.92 |
| 2 | FDA Audit process for Clinical Research | 85.00 | | | | | | 100.00 | 185.00 | 3.08 | 0.77 |
| 3 | Clinical Trial Project Management (CTPM) and Timelines | 100.00 | | | | | | 100.00 | 200.00 | 3.33 | 0.83 |
| 4 | Development of Monitoring Plan | 90.00 | | | | | | 100.00 | 190.00 | 3.17 | 0.79 |
| 5 | Protocol Deviation/Violation Management | 85.00 | | | | | | 100.00 | 185.00 | 3.08 | 0.77 |
| 6 | Trial Master File and QC Management | 85.00 | | | | | | 100.00 | 185.00 | 3.08 | 0.77 |
| 7 | Clinical Data Reconciliation and Archiving | 85.00 | | | | | | 100.00 | 185.00 | 3.08 | 0.77 |
| 8 | Management and Reconciliation of | 85.00 | | | | | | 120.00 | 205.00 | 3.42 | 0.85 |

| | | | | | | | |
|--|--|---------------------------------------|--|--------|--------|--------|------|
| | Investigational Product | | | | | | |
| 9 | Advanced Clinical Research Management Modules 1 thru 4 | 210.00 | | 225.00 | 435.00 | 7.25 | 1.81 |
| 10 | Planning and Conducting Global Clinical Trials | 85.00 | | 100.00 | 185.00 | 3.08 | 0.77 |
| 11 | Management of a Successful Clinical Research Site - Part A & B | 125.00 | | 100.00 | 225.00 | 3.75 | 0.94 |
| NET TOTAL | | | | | | 40.00 | |
| | | | | | | Hours | Days |
| Self-Paced Online Learning Hours | | Spends 3-4 hours / Day (Mon thru Fri) | | | 280.00 | 105.00 | |
| TOTAL CRPM PROGRAM DURATION - 280 Hours / 14 Weeks | | | | | | | |

| Lesson - Learning Delivery Type | Code |
|--|-------------|
| Presentation with Voice Over | PPT |
| Chapters - Reading Material | CH |
| Quiz for Practice (15 MCQs) | Q(15) |
| Quiz as Test (10 MCQs) | Q(10) |
| Discussion Based Questions (DBQ) - Top 3 | Q(3) |
| Hypothetical Exercises (Multiple) | Exer |
| Revision Hours | Rev |

Fees

| Clinical Research Project Management and Trial Monitoring (CRPM) Self-Paced Online Program with Support | Fees (CAD \$) |
|--|-----------------|
| Base Tuition fee | 4150.00 |
| Admission fee (Non-Refundable) | 65.50 |
| Course Material Book Binder | 229.25 |
| Test (Exam Fees) - 2 Attempts | 229.25 |
| Post Training Assistance (PTA) | 294.75 |
| Total fee per course | 4,968.75 |

The admission fee is non refundable. Students will need to meet all financial responsibilities before a Certificate of Completion is issued. Book Binder is provided within 3 business days after activation of Online Material access

19.2 Drug Safety-Pharmacovigilance Data Management (DSPM)

The DSPM Online training program contains **3 learnings modules** and enrollment is made based on education level, prior learnings gained (or) experience.

Below are the **3 Modules** included in this DSPM program.

- Module-1: Drug Safety Associate (DSAT) - 6 Weeks / 120 Hours
- Module-2: Advanced Drug Safety (ADSA) - 4 Weeks / 80 Hours
- Module-3: Additional Drug Safety (AADS) - 2 Weeks / 40 Hours

FEATURES: The program offers 24/7 online access to course material for duration of 12 Weeks (240 Hours), Self-Paced Online classes, student query interactive session, final exam, and optional job preparation and support (Post Training Assistance)

DESCRIPTION: A Drug Safety - Pharmacovigilance Data and Safety Monitoring reports are submitted to Authorities for Safety and Efficacy needs of New and Existing Drugs in market. In this program DSPM, student will learn about AE monitoring, Data collection, Analysis and Reporting of Drug safety information for compliance with drug safety regulations per Local and International markets.

Few of the learning gained are:

-
- Case processing: Understanding of full case information on the database, including quality review to ensure accuracy and completeness
 - Concept for Triage – incoming cases and prioritization for workflow management.
 - Data Entry: How to perform case data entry (including narrative or auto-narrative), manual coding, label and approval
 - Preparation of SAE summary: Analysis of Adverse Events, perform quality review of ICSR which includes review of source documents and ensuring that the case is accurate and that corrections to the case.
 - Liaison roles for Case Receipt and to clarify information required for case processing. Other activities relating to case processing, such as: Single case unblinding, Serious Adverse Event (SAE) / Adverse Event (AE) reconciliation, deviation memo preparation (SUSAR), deletion/admin edit requests, review protocol update request forms for accuracy
 - Database, Processes and procedures: Understanding of Global Pharmacovigilance Database (ARGUS), awareness of and input required- procedures and guidance, Completion of all assigned role-based tasks, available at Qtech LMS, relating to case processing and reporting. Understanding of relevant PV Agreements for products, revision / creation of case processing procedural documentation.
 - Project work: Understanding team, team roles of projects, including inspection/audit readiness activities, Participation in local or global project teams, including on-time delivery of assigned responsibilities
 - Understanding key aspects of inspections and audits procedures, preparing, and planning for internal and external audit.
 - Advanced concepts for Monitoring and Reporting, such as CAPA, PSUR, RMP, REMS and more.
 - Personal development: continuous development of personal skills whether task or competency related. Activities may include project involvement, technical training, shadowing and / or mentoring others, soft-skill development. Understanding of PTC/ PQC - Maintenance and compliance guidelines and Policies.

