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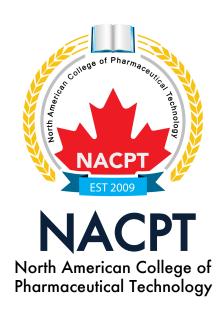
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NACPT does not only seek to educate its graduates, but also encourage and motivate them to a high degree of confidence within close quarters to the aspired career.

North American College of Pharmaceutical Technology (NACPT) is registered as a private career college under the Private Career Colleges Act, 2005 and operates under Devik Pharma Inc. Located in the heart of the City of Toronto, Ontario, NACPT was established to serve the needs of an ever increasing population of job seekers; to supplement their job-related inadequacies, thereby facilitating a smooth transition towards an ultimate career aspiration.

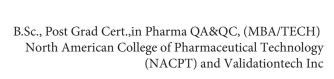
NACPT offers diploma and postgraduate diploma programs in different areas of Pharmaceutical and Bio-Pharmaceutical fields. NACPT provides hands-on-training through a highly qualified industrial expert team. NACPT operates in an environment furnished with the state- of- the -art technology; a representative pharmaceutical/bio-technology modern laboratory facility with all major equipments, including HPLC 1100, Chemstation, HP 6890 GC with head space, VK Dissolution Apparatus, Infra Red Spectroscopy V838 and UV.

NACPT also provides job assistance for graduates, newcomers, internationally trained professionals (medical doctors, dentists, pharmacists, nurses, engineers and related profession), laid-off workers (second career), and Ontario Work and WSIB clients. Our success rates are very high, and have approached 90 percent, which we strive to maintain.

Over the years, the Pharmaceutical and Bio-Pharmaceutical companies have shown challenging and upscale requirements for their prospective employees, particularly in the fields of Quality Control, Quality Assurance, Research and Development, Method Development, Validation and Manufacturing Technology, Formulation, Regulatory Affairs, and Clinical Research. To meet such soaring demands, NACPT's programs have been fine-tuned with impressive features that are precisely customized to be practical, scientific-industry oriented, career targeted, modern technologically driven and short-termed.

Message from The President

Rathi Param
President/Validation Scientist





Welcome!

What do we require for career advancements in the modern world? Change! There is a need to upgrade existing skills and knowledge or acquire new skills and knowledge. It is a known fact that pharmaceutical and biotechnology industries will thrive as long as there is a need for cure and medication. However, how do we connect ourselves to this art of science? Most colleges and universities provide degrees/ diplomas/ certificates allowing one to become a new graduate/ professional, however, we offer the transition state from education to launching into the job market thorough our expert team and the development of unique skills and knowledge.

When one chooses NACPT, they opt to engage in a modern pharmaceutical and biotechnology that goes above and beyond the pharmaceutical and biotechnology standards and requirements. Combined with Validationtech Inc. services, NACPT takes innovative paths to providing best career hands-on training for our clients.

By building partnership with pharmaceutical/biotechnology/ medical device industries, research and development laboratories, contract research organizations, and colleges and universities, NACPT has engaged in providing solid and effective career hands-on training for our clients. Our innovative expert team is committed to providing high level of skills and knowledge one requires to face the challenges in Pharmaceutical and biotechnology industries. By continuously seeking a change within their professional lives, anyone can reach their ultimate goal!

President's contact

Rathi Param 416.412.7374 • 416.857.7603 riappa@NacptPharmaCollege.com

Rathi Param

Rathi Param is the president/founder of the North American College of Pharmaceutical Technology and Validationtech Inc. She is an innovative and creative leader with more than fifteen years of hands-on experience in many scientific industries (medical devices, environmental, food, pharmaceutical and biopharmaceutical), complemented with more than ten years of training/teaching experience. She possesses extensive expertise and knowledge of Quality Control, Quality Assurance, Validation (Process, Cleaning, Sterile, Non-Sterile, Packaging, Equipment, Facility, Utility and etc.), Technology Transfer, Manufacturing Technology, **Process** Improvements, Auditing, Project Management and Inspection.

In the past fifteen years, Rathi has held strategic management roles in major Canadian name brand/generic pharmaceutical companies, where she was responsible for the overall performances of the Site Master Validation Plan, Master Validation Plans, Technology Transfer, Validation Projects and Process Improvements. Rathi's most recent positions were Validation Scientist at Patheon Inc., Whitby (former subsidiary of Novartis Pharmaceutical), Validation Services Manager at Sanofi Pasteur Limited, Toronto., Validation Specialist at Ciba Vision, Toronto., and Validation Quality Engineer (Consultant) at iPOC, Toronto.

In addition to her industrial experience, Rathi has successfully developed and launched many unique solid industrial career training programs which are approved by Ministry of Training Colleges and Universities and highly recognized by pharmaceutical and related industries. In 2011, she also developed and launched the Industrial Clean Safe Sanitization program for Ontario Works.

In addition to her academic and professional achievements, Rathi has contributed toward good causes which allowed her to actively participate in many social activities. In 1994, Rathi was nominated and awarded for a 5 Years of Honor and Volunteer Award by the Ministry of Citizenship. In 1995, she became the Vice President for TSU at the University of Ottawa. In 2003, she became the Vice President of TESO. In 2012, she received the Best Woman Entrepreneur Award by the CTCC for her contribution towards education and job development services in her areas of expertise.

In past years, Rathi had participated in many mentoring programs such as the events hosted by the Citizenship of Immigration for healthcare professionals. She played a role in the Women in Science and Engineering event hosted by University of Toronto, University Ottawa and University of Waterloo. She also participated in the Alternative Careers Roundtable Session hosted by the Foreign Qualifications Recognition Working Group (FQRWG).

Her motives echo, "What you dream can be achieved through your sheer hard work, dedication and commitment!"

"Rathi is an expert on pharmaceutical validation for sterile/aseptic processes as well as solid/liquid dosage manufacturing. She is a person of high professional integrity with a keen enthusiastic interest and definitive insight in the pharmaceutical industry."

Andrew Fan, Validation Manager Sanofi Pasteur, Canada Feb 24, 2010 worked directly with Rathi at Sanofi Pasteur

Affiliated Companies

Validationtech Inc.

NACPT affiliated with Validationtech Corporation in terms of outsourcing projects for facility validation, utility validation, equipment validation (IQ/OQ/PQ), method development and method validation, computer validation, cleaning validation, sterile validation, process validation, clean room certification, temperature mapping, and many more related services.

Validationtech provides co-op/contract positions for qualified NACPT candidates. Visit www.validationtech.com

A.S. Chemical Laboratories Inc.

NACPT affiliated with A.S. Chemical Laboratories in terms of chemical analyses, method development and validation. A.S. Chemical laboratories Inc. provides co-op/contract positions for qualified NACPT candidates.

CaChiCo Tech Consulting Inc.

NACPT affiliated with CaChiCo Tech Consulting in terms of providing corporate training services for pharmaceutical/biotechnology companies across the world and accruing suitable projects for NACPT graduates.

C Max Technologies Inc.

CMAX Technologies Inc. is a drug delivery company with expertise in solid oral dosages. NACPT affiliated with CMax Technologies Inc in terms of obtaining co-op, internship for NACPT graduates and performing other pharmaceutical services

Pharmamedica Research Inc.

NACPT is affiliated with Pharmamedica Research Inc. in terms of job placements and campus recruitments. NACPT invites Pharmamedica Research Inc. at the completion of the postgraduate diploma Pharmaceutical and Bio-pharmaceutical Clinical Research program to recruit the qualified NACPT graduates for a possible job opportunities within multiple sites of the company.

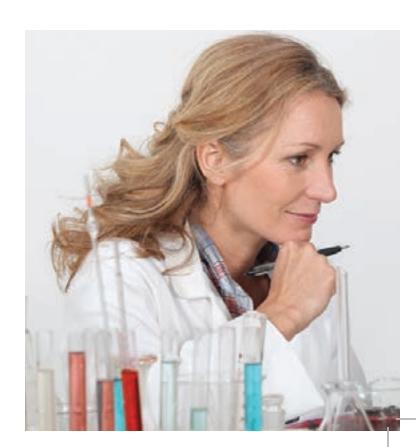
Chemi Pharmaceutical Inc.

NACPT affiliated with Chemi Pharmaceutical Inc. in terms of providing corporate training and placement services. Both NACPT and Chemi Pharmaceutical Inc., are working based on good will.

Why choose

NACPT?

- Covers both Pharmaceutical and Bio-Technology Industries
- Fast-track Training
- Short Term Hands-on Training
- Co-op & Job Placement Assistance
- Programs are Unique Open to Maximum Job Opportunities
- Instructors are Real Industrial Experts
- Modern Laboratory Facilities
- Full Time/Part Time Programs Availability
- Wi-Fi access to all training locations
- One on One Job Development / Job Assistance program
- Scholarship available for qualified candidates
- Work and Study option
- Helping on other potential needs: residence, insurance policy, travel arrangements, immigration matters and related services



Admission Requirements for **Domestic Students**

Admission Requirements and Procedures for Domestic Students

- Complete Student Application Form
- Certified copies of student's transcript and degree/diploma
- Student's profile educational background, experience and career goals (Profile must be attached along with the application form)

Postgraduate Diploma Programs

Program 1: Industrial Pharmaceutical & Bio-Pharmaceutical Modern Technology - Full-time

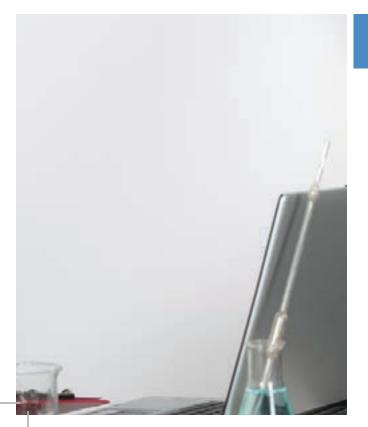
Program 2: Industrial Pharmaceutical & Bio-Pharmaceutical Modern Technology - Part-time

Program 3: Pharmaceutical & Bio-Pharmaceutical Clinical Research

Diploma Programs

Program 1: Industrial Pharmaceutical & Bio-Pharmaceutical Manufacturing Formulation and Validation Technology

Program 2: Industrial Pharmaceutical & Bio-Pharmaceutical Quality Control and Quality Assurance



Educational Requirements

Refer to each program list

Complete the student contract form (the form can be found at www.nacptpharmacollege.com or it can be picked-up directly at the college) and send the completed forms to:

Admission and Processing Department North American College of Pharmaceutical Technology (NACPT)

5310 Finch Avenue East, Unit#9 Scarborough, ON, M1S 5E8

For the current information on tuition and related program fees, please contact us at (416) 412-7374 or info@nacptpharmacollege.com.

