

Area of Interest: Environmental and Applied Sciences

## Regulatory Affairs - Sciences (Co-op and Non Co-op Version)

Ontario College Graduate Certificate

Program Code: 1523X01FWO

1 Year

Ottawa Campus

### Our Program

#### **Pursue a career in protecting the safety of people and the environment.**

The Regulatory Affairs - Sciences Ontario College Graduate Certificate program provides you with the skills and knowledge to pursue an entry-level career in industry and government regulatory agencies in Canada.

The regulation of products in industries such as healthcare, biotechnology, food, industrial chemical and agrochemical is of international concern. The resulting increase in regulation has driven the demand for qualified individuals in regulatory affairs.

With a focus on protecting the safety of people and the environment, professionals in this field have a positive impact on the public good.

Understand the regulatory environment in Canada, including the socioeconomic aspects of:

- regulations across industries
- how to interpret and apply regulations
- how to develop and manage regulatory submissions.

Learn project management and communications skills, and assess regulatory compliance and the frameworks that govern processes and products.

Students also have the option to gain real-world experience through a paid co-operative education (co-op) work term (see Additional Information for more details). Please note that places in the co-op work term are subject to availability and academic eligibility. Please note admission to the co-op program does not guarantee a co-op placement.

Graduates of this program have a strong understanding of regulation generally but develop a detailed understanding of regulation for protecting public, worker and environmental health and safety in the areas of:

- pharmaceuticals and medical devices
- agrochemicals
- industrial chemicals, including in manufacturing and consumer products.

You may also find employment in positions such as a(n):

- quality assurance specialist
- administrator in various regulated industries
- analyst
- associate

- consultant
- regulatory compliance officer

### **SUCCESS FACTORS**

This program is well-suited for students who:

- Possess strong written and oral communication skills.
- Are adept at analytical and critical thinking and are detail-oriented.
- Are inquisitive and able to analyze, evaluate and apply relevant information from a variety of sources.
- Effectively conduct research and analyze findings.
- Possess effective leadership skills.
- Have a strong interest in protecting the safety of people and the environment.

### **Employment**

Graduates are well positioned for a variety of entry-level employment opportunities in the regulatory affairs sector. Positions may include but are not restricted to regulatory affairs officers, associates, analysts and consultants, regulatory compliance officers and consultants, and quality assurance specialists and administrators in the various regulated industries. Depending on the type of prior industry experience and credentials held, graduates may rise into positions with increasing levels of responsibility.

Employment may be found in organizations of all sizes in both the public and private sectors.

### **Learning Outcomes**

The graduate has reliably demonstrated the ability to:

- Optimize processes, practices and products by interpreting and assessing the role of regulatory affairs in the healthcare, food, agrochemical and industrial chemical industries.
- Relate the roles and responsibilities of regulatory professionals in industry and government to explain their purposes to stakeholders.
- Distinguish between Canadian and international regulatory environments to anticipate the results of international harmonization.
- Ensure compliance with established regulations and laws that govern processes and products as per Canadian policies and professional standards.
- Prepare and evaluate components of regulatory submissions and supplemental documentation for products within the pharmaceutical, medical devices, biotechnology, agrochemical or industrial chemical sectors.
- Evaluate a wide range of data analyses to support decisions in the regulatory process.
- Anticipate the potential impact of regulatory changes to provide risk-mitigating recommendations.
- Conduct socio-economic impact analyses regarding the introduction of new products or policies on relevant industries and society.
- Apply collaborative project management principles, leadership techniques and effective communication to ensure the timely and successful completion of projects.
- Identify and apply discipline-specific practices that contribute to the local and global community through social responsibility, economic commitment and environmental stewardship.

## Program of Study

Level: 01	Courses	Hours
MGT4501	Project Management	56.0
RGL2000	Governance and Policy Instruments	42.0
RGL2100	Regulation Theory	42.0
RGL2200	Regulation Design	56.0
SCI4003	Scientific Communication for Public Policy	42.0
SCI4100	Science and Risk Assessment in Regulation	42.0
Level: 02	Courses	Hours
QUA3000	Critical Data Analysis in Regulation	56.0
RGL3000	Socioeconomics of Regulation Design	56.0
RGL3100	Regulatory Processes	56.0
RGL3200	Pre-Market Regulatory Submission	84.0
RGL3300	Submission Evaluation and Post-Market Analysis	42.0
Co-op:01	Courses	Hours
WKT2300	Work Term I	

## Fees for the 2023/2024 Academic Year

Tuition and related ancillary fees for this program can be viewed by using the Tuition and Fees Estimator tool at <https://www.algonquincollege.com/fee-estimator>.

Further information on fees can be found by visiting the Registrar's Office website at <https://www.algonquincollege.com/ro>.

Fees are subject to change.

Additional program related expenses include:

- Books and supplies cost approximately \$300.