After Completing this DSPM program, the student can apply for various job titles based on highest Education Background and Prior experience from Entry thru Senior roles.

Job Titles : Pharmacovigilance Assistant, Research Assistant, Drug Safety Assistant, Patient Safety Assistant, Pharmacovigilance Specialist, Local Safety Manager (LSM), Drug Safety Manager, Quality Safety Manager, Global Drug Safety Specialist, Therapeutic Area Lead, Occupational Health & Safety Specialist, Operational Specialist - Drug Safety, Medical Reviewer.

The LESSONS covered in the DSPM training program are:

| DSPM - Drug Safety-Pharmacovigilance Data Management | | | | | | | | | | | |
|---|---|-----------------------------------|-----------|--------------|--------------|-------------|-------------|------------|--------------|--------------|-------------|
| MODULE - 1 : DSAT PROGRAM SCHEDULE (Basics of Drug Safety Associate) | | | | | | | | | | | |
| | | Times Allocated in Minutes | | | | | | | Total | Total | |
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Introduction to Clinical Research | 45.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 205.00 | 3.42 | 0.85 |
| 2 | Drug Development Process | 45.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 205.00 | 3.42 | 0.85 |
| 3 | Introduction to Drug Safety / Pharmacovigilance | 45.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 235.00 | 3.92 | 0.98 |
| 4 | Role of DSA / PVA (Trials) | 90.00 | 40.00 | 25.00 | 15.00 | 20.00 | 90.00 | 90.00 | 370.00 | 6.17 | 1.54 |
| 5 | Introduction to Adverse Events | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | 90.00 | 90.00 | 340.00 | 5.67 | 1.42 |
| 6 | ICH-Good Clinical Practice Guidelines | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 7 | Drug Safety Regulation and Guidelines | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 8 | Overview of Clinical Trial Protocol | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 9 | Characteristics of a Case | 120.00 | 60.00 | 25.00 | 15.00 | 20.00 | 160.00 | 120.00 | 520.00 | 8.67 | 2.17 |
| 10 | Sources of Individual Case Reports | 120.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 330.00 | 5.50 | 1.38 |
| 11 | Drug Safety Data Extraction and Pre-Processing | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 285.00 | 4.75 | 1.19 |
| 12 | SOP Development | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |

| | | | | | | | | | | | |
|-----------|---|--------|-------|-------|-------|-------|--------|--------|--------|--------|------|
| 13 | Communication with Cross Functional Team | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 14 | Understanding 21 CFR Part 11 and HIPAA | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 15 | Basic of Coding in Drug Safety | 120.00 | 90.00 | 25.00 | 15.00 | 20.00 | 160.00 | 120.00 | 550.00 | 9.17 | 2.29 |
| 16 | Case Follow up approaches and handling of Cases | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | 140.00 | | | | |
| 17 | Clinical Trial Safety Surveillance | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 255.00 | 4.25 | 1.06 |
| 18 | Phase IV Trials and Pharmacovigilance | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 55.00 | 215.00 | 3.58 | 0.90 |
| 19 | Case Narratives | 120.00 | 90.00 | 25.00 | 15.00 | 20.00 | 140.00 | 110.00 | 520.00 | 8.67 | 2.17 |
| 20 | SAE Reconciliation | 120.00 | 90.00 | 25.00 | 15.00 | 20.00 | 160.00 | 120.00 | 550.00 | 9.17 | 2.29 |
| 21 | Drug Safety Database and Software | 120.00 | 90.00 | 25.00 | 15.00 | 20.00 | 140.00 | 100.00 | 510.00 | 8.50 | 2.13 |
| 22 | Special Scenarios | 100.00 | 45.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 265.00 | 4.42 | 1.10 |
| | Final Exam (Two Attempts provided to Pass - Exam 1 and 2) | | | | | | | 90.00 | 90.00 | 1.50 | 0.38 |
| NET TOTAL | | | | | | | | | | 120.00 | |

MODULE - 2 : ADSA PROGRAM SCHEDULE (Advanced Drug Safety-Pharmacovigilance Associate)

| | | Times Allocated in Minutes | | | | | | | Total | Total 1 | |
|------------------------|---|----------------------------|----|-------|-------|------|--------|--------|--------|---------|-------|
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Medical Record Extraction | 100.00 | | | | | 200.00 | 100.00 | 400.00 | 6.67 | 1.67 |
| 2 | Adverse Events Case Processing | 90.00 | | | | | 200.00 | 80.00 | 370.00 | 6.17 | 1.54 |
| 3 | CIOMS Line Listing | 90.00 | | | | | 100.00 | 80.00 | 270.00 | 4.50 | 1.13 |
| 4 | Case processing and FDA Reporting for Medical Devices | 100.00 | | | | | 150.00 | 90.00 | 340.00 | 5.67 | 1.42 |
| 5 | Revision of SOP Quality Control Procedure | 90.00 | | | | | 120.00 | 80.00 | 290.00 | 4.83 | 1.21 |
| 6 | SAE Reconciliation | 90.00 | | | | | 150.00 | 80.00 | 320.00 | 5.33 | 1.33 |
| 7 | PSUR - Periodic Safety Update Reporting | 90.00 | | | | | 120.00 | 80.00 | 290.00 | 4.83 | 1.21 |
| 8 | Advanced Triage | 100.00 | | | | | 200.00 | 90.00 | 390.00 | 6.50 | 1.63 |
| 9 | Data Entry Process | | | | | | | | | | 80.00 |