Note: The Diploma/Postgraduate Diploma Programs are revolving; applications are accepted for admissions throughout the year at any time.

Admission Requirements for International Students

Checklist: Documents Required to Process Application

- ☑ Complete student contract form (contact NACPT)
- Certified copies of student's transcripts and degree/diploma translated in English
- ☑ Student's profile educational background, experience and career goals (Profile must be attached along with the application form)
- ☑ Administration fee of CAN \$ 450 (Refer to the payment methods)
- ☑ TOEFL or IELTS score: English Proficiency requirements are as follows for consideration: Minimum TOEFL score of 550 (paper based) or 213 (computer based) or 88 (internet based), OR IELTS with an overall minimum score of 6.0 (no single test score below 5.0), OR CAEL (Canadian Academic English Language Assessment) with an overall band score of 60.

Complete the student contract form (the form can be found at www.naiptlabs.com or it can be picked-up directly at the college) and send the completed forms to:

Admission and Processing Department
North American College of Pharmaceutical Technology (NACPT)

5310 Finch Avenue East, Unit#9 Scarborough, ON, M1S 5E8

Payment Methods: Payments can be made in certified cheques or money order as payable to "North American College of Pharmaceutical Technology", Master Card, Visa Card or Debit Card. Tui ion fees must be paid directly to the college. Payment can not be paid through student consultants. Please contact NACPT, if you have any questions. Refer to the attached invoice for the tuition fee requirement.

Note: Any fee associated with enrolment process cannot be paid as cash. Administration fee is non-refundable. Upon receiving all the required documents along with the administrative fee by NACPT, our college will inform the decision of admission to the students as quickly as possible.

For the current information on tuition and related program fees, please contact us at (416) 412-7374 or info@nacptpharmacollege.com.

Note: The Diploma/Postgraduate Diploma Programs are revolving; applications are accepted for admissions throughout the year at any time.

Information for International Student

Life Style in Canada

As a multi-cultural city of the world, Toronto gives you great exposure to diversified ethnic groups. It has a wide variety of food and fashion available that are well received by Torontonians. Hence, these benefit international students as you get the opportunity to broaden your horizons about other cultures and communities all around the world within the Greater Toronto Area. Moreover, ethnic foods of all sorts are readily available, at all times, ensuring the food from back home is not missed. Throughout the year, many different cultural activities take place, which would surely entertain the students, as participants and/ or audience member, during their stay here.

There are a plenty of residency options in Toronto. Students can rent furnished or non-furnished basement apartments/building apartments, with or without food accommodations. There are many buildings and basement apartments available within walking distance to NACPT, which students may pursue.

Public Transportation

Toronto has an easily accessible transportation system which gives 24 hour public transit with frequent services in many parts of the city. Monthly passes can be used for one to travel anytime and anywhere within Toronto as desired. There are many subways close to NACPT within 30 minutes of travelling. Most importantly, NACPT is accessible by public transit as it lies within a minute walking distance from the main bus stop. The bus stop near NACPT provides 24 hour bus service, with buses stopping every two minutes.

Climate Conditions

In Toronto, students must be prepared to wear the right seasonal attires, i.e. warm clothing during the winter season, and very light clothing during the summer. During winter months, the average temperature hovers just slightly below freezing, with the exception of January, which is deemed to be the coldest month. Snowfall of more than 10 cm is rare. Spring and summer temperatures range from 15 °C to 25°C.

Easy Access to Non-Emergency City Services and Information

To the advantages of the residents of Toronto, the City of Toronto has launched 311 Toronto. Dialling 311 provides residents, businesses and visitors with easy access to non-emergency City services, programs and information 24 hours a day, seven days a week. With one call to 311, customer service representatives will be able to answer any queries and provide the necessary information, as well as to take service requests and resolve majority of the inquiries without a call transfer.

International Students Program (ISP)

As of June 1st, 2014, NACPT became a Designated Learning College by Canadian government (CIC) for recruiting International Student.

Who Can Come?

Science/Engineering/Healthcare graduates/professionals from any country. Our recent students came from USA, UK, Dubai, Iran, China, India and etc.





existing skills or obtain new skills. Each area of study will be covered in-depth for both pharmaceutical and bio-pharmaceutical sectors.

Admission Requirement

Science/Engineering/Technology Degree or Diploma/Equivalent.

Duration: 48 weeks of training + 4 weeks of break

Hands-on Training along with Job Assistance: The program includes 48 weeks of hands-on training, 4 months of optional Job Assistance for qualified students along with resume preparation and learning interview tactics and tips.

Areas of Study

Good Manufacturing & Good Clinical Practices, Course Code: GCCP01

This course will introduce the concepts and requirements necessary for compliance with Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) for pharmaceuticals and biopharmaceuticals. It will prepare students to establish and document a system of GMP controls required to manufacture drug products in Canada, the United States and in many parts of the world. It focuses on real work industrial scenarios.

The graduates will be able to demonstrate a good understanding of both GMP and GCP guidelines, the functional aspects of each guideline, responding to citations for audit agencies, corrective preventive action plans, change controls, and health risk classifications. It focuses on real work industrial scenarios.

Introduction to Laboratory Testing & GLP, Course Code:ILTP02

This course will introduce the concepts and requirements necessary for compliance with Good Laboratory Practice (GLP) for pharmaceuticals and biopharmaceuticals. It will address the most important laboratory techniques. Students will also get exposure and experience with all major pharmaceutical instrument. It focuses on real work industrial scenarios.

The graduates will have a good understanding of the GLP guidelines widely used in pharmaceutical and related sectors, the functional aspects of these guidelines in various processes and procedures, as well as a good understanding of instrumentations, calibration and the application of various instruments.



Dissolution & Dissolution Hands-on Training, Course Code: DIS003

This course will introduce dissolution current testing practices, testing requirements, critical components, sample preparation techniques, media preparation, sample testing, data analysis, report preparation, limitations, IQ/OQ/PQ, calibration, trouble shooting, maintenance, and out of specification investigation.

The graduates will have a good understanding of dissolution techniques, applications, USP apparatus, dissolution testing, report writing, calibration, trouble shooting, maintenance and out of specification investigation. It focuses on real work industrial scenarios.

High performance Liquid Chromatography (HPLC), Course Code: HPL004

This course will introduce HPLC theory, components, testing practices, testing requirements, sample preparation techniques, mobile phase preparation, sample testing, data analysis, report preparation, limitations, IQ/OQ/PQ, calibration, trouble shooting, maintenance, and out of specification investigation.

The graduates will have a good understanding of HPLC techniques, applications, Chemstation software, HPLC testing (identification, assay, content uniformity and etc.), report writing, calibration, trouble shooting, maintenance, and out of specification investigation. It focuses on real work industrial scenarios.

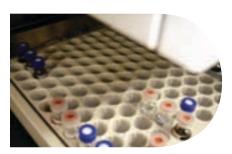




Gas Chromatography (GC), Course Code:GCT005

This course will introduce gas chromatography history, concepts, carrier gas, testing requirements, critical components, sample preparation techniques, sample testing, data analysis, report preparation, limitations, IQ/OQ/PQ, calibration, trouble shooting, maintenance, and out of specification investigation.

The graduates will have a good understanding of GC techniques, applications, Chemstation software, head space, GC testing (identification, assay, content uniformity and etc), report writing, calibration, trouble shooting, maintenance, and out of specification investigation. It focuses on real work industrial scenarios.



HPLC & UV for Dissolution: Method Development & Method Validation, Course Code: HPD001

This course will introduce how to initiate and perform method development and method validation using the HPLC /UV and the Dissolution Apparatus. It will cover major industrial regulations in terms of developing and validating testing methods.

The graduates will have a good understanding of HPLC method development and method validation for various pharmaceutical products, the application of Chemstation, validation guidelines, report writing and trouble shooting. It focuses on real work industrial scenarios

GC & UV Spectrometer: Method Development & Method Validation, Course Code:GCUV002

This course willintroduce how to initiate and perform method development and method validation using the GC /UV. It will cover major industrial regulations, in terms of developing and validating testing methods.

The graduates will have a good understanding of GC method development and method validation for various pharmaceutical products, the application of headspace, validation guidelines, report writing and trouble shooting. It focuses on real work industrial scenarios.



Pharmaceutical/Bio-Pharmaceutical Manufacturing Formulation & Validation Technology, Course Code: PMVT01

This course will introduce manufacturing technology, all types of validation (process, packaging, cleaning, utility, facility, computer and thermal), drug formulation (solid, liquid, suspension, powder and biopharmaceutical process such as fermentation and filtration) and manufacturing technologies (equipment dynamics and etc).

