Regulatory Affairs and Quality Operations
School of Health Sciences
RAQ1 - Regulatory Affairs and Quality Operations

This program has been permanently suspended.

Program Description
Regulatory affairs have become an essential and growing part of the health and life sciences industry. Companies that intend to develop and commercially distribute regulated pharmaceuticals and life-science products (such as drugs, biotechnology, food, recreational plant products, and medical devices) are required to have knowledge of the full spectrum of regulatory requirements. Students in this program will be introduced to regulatory authorities in Canada and around the world that provide approval for the product development, manufacturing, and marketing for these types of products.

Document of Recognition
Regulatory Affairs and Quality Operations

Program Type
A One-Year Ontario College Graduate Certificate Program

Learning Outcomes
- Analyze, synthesize and apply provincial, federal, and international regulatory processes as they relate to pharmaceutical, food, cannabis, biotechnology and medical device products
- Execute quality assurance and quality control processes to ensure compliance to Canadian and global regulatory requirements
- Employ appropriate use of IT software and systems to document, compile, manage and save content and data specific to regulatory affairs projects
- Use a wide range of data analysis methods to support decision making processes.
- Apply project management and risk management principles to the successful completion of regulatory submissions
- Conduct an industry and socio-economic impact analysis regarding the introduction of a new product and/or policy.
- Work collaboratively with product development teams, applying leadership techniques to complete projects in accordance with project timelines.
- Identify and apply regulatory strategies that contribute to and promote health equity in diverse communities.
- Examine the role of Canadian regulatory affairs professionals and participate in professional development activities to maintain currency in a changing regulatory affairs landscape.

- Adhere to the International Organization for Standardization (ISO), Therapeutic Products Program (TPP) and bioethical protocols and guidelines for drug, medical device, and biological product submissions
- Adhere to regulations when conducting pre-clinical and clinical studies of biological products
- Adhere to the use of appropriate communication conventions and tools when compiling and submitting regulatory affairs documents.

Approximate Costs
Fee details are available at www.fanshawec.ca/fees

Admission Requirements
One of:
Ontario College Diploma, Ontario College Advanced Diploma, Degree in a health or science related field.
OR
Equivalent qualification from another institution as judged by the College
OR
Equivalent professional background and experience as judged by the College

Applicant Selection Criteria
Where the number of program eligible applicants exceeds available spaces, the Applicant Selection Criteria for this program will be:
- Preference for Permanent Residents of Ontario
- Receipt of Application by February 1st (After this date, Fanshawe College will consider applicants on a first-come, first-served basis until the program is full)
- Achievement in the Admission Requirements

Recommended Academic Preparation
Previous business or IT post-secondary education and/or training and/or work experience

English Language Requirements
Applicants whose first language is not English will be required to demonstrate proficiency in English by one of the following methods:
- A Grade 12 College Stream or University Stream English credit from an Ontario Secondary School, or equivalent, depending on the program's Admission Requirements
- Test of English as a Foreign Language (TOEFL) test with a minimum score of 88 for the Internet-based test (iBT), with test results within the last two years
- International English Language Testing System (IELTS) Academic test with an overall score of 6.5 with no score less than 6.0 in any of the four bands, with test results within the last two years. SDS Program Requirements

- Canadian Academic English Language (CAEL) test with an overall score of 70 with no score less than 60 in any of the four bands, with test results within the last two years
- Pearson Test of English Academic (PTE) with a minimum score of 59, with test results within the last two years
- Cambridge English Test (FCE/CAE/CPE): with an overall score on the Cambridge English Scale of 176 with no language skill less than 169, with test results within the last two years
- Fanshawe College ESL4/GAP5 students: Minimum grade of 80% in ESL4/GAP5 Level 9 or 75% in ESL4/GAP5 Level 1

Program Curriculum

Level 1

Take all of the following Mandatory Courses:

CANS-6001	Contemporary Canadian Society - Credits 3.00
CANS-6002	Citizenship & Immigration in Canada - Credits 3.00
COMM-6046	Canadian Workplace Communications - Credits 3.00
DEVL-6035	The Canadian Workplace - Credits 3.00
DEVL-6036	Post-Secondary Learning in Canada - Credits 3.00
POLI-6001	Canadian Government & Politics - Credits 3.00
HLTH-6051	Canadian Health Care System - Credits 3.00

Level 2

Take all of the following Mandatory Courses:

HLTH-1301	Comm & Documentation in Reg Affairs 1 - Credits 4.00
HLTH-1302	Introduction to Regulatory Affairs - Credits 4.00
LAWS-6043	Principles of Cannabis Regulations - Credits 3.00
PHRM-1071	Regulatory Affairs in Pharmaceuticals - Credits 4.00
PHRM-1073	Regulated Chemicals & Biologics - Credits 2.00
MGMT-6084	Project Management - Credits 4.00
PHRM-1069	Introduction to Capstone Project - Credits 1.00
COOP-1020	Co-operative Education Employment Prep - Credits 1.00

Level 3

Take all of the following Mandatory Courses:

HLTH-3068	Health & Biosafety Regulations - Credits 4.00
HLTH-3067	Comm & Documentation in Reg Affairs 2 - Credits 2.00
HLTH-3066	Bioethics in Life Science - Credits 3.00
HLTH-3065	Clinical Research Regulations - Credits 3.00
PHRM-1072	QA in Pharmaceuticals & Life Science - Credits 4.00
SFTY-6012	Food Safety, Traceability & QA - Credits 4.00
PHRM-3031	Capstone Project - Credits 3.00