| | | | | | | | | |
|------------------|---|--------|--|--------|--------|--------|--------------|------|
| | | 100.00 | | 120.00 | | 300.00 | 5.00 | 1.25 |
| 10 | Signal Detection | 100.00 | | 200.00 | 80.00 | 380.00 | 6.33 | 1.58 |
| 11 | Labeling Edit check | 100.00 | | 150.00 | 80.00 | 330.00 | 5.50 | 1.38 |
| 12 | Quality Control Procedure | 100.00 | | 200.00 | 100.00 | 400.00 | 6.67 | 1.67 |
| 13 | Resolution of queries of pending cases | 100.00 | | 200.00 | 100.00 | 400.00 | 6.67 | 1.67 |
| 14 | SUSAR - Suspected Unexpected Serious Adverse Reaction | 90.00 | | 150.00 | 80.00 | 320.00 | 5.33 | 1.33 |
| NET TOTAL | | | | | | | 80.00 | |

MODULE - 3 : AADS PROGRAM SCHEDULE (Drug Safety Additional Lessons)

| | | Times Allocated in Minutes | | | | | | | | Total | Total |
|------------------------|--|----------------------------|----|-------|-------|------|------|--------|--------|-------|-------|
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Introduction to MedDRA | 90.00 | | | | | | 80.00 | 170.00 | 2.83 | 0.71 |
| 2 | MedDRA Coding Guidelines - Modules 1 thru 4 | 280.00 | | | | | | 150.00 | 430.00 | 7.17 | 1.79 |
| 3 | AE Causality assessments | 90.00 | | | | | | 80.00 | 170.00 | 2.83 | 0.71 |
| 4 | Introduction to Risk Management Plan (RMP) | 100.00 | | | | | | 100.00 | 200.00 | 3.33 | 0.83 |
| 5 | Introduction to Risk Management Plan (REMS) | 100.00 | | | | | | 100.00 | 200.00 | 3.33 | 0.83 |
| 6 | Argus Safety End-User Training - Modules 1 thru 6 | 280.00 | | | | | | 100.00 | 380.00 | 6.33 | 1.58 |
| 7 | Product Technical / Quality Complaints (PTC / PQC) | 90.00 | | | | | | 80.00 | 170.00 | 2.83 | 0.71 |
| 8 | Corrective and Preventative Actions (CAPAs) | 90.00 | | | | | | 80.00 | 170.00 | 2.83 | 0.71 |
| 9 | Overview of Aggregate Reporting (PSUR/ PBRER) | 150.00 | | | | | | 110.00 | 260.00 | 4.33 | 1.08 |
| 10 | Overview of Aggregate Reporting - PRAC / DSUR | 150.00 | | | | | | 100.00 | 250.00 | 4.17 | 1.04 |
| NET TOTAL | | | | | | | | | | | |

| | | | |
|--|---------------------------------------|--------|-------|
| | | 40.00 | 10.00 |
| | | Hours | Days |
| Self-Paced Online Learning Hours | Spends 3-4 hours / Day (Mon thru Fri) | 240.00 | 90.00 |
| TOTAL DSPM PROGRAM DURATION: 240 Hours / 12 Weeks | | | |

| Lesson - Learning Delivery Type | Code |
|--|-------|
| Presentation with Voice Over | PPT |
| Chapters - Reading Material | CH |
| Quiz for Practice (15 MCQs) | Q(15) |
| Quiz as Test (10 MCQs) | Q(10) |
| Discussion Based Questions (DBQ) - Top 3 | Q(3) |
| Hypothetical Exercises (Multiple) | Exer |
| Revision Hours | Rev |

Fees

| Drug Safety-Pharmacovigilance Data Management (DSPM) Self-Paced Online Program with Support | Fees (CAD \$) |
|---|-----------------|
| Base Tuition fee | 4150.00 |
| Admission fee (Non-Refundable) | 65.50 |
| Course Material Book Binder | 229.25 |
| Test (Exam Fees) - 2 Attempts | 229.25 |
| Post Training Assistance (PTA) | 294.75 |
| Total fee per course | 4,968.75 |

The admission fee is non refundable. Students will need to meet all financial responsibilities before a Certificate of Completion is issued. Book Binder is provided within 3 business days after activation of Online Material access

19.3 Clinical Research Data Management (CDMT)

The CDMT Distance (Online) training program contains the following lessons.

- **Clinical Research Data Management (CDMT) - 6 Weeks / 175 Hours**

FEATURES: The program offers 24/7 online access to course material for duration of 6 Weeks (175 Hours), Self-Paced Online classes, student query interactive session, final exam, and optional job preparation and support (Post Training Assistance)

DESCRIPTION: The Clinical Research Data Management training program offered at Qtech provides insights into Clinical Research Data Management activities along with exposure to real time documentation and scenarios pertaining to roles and responsibilities performed by Clinical Data Management specialist. Qtech provides in-depth into core area of clinical data management like Clinical data and its quality, data management plan, data entry, Clinical Research Data Management Systems (CDMS), Clinical data repository, loading of external data into CDM, Query management, data clarification form, database locking, patient diary, data cleaning and validation, and database archiving. The students will get practical exposure to real time documentation and scenarios for Data Management Plan, Query Management, Coding of Adverse Events, SAE Reconciliation, Data Cleaning and Data Validation, Elements of CRF, e-CRF designing, Data tracking from CRF, and Types of Reports generated.