Students will know the fundamental of drug formulation for solid, liquid, suspension, powder and biopharmaceutical process such as fermentation and filtration and manufacturing technology (equipment dynamics and etc). They will also get introduced to various validation technology, fundamentals and guidelines.

Collective Validation, Course Code:ETUF05

This course will cover collective validation technology and regulations related to specific validation topics: equipment qualification, thermal validation, utility qualification, computer validation and facility validation.

Students will get to know how to initiate and conduct equipment, thermal, utility, computer and facility validation studies. They will also learn the related regulations and report writing for those studies.

Cleaning & Sterile Validation, Course Code:CLVM01

This course will introduce current cleaning validation practices, rationale, worst case scenarios, writing protocols, reports and master validation plans, as well as the regulatory requirements of cleaning validation that lead to risk-based, practical and scientific informed decisions and planned activities. It focuses on real work industrial scenarios.

Students will know how to initiate and conduct cleaning validation studies. They will also learn the related current cleaning validation regulations and report writing for those validation studies.

Packaging Validation & Packaging Components, Course Code: PKV04

This course will cover packaging validation concept and packaging components, writing protocols, reports and master validation plans, as well as the regulatory requirements of packaging validation that lead to risk-based, reasonable and scientific informed decisions and planned activities. It focuses on real work industrial scenarios

Students will get to know how to initiate and conduct packaging validation studies. They will also learn the related current packaging validation regulations and report writing for those validation studies.

Process Validation, Course Code: PRV03

This course will cover process validation concept, rationale, writing protocols, reports and master validation plans, as well as the regulatory requirements of process validation that lead to risk-based, practical and scientific informed decisions and planned activities. It focuses on real work industrial scenarios.

Students will know how to initiate and conduct process validation studies in pharmaceutical and biopharmaceutical industries. They will also learn the related current process validation regulations and report writing for those validation studies.

Introduction to Regulatory Affairs, Course Code:IRA001

This course will introduce Introduction on Health Canada, role of regulatory affairs, regulatory terminologies – DIN, NDS, ANDS,OTC & CTC, drug discovery timeline, phases of clinical trials, ICH-GCP guidelines and common technical document, NDA / NDS submission, ANDA / ANDS submission, DIN# and NPN#, quality assurance and regulatory affairs and post approval activities.

The graduates of this course will have a good understanding of the laws and regulations governing regulatory process. At the end of the course, they will be able to complete the required regulatory documents (i.e. CTA, IND) for the regulatory agency, in order to obtain approval from the government for conducting further studies.

Professional Regulatory Affairs, Course Code: PRA004

This course builds upon the clinical regulatory foundation built in IRA001. It provides students with an understanding of the trends in pharmaceutical industry, with regards to policy making and product development. The topics also include regulatory strategies in developing a product and post approval management of the product.

The graduates of this course will have a good understanding of regulatory strategies in developing a product and post approval management of the product, along with PMS and related regulations.

Introduction to Clinical Studies, Course Code:ICS002

This course is aimed to introduce the concept of Good Clinical Practice in clinical research. The key elements of the ICH Good Clinical Practices will be discussed, including the ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

The graduates will be able to demonstrate a good understanding of the ethical principles related to clinical trial, understand the meaning of "protection of the rights, well-being and safety of the trial subjects", be able to list all the essential documents required to collectively permit evaluation throughout the conduct of a trial and the quality of the data produced, and be able to understand the roles and responsibilities of an investigator, a sponsor, a Clinical Research Organization, the Research Ethics Board and the subjects in a clinical trial.

Scientific Technical Writing, Course Code:STW005

This course will introduce different types of technical writing in many areas (QA, QC, R&D, Manufacturing, Formulation and Validation) and compiling scientific documents: SOPs, communication methods and issues, validation reports writing, validation protocols writing, dealing with batch records, auditing reports, investigations and real work industrial scenarios.

The graduates will be able to initiate and write various SOPs, protocols, study reports, OOS and deviation reports, batch records, change controls, and CAPAs. They will also learn the functionality of each department and the documentation aspect of each function.

Job Opportunities in Multiple Departments

Quality Control and Quality Assurance Area: Technologists, Raw Material Chemists, Finish Product Chemists, Stability Chemists, R&D Chemists, Scientists, Calibration Chemists, Document Reviewers, Laboratory Coordinators, Trainers, SOP Writers, Auditors, Supervisors and Managers.

Formulation Area: Laboratory Coordinators, Formulation Technicians, Production Operators, Formulation Scientists and Formulation Managers/Directors.

Technology Transfer Area: Validation Assistants, Process Development Scientists, Technology Transfer Specialists, Technology Transfer Coordinators and Document Coordinators.

Validation Area: Process Validation Scientists, IQ/OQ/PQ Specialists, Cleaning Validation Specialists, Packaging Validation Specialists, Thermal Validation Specialists, Computer Validation Specialists and Validation Managers.

Regulatory Affairs Area: Regulatory Affairs Associates, Reviewers, Auditors, and Managers/Supervisors/Directors.

Clinical Research Area: Clinical Research Scientists, Clinical Research Organizers /Associates, Managers/ Supervisors/Directors. Regulatory Affairs Area: Regulatory Affairs Associates, Auditors, and Regulatory Affairs Managers/ Supervisors/Directors.



Postgraduate Diploma **Programs**

Pharmaceutical & Bio-Pharmaceutical Clinical Research

This comprehensive postgraduate diploma program has been developed to meet the skill requirements for effectively performing duties in pharmaceutical/ bio-pharmaceutical clinical research industries for those who want to upgrade existing skills or obtain new skills. Each area of the study will be covered in an in-depth manner for both pharmaceutical and bio-pharmaceutical sectors.

Admission Requirement

Any Degree or Diploma/Equivalent

Duration: 52 weeks of training + 4 weeks of break

Hands-on Training along with Job Assistance: The program includes 52 weeks of hands-on training, 4 months of optional Job Assistance for qualified students, along with resume preparation and learning interview tactics and tips.

Areas of Study

Clinical Science, Course Code: ICS01

This course is aimed to review the sciences in clinical research, which includes anatomy, physiology, pathology, molecular biology, immunology and molecular genetics.

The graduates will get to know the sciences in clinical research including anatomy, physiology, pathology, molecular biology, immunology and molecular genetics for clinical research.

Introduction to Clinical Studies (GCP), , Course Code: ICS002

This course is aimed to introduce the concept of Good Clinical Practice in Clinical Research. The key elements of the ICH Good Clinical Practices will be discussed, including the ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

The graduates will be able to demonstrate a good understanding of the ethical principles related to clinical trial, understand the meaning of "protection of the rights, well-being and safety of the trial subjects", be able to list all the essential documents required to collectively permit evaluation throughout the conduct of a trial and the quality of the data produced, and be able to understand the roles and responsibilities of an investigator, a sponsor, a Clinical Research Organization, the Research Ethics Board and the subjects in a clinical trial.

Regulations and Standards in Clinical Research, Course Code:RGS01

This course is aimed to expose students to the regulations, guidelines and standards governing the clinical research with more in-depth review of the Canadian, the United States and the European regulations. This course will also include a review of the historical context that led to the creation of the Health Canada and Food and Drug Administration (U.S.) regulations. Current issues and topics in Canadian regulatory body will also be evaluated and discussed.

The graduates will be able to demonstrate a good understanding of Health Canada, US Food and Drug Administration and EMEA requirements for conducting clinical trials. They would be able to develop internationally recognized standard of knowledge, education and experience in the clinical industry. At the conclusion of the course, students will be able to complete a Clinical Trial Application to Health Canada and Investigational New Drug Application to US FDA.

Clinical Research in Medical Device, Course Code:CRMD01

This course is aimed to introduce students to clinical trials in the medical device industry. The term Medical Devices, as defined in the Health Canada Food and Drugs Act, covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. The course will review the protection of public health and safety with the development of useful devices intended for human use.

The graduates will be able to demonstrate a good understanding of clinical research in medical device industry, be able to list all the essential documents required to collectively permit evaluation throughout the conduct of a trial and the quality of the data produced, be able to understand the roles and responsibilities of an investigator, a sponsor, a Clinical Research Organization, the Research Ethics Board, and the subjects in a clinical trial within the medical device industry.

Ethics and human protection, Course Code:EHPC01

This course will introduce ethics and human protection in clinical research, which forms the fundamental framework for the generation of Good Clinical Practice. This is an advanced course designed to provide hands on practical knowledge for students in the role of the Research Ethics Board (REB) in safeguarding the rights, safety and wellbeing of all research subjects. The course will cover development and submission of clinical trial packages (compromising of protocol/amendments, Informed Consent Form, subject recruitment procedures, Investigator's Brochure etc.) to REB.

The graduates will know the importance of informed consent document in clinical research, demonstrate a good understanding of the role Research Ethics Board plays in safeguarding the rights, safety and wellbeing of research subjects and discuss the current issues in the ethics and human protection in clinical research.

Development of Clinical Trial Protocols, Course Code: DCTM01

This course will introduce protocol, which is an essential document in the conduct of clinical study that describes the objective, design, methodology, statistical considerations and organization of a trial. The document includes every detail of the study design, including the selection/withdrawal of study subjects, treatment of subjects, and even the retention of the clinical trial records collected during the trial. The development of clinical trial protocol is an advanced course designed to provide hands on practical knowledge for students in the development of clinical trial protocol.

The graduates will be able to demonstrate an understanding on the importance of a protocol in clinical trials, as well as to demonstrate a good understanding of the required context for a protocol, including trial objectives and purpose, trial design, selection and withdrawal of subjects, treatment design, assessment of efficacy and safety, statistical methodology and data quality assurance.