After Completing this CDMT program, the student can apply for various job titles based on highest Education Background and Prior experience from Entry thru Senior roles.

Job Titles: Clinical Data Associate, Clinical Data Manager, Documentation Specialist, Clinical Data Analyst, CRF Designer, Clinical Business Analyst, Clinical Data Quality Analyst, Clinical Data Audit Manager

The LESSONS covered in the CDMT training program are:

| CDMT - Clinical Research Data Management | | | | | | | | | | |
|--|--|----------------------------|--------|-------|-------|-------|--------|--------|--------|-------|
| | | Times Allocated in Minutes | | | | | | | | Total |
| | Lesson / Delivery Type | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours |
| 1 | Introduction to Clinical Trials | 45.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 225.00 | 3.75 |
| 2 | Phase I Clinical Trials | 45.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 225.00 | 3.75 |
| 3 | Phase II Clinical Trials | 45.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 255.00 | 4.25 |
| 4 | Phase III Clinical Trials | 90.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 330.00 | 5.50 |
| 5 | Phase IV Clinical Trials | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 270.00 | 4.50 |
| 6 | ICH Guidelines for Good Clinical Practice | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 240.00 | 4.00 |
| 7 | SOP Development | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 240.00 | 4.00 |
| 8 | Communication with Cross functional Team | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 240.00 | 4.00 |
| 9 | Introduction to Clinical Protocol | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 400.00 | 6.67 |
| 10 | Foundation Study of Clinical Data Management | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 400.00 | 6.67 |
| 11 | Good Clinical Data Management Practice (GCDMP) | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 285.00 | 4.75 |
| 12 | Data Management Plan | 120.00 | 120.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 590.00 | 9.83 |
| 13 | Clinical Trial Data and Quality Control | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 240.00 | 4.00 |
| 14 | Clinical Data Management Systems | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 240.00 | 4.00 |
| 15 | Clinical Data Repositories | 120.00 | 120.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 420.00 | 7.00 |
| 16 | Loading External Data into the CDM System | 90.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 340.00 | 5.67 |
| 17 | Exporting Data to Data Management Center | 90.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 300.00 | 5.00 |
| 18 | Clinical Trial data cleaning and Validation | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 570.00 | 9.50 |
| 19 | Query Management | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 570.00 | 9.50 |
| 20 | Data Clarification Form (DCF) | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 400.00 | 6.67 |
| 21 | Patient Diary and Patient Reported Outcome | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 110.00 | 390.00 | 6.50 |
| 22 | Remote Data Entry | 100.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 50.00 | 310.00 | 5.17 |
| 23 | SAE Reconciliation-II | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 570.00 | 9.50 |

| | | | | | | | | | | |
|------------------|------------------------------|--------|--------|-------|-------|-------|--------|--------|--------|---------------|
| 24 | Coding of Adverse Event-III | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 570.00 | 9.50 |
| 25 | Elements of CRF | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 570.00 | 9.50 |
| 26 | e-CRF Design & Data Tracking | 120.00 | 100.00 | 25.00 | 15.00 | 20.00 | 140.00 | 150.00 | 570.00 | 9.50 |
| 27 | Types of Reports Generated | 100.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 110.00 | 370.00 | 6.17 |
| 28 | Database Locking | 100.00 | 100.00 | 25.00 | 15.00 | 20.00 | | 110.00 | 370.00 | 6.17 |
| NET TOTAL | | | | | | | | | | 175.00 |

| Lesson - Learning Delivery Type | Code |
|--|-------------|
| Presentation with Voice Over | PPT |
| Chapters - Reading Material | CH |
| Quiz for Practice (15 MCQs) | Q(15) |
| Quiz as Test (10 MCQs) | Q(10) |
| Discussion Based Questions (DBQ) - Top 3 | Q(3) |
| Hypothetical Exercises (Multiple) | Exer |
| Revision Hours | Rev |

Fees

| Clinical Data Management (CDMT) Self-Paced Online Program with Support | Fees (CAD \$) |
|---|----------------------|
| Base Tuition fee | 1,899.50 |
| Admission fee (Non-Refundable) | 65.50 |
| Course Material Book Binder | 229.25 |
| Test (Exam Fees) - 2 Attempts | 229.25 |
| Post Training Assistance (PTA) | 294.75 |
| Total fee per course | 2,718.25 |

The admission fee is non refundable. Students will need to meet all financial responsibilities before a Certificate of Completion is issued. Book Binder is provided within 3 business days after activation of Online Material access

19.4 Clinical Trial SAS Data Analysis and Reporting (CDAR)

The CDAR Distance (Online) training program contains **3 Learnings modules** and enrollment is made based on education level, prior learnings gained (or) experience.

Below are the **3 Learning Modules** included in this CDAR program, the lessons included and Schedule.

- Module-1: Basic SAS Programming (BSAS) – Base, Macros, Sql – 6 Weeks / 200 Hours
- Module-2: Advanced SAS Programming (SSAS) – Stat, Graphs – 4 Weeks / 175 Hours
- Module-3: Clinical Trial SAS Data Analysis and Reporting (CDAR) – 8 Weeks / 200 Hours

FEATURES: The program offers 24/7 online access to course material for duration of 18 Weeks (575 Hours), Self-Paced Online classes, student query interactive session, final exam, and optional job preparation and support (Post Training Assistance)

DESCRIPTION: The Clinical Trial Data Analysis and Reporting (CDAR) provides intensive learning on how SAS is used in clinical and pharmaceutical industries. How codes, analysis and reports are generated using SAS. The CDAR program emphasizes on real time practice by providing variety of cases study data focusing on Oncology, Cardiology, CNS therapeutics areas. Details on CDISC and how to develop datasets in compliance with Standards, and instructions how data should be used and what parameters should be analyzed in order to successfully complete assigned real time scenario projects.

After Completing this CDAR program, the student can apply for various job titles based on highest Education Background and Prior experience from Entry thru Senior roles.

Job Titles: Statistical Programmer, SAS Data Modeler, SAS Data Analyst, SAS Programmer, Senior Programmer Analyst, Biostatistician, Data Scientist, Clinical Data Analyst

The **LESSONS** covered in the CDAR training program are:

BSAS - BASIC SAS PROGRAMMING - 200 Hours

MODULE - 1 : BASE SAS

| | | Times Allocated in Minutes | | | | | | | Total | Total | |
|-----------------------|---------------------|----------------------------|----|-------|-------|------|------|-----|--------|-------|------|
| Lesson/ Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | About SAS Institute | | | | 15.00 | | - | | 170.00 | | |

| | | | | | | | | | | |
|------------------|---|-------|-------|-------|-------|--------|-------|--------|---------------|--------------|
| | | 45.00 | 30.00 | 20.00 | | | 60.00 | | 2.83 | 0.71 |
| 2 | Introduction to SAS | 90.00 | 30.00 | 20.00 | 15.00 | 150.00 | 60.00 | 365.00 | 6.08 | 1.52 |
| 3 | Components of SAS Program and Code Writing | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 4 | Running SAS Programs | 60.00 | 30.00 | 20.00 | 15.00 | 150.00 | 60.00 | 335.00 | 5.58 | 1.40 |
| 5 | Mastering Fundamental Concepts | 60.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 370.00 | 6.17 | 1.54 |
| 6 | Diagnosis and Correcting Syntax Errors | 70.00 | 30.00 | 20.00 | 15.00 | 150.00 | 60.00 | 345.00 | 5.75 | 1.44 |
| 7 | SAS Options | 75.00 | 30.00 | 20.00 | 15.00 | 175.00 | 60.00 | 375.00 | 6.25 | 1.56 |
| 8 | Types of Input Statements | 90.00 | 30.00 | 20.00 | 15.00 | 225.00 | 60.00 | 440.00 | 7.33 | 1.83 |
| 9 | SAS Format and Informats | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 10 | Using Advanced Input Techniques | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 11 | SAS Date and Time | 90.00 | 30.00 | 20.00 | 15.00 | 150.00 | 60.00 | 365.00 | 6.08 | 1.52 |
| 12 | Subsetting, Combining and Sorting Datasets | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 13 | Merging and Updating Data | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 14 | Performing Conditional Processing | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 15 | Performing Iterative Processing - Looping | 90.00 | 30.00 | 20.00 | 15.00 | 185.00 | 60.00 | 400.00 | 6.67 | 1.67 |
| 16 | Creating Customized List Reports | 90.00 | 30.00 | 20.00 | 15.00 | 200.00 | 60.00 | 415.00 | 6.92 | 1.73 |
| 17 | Arrays | 90.00 | 30.00 | 20.00 | 15.00 | 175.00 | 60.00 | 390.00 | 6.50 | 1.63 |
| 18 | Creating Enhancing List and Summary Reports | 90.00 | 30.00 | 20.00 | 15.00 | 200.00 | 60.00 | 415.00 | 6.92 | 1.73 |
| 19 | Creating Proc Tabulate | 90.00 | 30.00 | 20.00 | 15.00 | 200.00 | 60.00 | 415.00 | 6.92 | 1.73 |
| NET TOTAL | | | | | | | | | 120.00 | 30.00 |

MODULE - 2 : SAS MACROS

| Lesson / Delivery Type | Times Allocated in Minutes | | | | | | | | Total | Total |
|------------------------|----------------------------|----|-------|-------|------|------|-----|-------|-------|-------|
| | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |

| | | | | | | | | | | |
|------------------|--------------------------|--------|-------|-------|-------|--------|--------|--------|--------------|--------------|
| 1 | Fundamentals of Macros | 90.00 | 40.00 | 25.00 | 15.00 | 150.00 | 80.00 | 400.00 | 6.67 | 1.67 |
| 2 | Macro Application | 90.00 | 40.00 | 25.00 | 15.00 | 150.00 | 150.00 | 470.00 | 7.83 | 1.96 |
| 3 | Macros Program Structure | 90.00 | 40.00 | 25.00 | 15.00 | 150.00 | 80.00 | 400.00 | 6.67 | 1.67 |
| 4 | Macros Statements | 100.00 | 40.00 | 25.00 | 15.00 | 150.00 | 100.00 | 430.00 | 7.17 | 1.79 |
| 5 | Macro Variables | 100.00 | 40.00 | 25.00 | 15.00 | 150.00 | 100.00 | 430.00 | 7.17 | 1.79 |
| 6 | Macro Functions | 100.00 | 40.00 | 25.00 | 15.00 | 155.00 | 100.00 | 435.00 | 7.25 | 1.81 |
| 7 | Writing Macro Programs | 100.00 | 40.00 | 25.00 | 15.00 | 175.00 | 80.00 | 435.00 | 7.25 | 1.81 |
| NET TOTAL | | | | | | | | | 50.00 | 12.50 |