Clinical Trial Monitoring, Course Code:CTM01

This course will introduce clinical trial monitoring, which is the process of overseeing the progress of a clinical trial and ensuring that the clinical trial is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirements. This course will review the process involved in clinical trial monitoring from site identification to performing study close out visit in a clinical trial site.

The graduates will understand the basic roles and responsibilities of a sponsor, a monitor, an investigator and regulatory agency, as they relate to the quality of clinical trials, and be able to demonstrate good understanding on how to ensure that the clinical trial and the data generated are accurate, factual, and meet the expectation of the sponsor and regulatory authorities.

Quality Assurance, Course Code:CQA01

This course will introduce quality assurance, which is defined in ICH GCP as "all those systematic actions that are established to ensure that the trial is performed and data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement. In another words, quality assurance is also known as the "clinical police". The course on clinical quality assurance will expose students to the quality management in clinical research and the value of audits

The graduates will be able to understand the role/responsibility of clinical quality assurance professional in ensuring data integrity of a clinical trial, understand quality management system, and be able to prepare for an audit, conduct an audit, generate audit reports and follow up on corrective actions.

Development of SOP, Course Code:DCS01

This course will introduce the development and use of Standard Operating Procedures (SOPs), which are an integral part of successful quality systems. SOPs provide instructions for staff to perform a job function properly and facilitate consistency in the quality and performance of the job function between staff. The development of clinical Standard Operating Procedure is an advanced course designed to provide practical hands on knowledge for students in the development, implementation and maintenance of SOPs.

The graduates will be able to understand why SOPs are generated in the pharmaceutical industry, the role of an SOP in clinical trials and how the SOPs form the fundamental framework for quality management system in any organization. The graduates will also have a thorough knowledge of the SOP life cycle.

Preparing and Hosting Audits and Inspections, Course Code: PHSA01

This course will introduce preparing and conducting sponsor audits and regulatory inspections, and it will introduce students to the process of preparation for the audit/inspections, hosting a regulatory inspection/sponsor audit, and responding to observations made by the regulatory authority or the sponsor.

The graduates will be able to demonstrate a good understanding on the purpose and scope of sponsor and regulatory inspections. They will have a good understanding for preparation, hosting and responding to sponsor audits/ regulatory inspection. The students will also gain knowledge of some of the gaps identified in the clinical trials by Health Canada and FDA regulatory agencies.



Good Documentation Practices, Course Code: GDPC01

This course will introduce documentation, which is defined in ICH GCP as the "records in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct and record the results of a trial, the factors affecting a trial, and the actions taken. This course will review the importance of good documentation practice in clinical trials.

The graduates will be able to understand good documentation practices when completing any essential documents in clinical trials, as well as to understand the importance of good documentation practices when performing duties that involve recording, reviewing, verifying and approving documents in clinical trials.

Clinical Data Management and Biostatistics, Course Code:CDMB01

This course will introduce clinical data management process in clinical research including data capture, validation and cleaning, query management and coding. This course will also introduce the students to various biostatistics techniques applied to the clinical data collected during the trials. The topics covered during the course include types of data, data distribution, measurement of central tendency and variability, confidence intervals, stratification, and crossover design.

The graduates will have a good understanding of the clinical data management process in clinical research, including data capture, validation and cleaning, query management, and coding. This course will also introduce the students to various biostatistics techniques applied to the clinical data collected during the trials. The topics covered during the course include types of data, data distribution, measurement of central tendency and variability, confidence intervals, stratification, and crossover design.

Principles and Practices in Pharmacovigilence, , Course Code:PPP01

This course will introduce students to the principles of pharmacovigilence used in clinical research. The guidelines and regulations governing pharmacovigilence, including the spontaneous reporting of adverse events and periodic safety reports will also be discussed in the course.

The graduates will have a good understanding of the principles of pharmacovigilence used in clinical research. Students will be introduced to the guidelines and regulations governing pharmacovigilence, including the spontaneous reporting of adverse events and periodic safety reports.

Clinical Regulatory Affairs I, Course Code: REG01

This course will discuss about the laws and regulations governing clinical trials. At the end of the course, students will be able to complete the required regulatory documents (i.e. CTA, IND) for the regulatory agency, in order to obtain approval from the government for conducting clinical trials.

The graduates of this course will have a good understanding of the laws and regulations governing clinical trials. At the end of the course, students will be able to complete the required regulatory documents (i.e. CTA, IND) for the regulatory agency, in order to obtain approval from the government for conducting clinical trials.

Clinical Regulatory Affairs II, Course Code: REG02

This course builds upon the clinical regulatory foundation built in REG01. It provides students with an understanding of the trends in the pharmaceutical industry with regards to policy making and product development. The topics also include regulatory strategies in developing a product and post approval management of the product.

The graduates of this course will have a good understanding of the regulatory strategies in developing a product and post approval management of the product, along with PMS and related regulations. At the end of the course, students will be able to complete the required regulatory documents (i.e. CTA, IND) for the regulatory agency, in order to obtain approval from the government for conducting clinical trials.

Electronic Records and Computer Validation, Course Code: ERCV01

This course will outline the requirements for computerized systems used at clinical sites to collect data. Students will understand the importance of electronic records and computer validation.

The graduates will have a good understanding of the requirements for computerized systems used at clinical sites to collect data. Students will be able to understand the importance of electronic records and computer validation to ensure that the data collected from computerized system is no less reliable than the data in paper form. The importance of data quality, where computerized systems are being used to create, modify, maintain, archive, retrieve or transmit clinical data will also be discussed.

Project Management I, Course Code: PMCS01

This course will introduce successful planning, scheduling and executing clinical study projects. This course will also introduce high level of leadership skills, and produce productive and quality results for targeted projects.

The graduates will have a good understanding of project planning, scheduling, strategies, elements of execution, critical decisions, and effective leadership.

Project Management II, Course Code:PMCS02

This course will outline tasks related to the use of a negotiation method, an unplanned negotiation, post negotiation self-assessment, and to plan and conduct technical and non-technical negotiations. The course will further address the proper method of negotiation while dealing with tough negotiators, angry clients/ customers, extremely technical clients, the communicational aspect while dealing with different cultures, as well as in negotiating with internal clients, tough negotiators and handing any politics.

The graduates will develop proper communication & negotiation methods, effective & internal communication processes, skills for listening and questioning, how to communicate nonverbally, methods of dealing with non-technical people, negotiation overview, and negotiation process and planning.

Privacy, Course Code:PVC01

This course is aimed to introduce the Canadian Regulation PIPEDA "Privacy" in clinical studies along with privacy principals, interpretation of the principals, and applications in real work scenarios.

The graduates will have a good understanding of ICH GCP and the requirement for privacy, Canadian Act PIPEDA (personal information protection and electronic documents act) and the 10 principles of PIPEDA. They will also be able to apply the 10 principles of Privacy to clinical trials, interpret the principles of PIPEDA in clinical trials, understand the meaning of privacy as it applies to clinical trials, understand the principles of PIPEDA, as well as to apply the principles of PIPEDA to everyday clinical trials while dealing with subjects.

Job Opportunities in Multiple Sectors*

Clinical Research Scientists, Clinical Research Organizers /Associates, Clinical Research Managers/ Supervisors/Directors, Regulatory Affairs Associates, Auditors, and Regulatory Affairs Managers/Supervisors/Directors

*Universities' research sector, pharmaceutical and Bio-pharmaceutical companies, hospital environment, and Clinical Research Organization (CRO).



Admission Requirement

Minimum of Grade 12 Diploma Minimum of Grade 12 Diploma with required science and math courses/Equivalent.

Duration: 7 Months

Hands-on Training along with Job Assistance: 7 months hands-on training, 4 months of Job Assistance for qualified students along with resume preparation and learning interview tactics and tips.

Areas of Study

Good Manufacturing & Good Clinical Practices, Course Code: GCCP01

This course will introduce the concepts and requirements necessary for compliance with Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) for pharmaceuticals and biopharmaceuticals. It will prepare students to establish and document a system of GMP controls required to manufacture drug products in Canada, the United States and in many parts of the world. It focuses on real work industrial scenarios.

The graduates will be able to demonstrate a good understanding of both GMP and GCP guidelines, the functional aspects of each guideline, responding to citations for audit agencies, corrective preventive action plans, change controls, and health risk classifications. It focuses on real work industrial scenarios.

Introduction to Laboratory Testing & GLP, Course Code: ILTP02

This course will introduce the concepts and requirements necessary for compliance with Good Laboratory Practice (GLP) for pharmaceuticals and biopharmaceuticals. It will address the most important laboratory techniques. Students will also get exposure and experience with all major pharmaceutical instrument. It focuses on real work industrial scenarios.

The graduates will have a good understanding of the GLP guidelines widely used in pharmaceutical and related sectors, the functional aspects of these guidelines in various processes and procedures, as well as a good understanding of instrumentations, calibration and the application of various instruments.



Dissolution & Dissolution Hands-on Training, Course Code:DIS003

This course will introduce dissolution current testing practices, testing requirements, critical components, sample preparation techniques, media preparation, sample testing, data analysis, report preparation, limitations, IQ/OQ/PQ, calibration, trouble shooting, maintenance, and out of specification investigation.

The graduates will have a good understanding of dissolution techniques, applications, USP apparatus, dissolution testing, report writing, calibration, trouble shooting, maintenance and out of specification investigation. It focuses on real work industrial scenarios.

High performance Liquid Chromatography (HPLC), Course

Code: HPL004

This course will introduce HPLC theory, components, testing practices, testing requirements, sample preparation techniques, mobile phase preparation, sample testing, data analysis, report preparation, limitations, IQ/OQ/PQ, calibration, trouble shooting, maintenance, and out of specification investigation.

The graduates will have a good understanding of HPLC techniques, applications, Chemstation software, HPLC testing (identification, assay, content uniformity and etc.), report writing, calibration, trouble shooting, maintenance, and out of specification investigation. It focuses on real work industrial scenarios.



Gas Chromatography (GC), Course Code:GCT005

This course will introduce gas chromatography history, concepts, carrier gas, testing requirements, critical components, sample preparation techniques, sample testing, data analysis, report preparation, limitations, IQ/OQ/PQ, calibration, trouble shooting, maintenance, and out of specification investigation.

The graduates will have a good understanding of GC techniques, applications, Chemstation software, head space, GC testing (identification, assay, content uniformity and etc), report writing, calibration, trouble shooting, maintenance, and out of specification investigation. It focuses on real work industrial scenarios.

HPLC & UV for Dissolution: Method Development & Method Validation, Course Code: HPD001

This course will introduce how to initiate and perform method development and method validation using the HPLC /UV Spectrometer and the Dissolution Apparatus. It will cover major industrial regulations in terms of developing and validating testing methods.

The graduates will have a good understanding of HPLC method development and method validation for various pharmaceutical products, the application of Chemstation, validation guidelines, report writing and trouble shooting. It focuses on real work industrial scenarios.



GC & UV Spectrometer: Method Development & Method Validation,

Course Code:GCUV002

This course will introduce how to initiate and perform method development and method validation using the GC /UV Spectrometer. It will cover major industrial regulations, in terms of developing and validating testing methods.

The graduates will have a good understanding of GC method development and method validation for various pharmaceutical products, the application of headspace, validation guidelines, report writing and trouble shooting. It focuses on real work industrial scenarios.

Advance Scientific Technical Writing, Course Code:STW006

This course will introduce different types of writing and compiling scientific documents in QC and QA areas: SOPs, communication methods and issues, method validation reports writing, method validation protocols writing, dealing with batch records, auditing reports, investigations, and real work industrial scenarios.

The graduates will be able to initiate and write various SOPs, method validation protocols and reports, OOS, change controls, and CAPAs. They will also learn the functionality of each departments and the documentation aspect of each function.

Job Opportunities in Multiple Areas*

Technologists, Raw Material Chemists, Finish Product Chemists, Stability Chemists, R&D Chemists, Scientists, Calibration Chemists, Document Reviewers, Laboratory Coordinators, Trainers, SOP Writers, Auditors, Supervisors and Managers.

*Quality Control (QC - Raw Materials, in-process and finish product tests), Quality Assurance (QA), Analytical development (AD), Research and Development (R&D), Stability and Formulation



This diploma program has been designed to meet the skill requirements for effectively performing duties in Manufacturing Formulation and Validation Technology areas in Pharmaceutical/Bio-Pharmaceutical industries for those who want to upgrade existing skills or obtain new skills. Each area of the study will be covered in an in-depth manner for both Pharmaceutical and Bio-Pharmaceutical sectors.

Admission Requirement

Minimum of Grade 12 Diploma with required science and math courses.

Duration: 7 Months

Hands-on Training along with Job Assistance: 7 months hands-on training, 4 months of Job Assistance for qualified students along with resume preparation and learning interview tactics and tips.

Areas of Study

Good Manufacturing & Good Clinical Practices, Course Code: GCCP01

This course will introduce the concepts and requirements necessary for compliance with Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) for pharmaceuticals and biopharmaceuticals. It will prepare students to establish and document a system of GMP controls required to manufacture drug products in Canada, the United States and in many parts of the world. It focuses on real work industrial scenarios.

The graduates will be able to demonstrate a good understanding of both GMP and GCP guidelines, the functional aspects of each guideline, responding to citations for audit agencies, corrective preventive action plans, change controls, and health risk classifications. It focuses on real work industrial scenarios.



Pharmaceutical/Bio-Pharmaceutical Manufacturing Formulation & Validation Technology, Course Code:PMVT01

This course will introduce manufacturing technology, all types of validation (process, packaging, cleaning, utility, facility, computer and thermal), drug formulation (solid, liquid, suspension, powder and bio-pharmaceutical process such as fermentation and filtration) and manufacturing technologies (equipment dynamics and etc).

Students will know the fundamental of drug formulation and equipment mechanisms for solid, liquid, suspension, powder and bio-pharmaceutical process such as fermentation and filtration and manufacturing technology (equipment dynamics and etc). They will also get introduced to various validation technology, fundamentals and guidelines.

Collective Validation, Course Code: ETUF05

This course will cover collective validation technology and regulations related to specific validation topics: equipment validation, thermal validation, utility validation, computer validation and facility validation.

Students will get to know how to initiate and conduct equipment, thermal, utility, computer and facility validation studies. They will also learn the related regulations and report writing for those studies.



Manufacturing Formulation 1, Course Code: PMF001

This course will cover the objectives of formulation, pre-formulation techniques, manufacturing formulation techniques, and related regulations.

Students will know how to use pre-formulation techniques in their new drug formulation processes and effectively apply manufacturing formulation techniques in various processes.



Manufacturing Formulation 2, Course Code: PMF002

This course will cover the formulation mechanism for solid dosages, liquid, suspension, power, fermentation, filtration, media preparation and etc, along with process analytical techniques and solid dosage evaluation.

Students will know how to effectively use solid dosages, liquid, suspension, powder, fermentation, filtration, media preparation and related mechanisms in pharmaceutical, bio-pharmaceutical and medical device industries, along with process analytical techniques and solid dosage evaluation.

Cleaning & Sterile Validation, Course Code: CLVM01

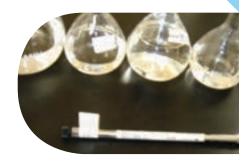
This course will introduce current cleaning validation practices, rationale, worst case scenarios, writing protocols, reports and master validation plans, as well as the regulatory requirements of cleaning validation that lead to risk-based, practical and scientific informed decisions and planned activities. It focuses on real work industrial scenarios.

Students will know how to initiate and conduct cleaning validation studies. They will also learn the related current cleaning validation regulations and report writing for those validation studies.

Advance Cleaning Validation, Course Code: CLVM02

This course will introduce assessment of complex cleaning validation processes, how to develop process of new equipment/product, worst case selection process, and risk base analysis for technical overview. It focuses on real work industrial scenarios.

Students will know how to initiate and conduct complex cleaning validation studies. They will also learn how to develop process of new equipment/product, worst case selection process, and risk base analysis.



Packaging Validation & Packaging Components, Course Code: PKV04

This course will cover packaging validation concept and packaging components, writing protocols, reports and master validation plans, as well as the regulatory requirements of packaging validation that lead to risk-based, reasonable and scientific informed decisions and planned activities. It focuses on real work industrial scenarios.

Students will get to know how to initiate and conduct packaging validation studies. They will also learn the related current packaging validation regulations and report writing for those validation studies.



Process Validation, Course Code: PRV03

This course will cover process validation concept, rationale, writing protocols, reports and master validation plans, as well as the regulatory requirements of process validation that lead to risk-based, practical and scientific informed decisions and planned activities. It focuses on real work industrial scenarios.

Students will know how to initiate and conduct process validation studies in pharmaceutical and bio-pharmaceutical industries. They will also learn the related current process validation regulations and report writing for those validation studies.

Advance Process & Packaging Validation, Course Code: PPRV05

This course will cover both complex processes and packaging validation techniques. It will also cover the risk based analysis, technology transfer, feasibility studies and etc.

Students will know how to initiate and conduct complex processes and packaging validation techniques. It will also cover risk based analysis, technology transfer, feasibility studies and etc. in pharmaceutical, bio-pharmaceutical and medical device industries. They will also learn the related current process validation regulations and report writing for those validation studies.



Scientific Technical Writing, Course Code: STW005

This course will introduce different types of writing and compiling scientific documents: SOPs, communication methods and issues, validation reports writing, validation protocols writing, dealing with batch records, auditing reports, investigations, and real work industrial scenarios.

The graduates will be able to initiate and write SOPs, protocols, reports, OOS, deviation reports, batch records, change controls, and CAPAs. They will also learn the functionality of each departments and the documentation aspect of each function.

Pharmaceutical/Bio-Pharmaceutical Manufacturing Formulation & Validation Technology, Course Code:PMVT01

This course will introduce manufacturing technology, all types of validation (process, packaging, cleaning, utility, facility, computer and thermal), drug formulation (solid, liquid, suspension, powder and biopharmaceutical process such as fermentation and filtration) and manufacturing technologies (equipment dynamics and etc).

Students will know the fundamental of drug formulation and equipment mechanisms for solid, liquid, suspension, powder and bio-pharmaceutical process such as fermentation and filtration and manufacturing technology (equipment dynamics and etc). They will also get introduced to various validation technology, fundamentals and guidelines.

Job Opportunities in Multiple Departments

Formulation Area: Formulation Chemists, Formulation Technicians, Production Operators, Formulation Scientists and Formulation Managers / Directors.

Technology Transfer Area: Process Development Scientists, Technology Transfer Coordinators and Document Coordinators.

Validation Area: Validation Assistants, Process Validation Scientists, Technology Transfer Scientists, IQ/OQ/PQ Specialists, Cleaning Validation Specialists, Packaging Validation Specialists, Thermal Validation Specialists, Computer Validation Specialists and Validation Managers.