MODULE - 3 : SAS SQL

| | | Times Allocated in Minutes | | | | | | | | Total | Total |
|------------------------|---|----------------------------|-------|-------|-------|------|-------|--------|--------|-------|-------|
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Introduction to the SQL Procedure | 40.00 | 40.00 | 25.00 | 15.00 | | 60.00 | 100.00 | 280.00 | 4.67 | 1.17 |
| 2 | Retrieving Data from a Single Table | 40.00 | 40.00 | 25.00 | 15.00 | | 90.00 | 100.00 | 310.00 | 5.17 | 1.29 |
| 3 | Retrieving Data from Multiple Tablets | 40.00 | 40.00 | 25.00 | 15.00 | | 90.00 | 100.00 | 310.00 | 5.17 | 1.29 |
| 4 | Creating and Updating Tables and Views | 40.00 | 40.00 | 25.00 | 15.00 | | 60.00 | 100.00 | 280.00 | 4.67 | 1.17 |
| 5 | Programming with the SQL Procedure | 40.00 | 40.00 | 25.00 | 15.00 | | 90.00 | 100.00 | 310.00 | 5.17 | 1.29 |
| 6 | Practical Problem-Solving with PROC SQL | 40.00 | 40.00 | 25.00 | 15.00 | | 90.00 | 100.00 | 310.00 | 5.17 | 1.29 |
| NET TOTAL | | | | | | | | | | 30.00 | 7.50 |

SSAS - ADVANCED SAS PROGRAMMING - 175 Hours**MODULE - 4 : SAS STAT**

| | | Times Allocated in Minutes | | | | | | | | Total | Total |
|--------------------------|----------------------------|----------------------------|--------|-------|-------|------|--------|--------|--------|-------|-------|
| Lesson/ Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Introduction to Statistics | 150.00 | 60.00 | 25.00 | 15.00 | | - | 100.00 | 350.00 | 5.83 | 1.46 |
| 2 | Hypothesis Testing | 200.00 | 125.00 | 25.00 | 15.00 | | 350.00 | 175.00 | 890.00 | 14.83 | 3.71 |

| | | | | | | | | | | |
|------------------|--------------------------------|--------|--------|-------|-------|--------|--------|--------|---------------|--------------|
| 3 | One-Sample T-tests | 125.00 | 125.00 | 25.00 | 15.00 | 350.00 | 175.00 | 815.00 | 13.58 | 3.40 |
| 4 | Paired T-tests | 125.00 | 125.00 | 25.00 | 15.00 | 250.00 | 175.00 | 715.00 | 11.92 | 2.98 |
| 5 | Two-Sample T-tests | 125.00 | 125.00 | 25.00 | 15.00 | 250.00 | 175.00 | 715.00 | 11.92 | 2.98 |
| 6 | Analysis of Variance (ONE-WAY) | 200.00 | 150.00 | 25.00 | 15.00 | 350.00 | 175.00 | 915.00 | 15.25 | 3.81 |
| 7 | Analysis of Variance (TWO-WAY) | 200.00 | 150.00 | 25.00 | 15.00 | 350.00 | 175.00 | 915.00 | 15.25 | 3.81 |
| 8 | Linear Regression | 200.00 | 150.00 | 25.00 | 15.00 | 350.00 | 175.00 | 915.00 | 15.25 | 3.81 |
| 9 | Multiple Regression | 150.00 | 150.00 | 25.00 | 15.00 | 350.00 | 200.00 | 890.00 | 14.83 | 3.71 |
| 10 | Regression Diagnostics | 200.00 | 150.00 | 25.00 | 15.00 | 350.00 | 200.00 | 940.00 | 15.67 | 3.92 |
| 11 | Categorical Data Analysis | 200.00 | 150.00 | 25.00 | 15.00 | 350.00 | 200.00 | 940.00 | 15.67 | 3.92 |
| NET TOTAL | | | | | | | | | 150.00 | 37.50 |

MODULE - 5 : SAS GRAPHS

| | | Times Allocated in Minutes | | | | | | | | Total | Total |
|--------------------------|-------------------------------------|----------------------------|-------|-------|-------|------|--------|--------|--------|-------|-------|
| Lesson/ Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Producing Bar and Pie Charts | 40.00 | 30.00 | 25.00 | 15.00 | | 70.00 | 100.00 | 280.00 | 4.67 | 1.17 |
| 2 | Enhancing the Output in the Graphs | 40.00 | 30.00 | 25.00 | 15.00 | | 90.00 | 100.00 | 300.00 | 5.00 | 1.25 |
| 3 | Producing Plots | 40.00 | 30.00 | 25.00 | 15.00 | | 90.00 | 100.00 | 300.00 | 5.00 | 1.25 |
| 4 | ODS (Output Delivery System) | 40.00 | 30.00 | 25.00 | 15.00 | | 100.00 | 100.00 | 310.00 | 5.17 | 1.29 |
| 5 | Creating 3rd and Geographic Reports | 40.00 | 30.00 | 25.00 | 15.00 | | 100.00 | 100.00 | 310.00 | 5.17 | 1.29 |
| NET TOTAL | | | | | | | | | | 25.00 | 6.25 |