Individual Certificate

Good Manufacturing Practice (GMP) & Good Clinical Practice (GCP)

Code #	Program Name	Awarded
GMP013	Good Manufacturing Practices	Certificate
GCP014	Good Clinical Practices	Certificate

Quality Control (QC)& Quality Assurance (QA)Programs

DIS004	Application of Dissolution Techniques (Lab)	Certificate
DIS005	Introduction to Dissolution Systems	Certificate
HPL005	Introduction to High Performance Liquid Chromatography	Certificate
HPL006	Application of High Performance Liquid Chromatography (Lab)	Certificate
GC0007	Introduction to Gas Chromatography	Certificate
GC0008	Application of Gas Chromatography (Lab)	Certificate
SW003	Scientific Technical Writing	Certificate

R&D, Method Validation and Method Development

HPD002	Introduction to HPLC Method Development and Method Validation	Certificate
HPD003	HPLC Method Development and Method Validation Techniques (Lab)	Certificate
GCD004	Introduction to GC Method Development and Method Validation	Certificate
GCD004	GC Method Development and Method Validation Techniques (Lab)	Certificate
GCMSD1	GC-MSD Hands-on Training	Certificate
HPLCMSD1	HPLC-MSD Hands-on Training	Certificate

Validation

PMVT01	Pharmaceutical/Bio-Pharmaceutical Manufacturing Formulation & Validation Tech	Certificate
CLVM01	Cleaning Sterile and Method Validation	Certificate
ETUF05	Collective (Equipment, Thermo, Utility, Computer and Facility) Validation Tech	Certificate
PKV04	Packaging Validation & Packaging Components	Certificate
PRV03	Process Validation	Certificate
CLVM02	Advance Cleaning Validation	Certificate
PKV04	Packaging Validation & Packaging Components	Certificate
PPRV05	Advance Process & Packaging Validation	Certificate

Courses

Regulatory Affairs

Code #	Program Name	Awarded
IRA001	Introduction to Regulatory Affairs	Certificate
PRA004	Professional Regulatory Affairs	Certificate
ICS002	Introduction to Clinical Studies	Certificate

Clinical Research

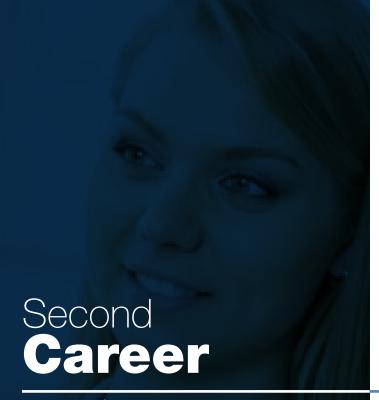
ICS01	Clinical Science	Certificate
CS001	Introduction to Clinical Studies (GCP)	Certificate
RGS01	Regulations and Standards in clinical research	Certificate
CRMD01	Clinical Research in Medical Device	Certificate
EHPC01	Ethics and Human Protection	Certificate
PPP01	Pharmacovigilence	Certificate
DCTP01	Development of Clinical Trial Protocols	Certificate
CTM01	Clinical Trial Monitoring	Certificate
CQA01	Quality Assurance	Certificate
DCSO01	Development of SOP	Certificate
PHSA01	Preparing and Hosting Audits and Inspections	Certificate
GDPC01	Good Documentation Practices	Certificate
CDMB01	Clinical Data Management and Biostatistics	Certificate
REG01	Clinical Regulatory Affairs I	Certificate
REG02	Clinical Regulatory Affairs II	Certificate
ERCV01	Electronic Records and Computer Validation	Certificate
PMCS01	Project management I	Certificate
PMCS01I	Project Management II	Certificate
PVC01	Privacy	Certificate

Manufacturing Formulation

PMVT01	Pharmaceutical/Bio-Pharmaceutical Manufacturing Formulation & Validation Technology	Certificate
PMF001	Manufacturing Formulation 1	Certificate
PMF002	Manufacturing Formulation 2	Certificate

Exam Preparation

 Language Training for IELTS	
 Pharmacy Licensing	



Out of work? Need a new direction? Second Career is an Ontario government program that will pay for your tuition.

www.secondcareerontario.com

Second Career Counselling Service

Our Second Career information sessions are designed to provide you with all the information that you will need to apply to North American College of Pharmaceutical Technology. You may direct any further inquiries to North American College of Pharmaceutical Technology Advising Services, a comprehensive service committed to helping you achieve your skills-training goals. We offer information and advice on our Second Career programs and pathways, admission requirements, academic upgrading, language training, and applicant supports, as well as referrals to foreign credential assessment and recognition services, career advising services, and community resources.

Visit an advisor at North American College of Pharmaceutical Technology. Our offices are open Monday – Friday, 9:00 a.m. – 5:00 p.m. Saturday, 10:00 a.m. – 3:00 p.m. (We suggest that you make an appointment with an advisor before making a trip to campus. Drop-in visits are subject to advisor availability.)

Please call at (416) 412-7374/ or e-mail to: info@nacptpharmacollege.com for more information.

TAKE ADVANTAGE OF SECOND CAREER

The Second Career strategy launched by the Ontario Ministry of Training, Colleges and Universities pays for the training or education that Ontarians require to get a better job. It provides financial help up to \$28,000, or more in some cases, to pay for:

- Tuition
- Living Expenses
- Help caring for dependents
- Travel
- Transportation
- Disability supports
- Other living and training costs
- Books

Those who qualify may have some or all of these costs covered within the Second Career Strategy. In order to find out if you qualify for Second Career or any other government funding, all candidates must visit an Employment Ontario assessment centre for an assessment interview.

Who is eligible?

Eligibility for Second Career Funding

Eligible individuals are those who have been laid-off on or after January 1, 2005 - including El active claimants, El "reachbacks," and non-El-eligible individuals - who require skills training for employment in demand occupations in Ontario.

"Laid-off worker" is an individual who has been laid off on or after January 1, 2005, including someone who:

- is still unemployed.
- has taken one or more interim jobs to make ends meets but is currently unemployed.
- has taken one or more interim jobs to make ends meets and is currently employed in such a job.
- is on salary continuance. (Salary continuance is an alternative to providing a laid-off worker with pay in lieu of notice or severance. The employees receive their salary as per the regular pay schedule for a designated period and they may receive some or all of their benefits as well.)
- is on severance. (Severance is a lump sum entitlement paid to an employee upon termination of employment. Severance compensates the employee for loss of seniority and job related benefits.)

Please contact your local Employment Ontario office for confirmation of your eligibility for financial assistance under the Second Career program.

What program is eligible?

Program Eligibility

For EI active claimants and EI reachbacks:

- skills training of between six months and two years in duration for National Occupational Classification (NOC) skill level B and equivalent occupations in demand within Ontario;
- Where necessary, as a prerequisite for skills training, up to one year of academic upgrading.

For Non-El-eligible individuals:

- skills training of any duration up to two years for either NOC skill level B or NOC skill level C occupations and equivalent in demand in Ontario;
- Where necessary, as a prerequisite for skills training, up to one year of academic upgrading.

To get the ball rolling on your Second Career at North American College of Pharmaceutical Technology, please register for and join us at an information session.

NOC Codes at NACPT: Level B

- 2221 Biological Technicians/Technologists
- 2263 Health Inspectors
- 2243 Industrial instrument technicians
- 9511 Machining Tool Operators
- 2283 Information systems testing technicians

Reference link:

http://www.secondcareerontario.com

Register for a Second Career Information Session at North American College of Pharmaceutical Technology

To get the ball rolling on your Second Career at North American College of Pharmaceutical Technology, please register for and join us at an information session.

Advisory Committee



Milica Jovanovic, B.Sc., M.Sc. CEO of MJ Pharm Consulting Chief Scientific Officer – Senior Consultant

Milica Jovanovic is the founder and the owner of MJ Pharm Consulting located in Mississauga, Ontario, Canada. Milica is a creative and resourceful problem solver with 25 years of leadership and hands-on experience in the industry, complemented with 5 years of teaching experience. She possesses extensive expertise and knowledge of analytical development and regulatory compliance.

In the past 20 years, Milica has held strategic management roles in major Canadian generic pharmaceutical companies, where she was responsible for overall performances of Analytical Method Development and Validation, Product Development and R&D Stability Laboratories. Her most recent positions were Director of Analytical R&D Laboratory at Genpharm Inc., Toronto (former subsidiary of Merck KGaA, Darmstadt) and Manager of Analytical Development at Apotex Inc., Toronto.



Salvador Y. Funcion, BSChe, MBA, CQA

Salvador Funcion, MBA, CheEng, was until recently the Quality Assurance Manager for regulatory affairs at Niagara Pharmaceuticals. Salvador is an auditor, regulatory coach, consultant and instructor for global matters pertaining to pharmaceutical regulatory affairs, regulatory compliance, quality and clinical affairs. He obtained his Chemical Engineering and MBA from De La Salle University and is a certified quality auditor (CQA) by the American Society for Quality (ASQ).

He has spent 15 years working for pharmaceutical and medical gas companies manufacturing medical drugs and medical devices. He is an expert in pharmaceutical regulatory and quality compliance. He has a broad background and a crucial leadership role in functional areas, such as API product development/manufacturing, business process optimization, quality compliance, clinical development, and regulatory strategy. He also has hands on experience with global regulatory management and submission.

Prior to founding his own consulting firm (QAFM Services), he was the Quality Assurance Manager and Regulatory Affairs at BOC Canada, Limited in Toronto, wherein he provided inspiring and actionable solutions for sustainable business operation in the manufacture of medical drugs and medical devices gases. He provides practical, actionable and strategic solutions integrated with equipment validations, QE/QA/QC guidance, systems design and implementations in compliance to ISO 13485, GMP, GCP standards, CAPA, FMEA and auditing. Over the years, he has assisted several pharmaceutical clients to analyze and come up with solutions for their Health Canada and US FDA inspection 483s. He is familiar with more than 100 medical products (medical devices including IVD products, biologics, drugs and combination products). He provides directions for regulatory strategy, regulatory submission, clinical studies, and CMC requirements for different development stages, product indications, and labeling.

He has experience working with the US, Canadian and Southeast Asian regulatory regulations. He co-authored the IDRAC®, a complete pharmaceutical regulatory intelligence solution from Thomson Reuters that provides regulatory professionals with a one-stop source of information across the globe. Being a Certified Quality Auditor by ASQ, Salvador has more than 3 years experience performing ISO and GCP Clinical Trial Audits to a number of CROs in Ontario. Salvador currently teaches quality assurance, regulatory affairs and GCP compliance for North American College of Pharmaceutical Technology (NACPT) in Toronto, Canada.



Dr. Hameed A. Mirza, Ph.D. Vice President (R&D) of A.S. Chemical laboratory Inc.

Dr. Hameed is the Vice President (R&D) of A.S. Chemical laboratory Inc in Toronto, Ontario, Canada. He is a Chemistry professor at the University of York in Toronto, Ontario, Canada. He has more than 25 years of leadership and hands-on experience in the pharmaceutical industry, complemented with many years of academic teaching experience. He possesses extensive expertise and knowledge of Research and Development in pharmaceutical and bio-technology industries.



Sam Subramaniam, M.Sc., CA, Eng Vice President- North American College of Pharmaceutical Technology (NACPT)

Sam Subramaniam is the Vice President of North American College of Pharmaceutical Technology. He has extensive knowledge and skills in science, engineering and accounting fields. Currently he is overseeing training activities within Canada and Overseas.



Dr. Odilia Osakwe, Ph.D.

Dr. Odilia Osakwe, holds a BSc in Industrial Chemistry from Abia State University, MSc in Chemistry from Tennessee State University, followed by a two-year Initiative for Maximizing Student Diversity (IMSD) fellowship at Vanderbilt University Medical Centre (researched in Molecular Biology, Cell Biology and Pharmacology) and Ph.D. in Pharmaceutical Science from the College of Pharmacy and Health Sciences in Mercer University. In association to this endeavor, she has made oral and poster presentations at professional conferences on topics in gene therapy; and publications in Journal of Microencapsulation, and Journal of Enzyme Inhibition and Medicinal Chemistry.

Dr. Odilia has acquired a diversified experience in Centers for Disease and Control Prevention, Atlanta, Georgia. During much of that period, has been involved with validation of the methodologies for Vaccines development. Prior to that, was Adjunct Professor of Chemistry at Georgia Perimeter College for two years. Aside from the above activities, has been a peer reviewer for the Journal of Microencapsulation, a contributor to Healthy Knowledge Magazine (HK), Sway magazine, a member of the advisory board of PharmaFocus magazine (published by the Pharmaceutical Science Group) with a regular quarterly article editing and writing for the quarterly publications.

Dr. Odilia is an award recipient of Natural Science and Engineering Council of Canada post-doctoral Industrial Research and Development Fellowship award (NSERC-IRDF), working as a Research and Development Scientist position in the Industrial BioDevelopment Laboratory, Toronto, Canada. During this period, a novel product 'A Novel Standardized Oxygen Radical Absorbance Assay for Evaluating Antioxidant Natural Products' was published in the Journal of Association Official Analytical Chemists (two more publications are forthcoming). She has developed, designed and supervised various projects with University of Toronto undergraduate students which has resulted in various publications. Dr. Odilia has received many awards. In addition to the NSERC, she has been a beneficiary of the highly competitive Mitacs enterprise fellowship and the Office of Research Trainees (ORT) travel award.



Dr. Denis Bangala, Ph.D., MBA

Dr. Bangala has earned the right to speak and the trust from his peers through his formal education and on job hands—on experience of more than 15 years in Pharmaceutical/Biotechnology industry. He has extensive experience in Process improvement, validation/ optimization/ robustness; Equipment qualification; Cleaning validation; Utilities qualification; Lean six sigma for waste elimination and process variability reduction; cGMP manufacturing; Change management; technology innovation and knowledge transfer; Direct interaction with several regulatory bodies inspectors (FDA, PMDA Japan, Health Canada). In addition, he has tremendous knowledge of Quality systems, as well as Regulatory affairs, and the health, environmental, safety impact on organization efficiency.

Dr. Bangala holds a Ph.D. in Chemical Engineering from Sherbrooke University (Québec, Canada); a Bachelor and a Master of Applied Science in Chemical Engineering from East China University of Science and Technology (ECUST) in Shanghai, People Republic of China. His outstanding Ph.D. thesis led to a novel catalyst with direct industrial application (USA Patent #5,679,614) and three major scientific publications in the most prestigious Chemical Engineering journals in the world (such as AIChE Journal). Additionally, He holds an M.B.A. from Queen's School of Business, Queen's University in Kingston, Canada. He is a Licensed Professional Engineer in Ontario (PEO) and holds a Master Certificate in Lean Six Sigma Black Belt from Schulich School of Business, York University.



Patrick Hillan, M.Sc.
Recruitment Consultant, Life Sciences Practice Lead

Patrick moved to Toronto in 2011 after graduating from The University of Edinburgh with a Masters Degree in Neuroscience. He started his professional career as an integral member of the Life Science division of an international recruitment consultancy, working globally on placing mid-senior life science and healthcare professionals in a range of clinical and therapeutic roles. Recent placements have included Director Level Medical Advisor, Health Economics and Regulatory Affairs professionals at multinational pharmaceutical and healthcare organizations.

Joining IQPARTNERS to Lead the Life Science Practice, Patrick works closely with many major Canadian pharmaceutical and healthcare organizations where he utilizes both his academic and consultative training to act as a subject matter expert within the Life Sciences. His knowledge and experience place him in the unique and valuable position of truly understanding the needs of his clients.

Patrick is an inquisitive team player who takes pride in going above and beyond and completing tasks to the highest standards. He continuously seeks to improve both his own work-flow as well as strengthening his industrial knowledge through meaningful dialogue with candidates and clients.



A unique Job
Development Program
has been designed by
our job development
team to provide one on
one job coaching and
mentoring services for
our graduates.

Job Development Program includes:

- One on one skill development process
- Develop resume for target jobs
- Job application process within industries
- Focus on hidden job market
- Interview Coaching
- Reference for qualified candidates
- Mentoring Service

Outcomes

- Will have clear career plan for their future
- Be able to face interview with confidence
- Will have industrial knowledge regarding various fields
- Will be able to perform career research
- Produce appropriate resume for their background
- Connect with industrial experts/ companies
- Access to hidden job market
- Be able to make fast transition to target industry



Pharmaceutical/Bio-Technology Job Orientation Event

NACPT conducts Job Orientation Workshop once a month.

We invite you to an information session and mentoring session for the following industries:

- Health Care
- Pharmaceutical
- Cosmetics
- Environmental
- Chemical
- Food Processing
- Nutraceutical

For Job Prospects as a:

- Scientist
- Process Engineer
- Chemist
- QC & QA Associate
- Validation Specialist
- R&D Associate
- Technician
- Technologist
- RA Representative
- RA Supervisor
- RA Manager
- Clinical Researcher

Who Can Attend this Seminar?

- Recent graduates (Science and Engineering)
- Professional who wants to get into scientific industries
- Healthcare professionals (doctors, nurses, pharmacists and etc)
- Anyone who wants to get into stable professional job
- Unemployed Professionals
- Second Careers
- Newcomers / social assistance / WSIB receivers

Agenda

- Introduction to Pharma/Bio-tech and other scientific industries
- Job Available in the Health Care,
 Pharmaceutical/Bio-Pharmaceutical,
 Cosmetic, Food, Environmental and Chemical industries
- Target Industries: hidden jobs in Canadian and USA Pharma/Bio-tech companies
- Salary Range for various jobs
- Skills/knowledge needed new skills and transferrable skills
- Eligibilities/qualifications and requirements for various job oriented programs
- Scholarships/grants
- How NACPT can help you

Receive a complimentary job practice and demonstration on specialized instruments (HPLC, GC, dissolution, etc.) within the industry.

Call or email for registration

(416) 857-7603 (416) 412-7374 info@nacptpharmacollege.com

5310 Finch Avenue East, Unit #9 Scarborough, ON, M1S 5E8



Scholarship for University/College/High School Graduates

The North American College of Pharmaceutical Technology (NACPT) Scholars Program

All applicants who meet the scholarship criteria will receive admission scholarship(s) from North American College of Pharmaceutical Technology totalling at least \$2,000, provided that they enrol in the first/second semester throughout the year.

Scholarship Criteria:

- GPA usually more than 80%
- Financial conditions
- Other academic achievements

Application is required. Please contact our college for further information. Outstanding students are considered automatically for these awards.

Payment of the award is conditional on full-time registration at the College in the year the award is granted.

Scholarship for Newcomers to Canada

(internationally trained professionals)

All applicants who meet the following criteria will receive admission scholarship(s) from North American College of Pharmaceutical Technology totalling at least \$3,000 provided that they enrol in first/second semester throughout the year. No application is required.

Scholarship Criteria:

- Canadian citizens or permanent residents;
- have completed required degree/diploma, with "A" standing;
- Financial conditions

Payment of the award is conditional on full-time registration at the College in the year the award is granted.

Health & Safety

WHMIS

This workshop is offered to all employees and students who are exposed or likely to be exposed to hazardous materials. It is designed to provide a 2 hour overview of occupational health and safety at the college.