CDAR - CLINICAL TRIAL SAS DATA ANALYSIS & REPORTING - 200 Hours**FUNCTIONAL: CLINICAL TRIAL AND DATA MANAGEMENT**

| | | Times Allocated in Minutes | | | | | | | Total | Total | |
|------------------------|-------------------------|----------------------------|-------|-------|-------|-------|------|-------|--------|-------|------|
| Lesson / Delivery Type | | PPT | CH | Q(15) | Q(10) | Q(3) | Exer | Rev | Total | Hours | Days |
| 1 | Elementary SAS Concepts | 45.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 205.00 | 3.42 | 0.85 |

| | | | | | | | | | | | |
|----|--|-------|-------|-------|-------|-------|--------|--------|--------|------|------|
| 2 | SAS Efficiency Programming | 45.00 | 40.00 | 25.00 | 15.00 | 20.00 | 150.00 | 60.00 | 355.00 | 5.92 | 1.48 |
| 3 | Introduction to Clinical Trials | 45.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 235.00 | 3.92 | 0.98 |
| 4 | Types and Data in Clinical Trials | 90.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 280.00 | 4.67 | 1.17 |
| 5 | Clinical Trial Protocol Development | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 250.00 | 4.17 | 1.04 |
| 6 | Elements of CRF Design | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 7 | Electronic Data Capture (EDC) | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 8 | Good Clinical Practices | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 9 | Good Documentation Practices | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 300.00 | 5.00 | 1.25 |
| 10 | Workflow Instruction Request | 60.00 | 60.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 270.00 | 4.50 | 1.13 |
| 11 | Documentation Templates | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | | 90.00 | 285.00 | 4.75 | 1.19 |
| 12 | Introduction to Data Validation | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 60.00 | 220.00 | 3.67 | 0.92 |
| 13 | Data Based Validation | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | 150.00 | 60.00 | 370.00 | 6.17 | 1.54 |
| 14 | Protocol Based Validation | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | 150.00 | 60.00 | 370.00 | 6.17 | 1.54 |
| 15 | Basic of Statistics | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 330.00 | 5.50 | 1.38 |
| 16 | Statistical Analysis Planning | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 295.00 | 4.92 | 1.23 |
| 17 | Elements of Hypothesis Testing | 90.00 | 45.00 | 25.00 | 15.00 | 20.00 | 150.00 | 60.00 | 405.00 | 6.75 | 1.69 |
| 18 | Basic of Efficiency | 60.00 | 40.00 | 25.00 | 15.00 | 20.00 | | 55.00 | 215.00 | 3.58 | 0.90 |
| 19 | Integrated Summary of Effectiveness (ISE) | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 110.00 | 320.00 | 5.33 | 1.33 |
| 20 | Integrated Summary of Safety (ISS) | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 120.00 | 330.00 | 5.50 | 1.38 |
| 21 | Clinical Data Interchange Standards Consortium (CDISC) | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 155.00 | 100.00 | 465.00 | 7.75 | 1.94 |
| 22 | Preparing Analysis Data sets | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 160.00 | 100.00 | 470.00 | 7.83 | 1.96 |
| 23 | Creating Tables Listing and Graphs (TLG) | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 24 | Understanding Various Therapeutics Areas | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 25 | Data Based Therapy | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 26 | Introduction to Phase | | | | | 20.00 | | | 310.00 | | |

| | | | | | | | | | | | |
|-------------------------------------|---|-------|-------|-----------------------|-------|-------|--------|--------|--------|--------|-------|
| | I Studies | 60.00 | 90.00 | 25.00 | 15.00 | | | 100.00 | | 5.17 | 1.29 |
| 27 | Oncology Project | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 250.00 | 100.00 | 560.00 | 9.33 | 2.33 |
| 28 | Introduction to Phase II Studies | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 29 | Ophthalmology Project | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 250.00 | 100.00 | 560.00 | 9.33 | 2.33 |
| 30 | Introduction to Phase III Studies | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 31 | Cardiology Project | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 250.00 | 100.00 | 560.00 | 9.33 | 2.33 |
| 32 | Introduction to Phase IV Studies | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 33 | Central Nervous Systems (CNS) Project | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 250.00 | 100.00 | 560.00 | 9.33 | 2.33 |
| 34 | Introduction to Pharmacovigilance | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | | 100.00 | 310.00 | 5.17 | 1.29 |
| 35 | Pharmacovigilance Reporting | 60.00 | 90.00 | 25.00 | 15.00 | 20.00 | 250.00 | 100.00 | 560.00 | 9.33 | 2.33 |
| | Final Exam (Two Attempts provided to Pass - Exam 1 and 2) | | | | | | | 90.00 | 90.00 | 1.50 | 0.38 |
| NET TOTAL | | | | | | | | | | 200.00 | 50.00 |
| | | | | | | | | | Hours | Days | |
| Self-Paced Online Learning Hours | | | | Spend 4-5 hours / Day | | | | | | | |
| TOTAL CDAR PACKAGE PROGRAM DURATION | | | | | | | | | 575.00 | 143.75 | |

| Lesson - Learning Delivery Type | Code |
|--|-------------|
| Presentation with Voice Over | PPT |
| Chapters - Reading Material | CH |
| Quiz for Practice (15 MCQs) | Q(15) |
| Quiz as Test (10 MCQs) | Q(10) |
| Discussion Based Questions (DBQ) - Top 3 | Q(3) |
| Hypothetical Exercises (Multiple) | Exer |
| Revision Hours | Rev |