Objectives

To provide participants with a working knowledge of chemical safety principles and the Workplace Hazardous Materials Information System (WHMIS). To ensure that employees and students are fully aware of their right and need to know about potential hazards associated with hazardous materials in the workplace.

Topics to be covered include:

- Overview of Health and Safety at the College
- Chemical Hazards in the Workplace
- Personnel Protective Equipment
- Chemical Safety and the Law
- WHMIS: Labels, MSDSs, and Training

Contact for more details

(416) 412-7374 info@nacptpharmacollege.com

5310 Finch Avenue East, Unit #9 Scarborough, ON, M1S 5E8



Success Stories

Testimonials



Recipient of Outstanding Leadership Award by NACPT

It is with great pride that I draft this letter of appreciation to North American College of Pharmaceutical Technology (NACPT) in acknowledgement of their immense support and guidance from the onset of my training phase to my entry into the pharmaceutical industry. During 2012, I had enrolled in the Pharmaceutical and Bio-pharmaceutical Clinical Research, one of the Post-Degree Diplomas offered at NACPT.

The program was designed exceptionally well to accommodate academic teaching with hands-on training experiences, through which I had enriched my understanding of the pharmaceutical industry and all the regulatory bodies that govern it. Each class was conducted by industrial experts who brought interesting insights into current and best practices within the industry. Apart from the quality - hands on training I had attained, NACPT had also helped me get a government grant in support of my work term, and also supplemented with a scholarship of \$ 3000. I have also had the opportunity to work at NACPT as a Program Coordinator (co-op position), which allowed me to further strengthen my leadership and interpersonal skills.

Most importantly, NACPT had set itself apart by building partnership with various pharmaceutical companies and inviting them for on-campus hiring. It was truly a great experience and one of the greatest rewards was the number of job opportunities that had come my way upon completion of the program. Last but not the least, NACPT helped me to build confidence and prepared me thoroughly for all the interviews I had to face! As I begin a new journey within the pharmaceutical industry, I will cherish each memorable moment at NACPT for a lifetime!

My hearty thanks to the CEO of NACPT and all industrial experts once again for all that you have done to help me begin a new chapter in my life!

Pradha Muruganathan

M.Sc., University of Calgary

Company: Sanofi Pasteur, Canada

Position: Advanced Technician Downstream

Program Enrolled in at NACPT Labs:

Pharmaceutical & Bio-Pharmaceutical Clinical Research



Tam a newcomer to Canada, and a Ph.D. holder. I was a professor back in my country. I came to Canada with a lot of expectation. But, I could not find any related jobs within my profession. Hence, I enrolled in a program provided by NACPT 4 months ago, and am currently working in a leading pharmaceutical company, as a formulator. NACPT provided a lot of help and training for me to get this job.

Hadi Mehrgan Ph.D.

Company: Apotex

Position: Formulation Chemist Program Enrolled in at NACPT Labs: Introduction to HPLC

Two months ago, I had come to know about NACPT while browsing through the internet. I enrolled in the program soon after, and liked the environment, because you learn everything through a practical approach. Their teaching methods make it easy to understand the content. NACPT further helped me with my interview skills and I got the job before I finished the program.

The professors are highly qualified and they are all from the pharmaceutical/bio-pharmaceutical industry. The unique thing about this college is that the professors cover the essential content that you need to know for the pharmaceutical related job market.

NACPT is different from other colleges in many ways, including the short, fast track and in-depth programs. We also get special individual attention in terms of hands-on training, job searching and connections within industries. I also received a \$2000 scholarship from NACPT for my program. I strongly recommend NACPT to other students because of the excellent teaching environment, coaching techniques, job assistance service and more.

Subagini Baskaran

B.Sc. from York University

Company: Lynden International Logistics

Position: QPIC/QA Coordinator
Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical and Bio-Pharmaceutical Modern Technology



Recipient of Outstanding Graduate Award by NACPT



All of the courses that I have enrolled in at NACPT have given me a tremendous boost in confidence for seeking jobs in the pharmaceutical industry. These programs are not just theory based, all the professors emphasize on real circumstances and practical examples within current companies. I have also received a \$2000 scholarship for my program at NACPT. I will strongly recommend future students to take the Pharmaceutical and Bio-Pharmaceutical Modern Technology Postgraduate diploma program at NACPT.

Suvisikaa Selvanathan

B.Sc. from Western University

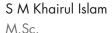
Company: Cosmetica Position: QA Associate

Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical and Bio-Pharmaceutical Modern

Technology

If first heard about NACPT at a job fair, but at that time I was confused about the modern technology program offered by NACPT. After a couple discussions with the director, I got the real scenario of the program. I am really satisfied with the co-operation given by NACPT to build up my confidence level to face job interviews. By taking the modern technology program, I have gathered the power of knowledge about the pharmaceutical industry. NACPT gave me guidelines time to time to update my resume as per job requirements. I would like to thank all my instructors and especially to the director of NACPT who gave me lots of coaching during various interview processes. I wish success to all the students of NACPT.



Company: Automatic Coating Limited

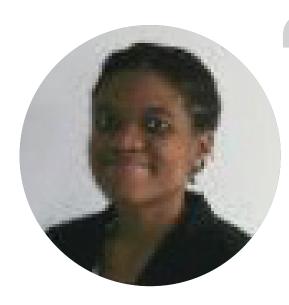
Position: QA inspector

Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical & Bio-Pharmaceutical Modern Technology



Testimonials



Ilike the fact that the program was flexible and class sizes were small. It's a program you could pursue while working full- or part-time, and it's very easy to ask questions or get clarifications on issues. I think there are a lot of colleges that don't really provide the knowledge in exchange for the money invested by students, which makes people wary of attending private colleges. However, I got the knowledge that was promised from NACPT. For new science graduates with no industrial experience, it is helpful to learn about the GMP, GLP etc. standards which are essential to the pharmaceutical industry and are not taught in most university science programs.

Camille A. Thorpe M.Sc.

Company: Baylis Medical

Position: Regulatory & Scientific Affairs Assistant

Program Enrolled in at NACPT Labs:

Good Manufacturing and Good Clinical Practices

gained enough knowledge about the quality control and quality assurance field, by joining NACPT helped me to find a job in the industry. They help students by posting different jobs every month, and they prepare students for interviews as well.

Sanjay Panchal

B.Sc.

Company: Teva Canada

Position: AQPIC (Alternate Qualified Person in Charge)

Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical & Bio-Pharmaceutical Quality Control & Quality

Assurance



Testimonials



Taking the program at NACPT has given me the relevant pharmaceutical knowledge and experience that gave me further opportunity to have a great start to my career move in Validation. The hands on experience with in-process test equipments and analytical instruments were vital in understanding the concepts and process as well. The career support at NACPT is impeccable and provides students with the necessary support, advice and guidance to be successful in the life career domains.

I am excited to announce the job offer from Apotex! I wanted you to be the first person to know this. I have every reason to believe your excellent support helped me to seal the deal. I was very fortunate to have learned a great deal from you, and I am deeply grateful to you. I know it takes a great deal of time to provide good reference, and I deeply appreciate your kindness. I will do my best to deserve your confidence. Thank you very much.

Nazeem Shamsuddin Ph.D.

Company: Apotex Inc.

Position: Coordinator, Process Validation Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical & Bio-Pharmaceutical Modern

Technology

NAIPT helped me to modify my resume and search for available positions. I will recommend about this program and college (NACPT) to my friends.

Baskaran Kandasamy

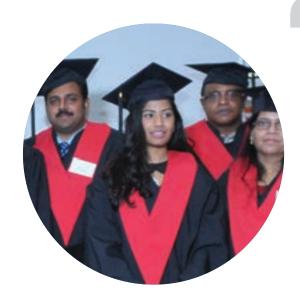
Company: Industrial Polymers

Position: R&D Associate

Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical & Bio-Pharmaceutical Modern Technology





Recipient of Outstanding
Graduate Award by
Ontario Career Colleges in
Healthcare Sector

fter completing my Bachelor of Science at University of Waterloo, I came straight to North American College of Pharmaceutical Technology. I had a lot of uncertainly about my future. However, the instructors at North American College of Pharmaceutical Technology were very welcoming and approachable. I strongly believe the coaching and guidance I received here not be comparable to other schools. The one-on-one coaching and availability of instructors for extra hours was very useful in learning the course material. The instructors were all industrial experts, with years of pharmaceutical working experience and were very compassionate about passing their knowledge onto fresh minds. I worked closely with the school for job assistance and interview preparation. I got two interviews through North American College of Pharmaceutical Technology which refined my interview skills and they allowed me to use their name for reference purpose. Plus, I appreciated the \$2000 scholarship and the financial assistance I received from North American College of Pharmaceutical Technology. With the practical knowledge I gained here, I can surely say that now I am prepared to achieve success and build a career on my own.

Meena Luxmanan

B.Sc. from University of Waterloo

Company: Pharmaceutical Partners of Canada

Position: QA/QC Compliance Analyst Program Enrolled in at NACPT Labs:

Industrial Pharmaceutical and Bio-Pharmaceutical Modern

Technology

have no words to thank NACPT for all the help they had provided to help me make a smart move within the industry. NACPT gave me a chance to improve my skills and knowledge on laboratory instrumentations, according to the current industrial standards. NACPT also helped me to update my resume, coached me for interviews, as well as provide necessary references. I also received a 4 month CO-OP position within the NACPT laboratory, which gave me solid work experience in the laboratory environment.

Kazi Perveen

M.Sc.

Company: Contract Pharmaceuticals LTD (CPL)

Position: QC Analyst

Program Enrolled in at NACPT Labs:

HPLC Method Development and Method Validation



Past Graduation Ceremonies