Fees:

| Clinical Trial SAS Data Analysis and Reporting (CDAR) Self-Paced Online Program with Support | Fees (CAD \$) |
|---|----------------------|
| Base Tuition fee | 3,805.55 |
| Admission fee (Non-Refundable) | 65.50 |
| Course Material Book Binder | 229.25 |
| Test (Exam Fees) - 2 Attempts | 229.25 |
| Post Training Assistance (PTA) | 294.75 |
| Total fee per course | 4,329.55 |

The admission fee is non refundable. Students will need to meet all financial responsibilities before a Certificate of Completion is issued. Book Binder is provided within 3 business days after activation of Online Material access

20. Reimbursement Scale

The right to reimbursement would occur based on following indicated below.

- Qtech offers distance learning program as Pure Internet Program (SIP) - Self-Paced
The Calculation is made based on Net Hours and % of completion by each lesson.
- Net Fees retained by Qtech includes, sum of “% of Eligible Retained Tuition” + “Admission Fee” + “Book Binder Cost (If material is shipped prior to withdrawal notice)”.

| Circumstance | Reimbursement |
|--|---|
| A student is enrolled in an approved program Without having met the admission requirements and Without having misrepresented his/her knowledge and skills while applying | 100% Tuition Refund and a refund of all fees |
| Student withdraws or is dismissed from a distance-education-only program | |
| When the student has received an evaluation for completing upto 30% of the program | Institution will retain up to 50% of the Tuition |
| When the student has received an evaluation for completing above 30% of the program | Institution will retain 100% of the Tuition |

22. Post Training Assistance

Additional 14 hours of post training support is provided to students as an option. Those 14 additional hours do not influence reimbursement scale.

Post training support include:

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

Finding Jobs Criterion depends on various factors, few of them are :

- Candidate – Active Vs Passive Job Seekers.
- Location Preference – Local Vs Open for relocation.
- Salary Expected – Current Vs Next.
- Skill – Fresh Vs Experienced.
- Job Title – Entry - Mid - Senior roles.
- Type of Job – Contract Vs Full-time.
- Work – Onsite Vs remote.

PTA Program and Process Steps

The Student will be closely be working with Qtech-Sol professional for next 2 Weeks after program certification, to ensure the candidate is prepared and ready for Interviewing. During this program, the first step is to get your resume aligned to roles and duties performed. Aligning the learnings gained to meet job market on resume. The Narrative writing process will allow you to better explain details of the resume during interviews and to position yourself to open positions applied. Take a mock session to test your skills and understand most frequently asked questions during interviews.

Ways to Gain Experience

Here are four ways to gain experience and get your foot in the door so you can obtain your first job. Qtech helps its students by providing.

1. Experiential Practicum
2. Volunteering
3. Networking
4. Freelancing

Five (5) Steps followed at Qtech

Step-1: Exercise to do to get started

We expect each student looking for job as next steps, to follow the following process:

1. Please investigate various possible jobs open in job sites, such as indeed, career-builder, dice etc., open jobs open or closed.
2. Use key words search, based on lessons and job titles, during your search to identify positions.
3. Copy and paste the job duties of each job identified into a word document and compare them with learning gained from the certificate program.

4. Bucket the duties per lessons learnt during the training program (Basic, Advanced, Additional)
5. Prepare a word document by lesson and map to the job duties buckets.
6. Compare the learnings gained to the job requirements and identify your strengths to prepare a document.

Step-2: Resume Preparation

Qtech-Sol will provide some sample resumes to candidate along with learning curve document gained from certification program received. These documents allow the candidate to get started with resume preparation. Copy of the draft resume prepared by candidate must be emailed to the director for review. We will review the resume and will provide suggestive meeting job market needs.

Step-3: Narrative Writing

The finalized resume will allow candidate to write down the narrative form of resume in first tense. This document allows the candidate to prepare for possible interviews and defend it per client job requirement. The narrative form document will be emailed to the course director for review and feedback, before proceeding for mock session. A Subject matter expert will be deputed conducting mock session when the candidate is ready. Prior experiences of candidate (if any) helps to prepare for the type of job (Entry, Medium or Senior Roles)

Step-4: Mock Sessions

The Subject matter expert will conduct the mock session and will list out all possible and anticipated interview questions usually asked by client during the interview. Preparing the candidate for face-to-face and initial telephonic round is a key success to get job.

Step-5: Readiness and Taking Interviews

Qtech-Sol will work closely with candidate and will help student in application process with promising clients. The student will be provided a list of matching positions that fits to maximize opportunities. The student will get engaged with one of our placement experts to be successful. We strive to provide contractual opportunities with client and will have an option to work as Qtech full-time employee. Full-time positions will be applied by candidate per guidelines and lead shared.

23. 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.

24. 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 the 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 acts 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.

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