## Admission Requirements for the 2024/2025 Academic Year

### Program Eligibility

- Ontario College Advanced Diploma, Degree or equivalent.
- Applicants with international transcripts must provide proof of the subject-specific requirements noted above and may be required to provide proof of language proficiency. Domestic applicants with international transcripts must be evaluated through the International Credential Assessment Service of Canada (ICAS) or World Education Services (WES).
- IELTS -International English Language Testing Service-Overall band of 6.5 with a minimum of Reading: 6.0; Listening: 6.0; Speaking: 6.0; Writing: 6.5; OR TOEFL-Internet-based (iBT)-overall 90, with the minimum in each component: Reading: 22; Listening: 22; Speaking: 22; Writing: 24

- IELTS -International English Language Testing Service-Overall band of 6.5 with a minimum of Reading: 6.0; Listening: 6.0; Speaking: 6.0; Writing: 6.5; OR TOEFL-Internet-based (iBT)-overall 90, with the minimum in each component: Reading: 22; Listening: 22; Speaking: 22; Writing: 24 OR Duolingo English Test (DET) Overall 120, minimum of 120 in Literacy and no score below 105.

## Admission Requirements for 2023/2024 Academic Year

### Program Eligibility

- Ontario College Advanced Diploma, Degree or equivalent.
- Applicants with international transcripts must provide proof of the subject specific requirements noted above and may be required to provide proof of language proficiency. Domestic applicants with international transcripts must be evaluated through the International Credential Assessment Service of Canada (ICAS) or World Education Services (WES).
- IELTS -International English Language Testing Service-Overall band of 6.5 with a minimum of Reading: 6.0; Listening: 6.0; Speaking: 6.0; Writing: 6.5 OR TOEFL-Internet-based (iBT)-overall 90, with the minimum in each component: Reading: 22; Listening: 22; Speaking: 22; Writing: 24.

### Application Information

#### REGULATORY AFFAIRS - SCIENCES (CO-OP AND NON CO-OP VERSION) Program Code 1523X01FWO

Applications to full-time day programs must be submitted with official transcripts showing completion of the academic admission requirements through:

ontariocolleges.ca  
60 Corporate Court  
Guelph, Ontario N1G 5J3  
1-888-892-2228

Applications are available online at <http://www.ontariocolleges.ca/> .

Applications for Fall Term admission received by February 1 will be given equal consideration. Applications received after February 1 will be processed on a first-come, first-served basis as long as places are available.

International applicants applying from out-of-country can obtain the International Student Application Form at <https://algonquincollege.force.com/myACint/> or by contacting the Registrar's Office.

For further information on the admissions process, contact:

Registrar's Office  
Algonquin College  
1385 Woodroffe Ave  
Ottawa, ON K2G 1V8  
Telephone: 613-727-0002  
Toll-free: 1-800-565-4723  
TTY: 613-727-7766  
Fax: 613-727-7632  
Contact: <https://www.algonquincollege.com/ro>

### Additional Information

#### CO-OP INFORMATION:

All applicants apply directly to the non-co-op version of this program through <http://www.ontariocolleges.ca/> or our International Application Portal. Students may elect to participate in the co-op version, two terms prior to the first co-op work term, subject to availability and academic eligibility.

Co-operative education (Co-op) allows students to integrate their classroom learning with a real-world experience through paid work terms. Two academic terms prior to the cooperative education work term, students are required to actively participate in and successfully complete the

self-directed co-op course, readiness activities and workshops.

Students must actively conduct a guided, self-directed job search and are responsible for securing approved program-related paid co-op employment. Students compete for co-op positions alongside students from Algonquin College and other Canadian and international colleges and universities. Algonquin College's Co-op Department provides assistance in developing co-op job opportunities and guides the overall process, but does not guarantee that a student will obtain employment in a co-op work term. Co-op students may be required to relocate to take part in the co-op employment opportunities available in their industry and must cover all associated expenses; e.g., travel, work permits, visa applications, accommodation and all other incurred expenses.

Co-op work terms are typically 14 weeks in duration and are completed during a term when students are not taking courses. For more information on your program's co-op level(s), visit the courses tab on your program's webpage.

International students enrolled in a co-op program are required by Immigration, Refugees and Citizenship Canada (IRCC) to have a valid Co-op/Internship Work Permit prior to commencing their work term. Without this document International students are not legally eligible to engage in work in Canada that is part of an academic program. The Co-op/Internship Work Permit does not authorize international students to work outside the requirements of their academic program.

For more information on co-op programs, the co-op work/study schedule, as well as general and program-specific co-op eligibility criteria, please visit <https://www.algonquincollege.com/coop>.

This program is also available via AC Online at <https://www.algonquincollege.com/online>.

While admission requirements specify that an Ontario College Advanced Diploma is required for entry into the program, please be advised that most government and some industry positions require a degree. In particular, a B.Sc. is required by government agencies, such as Health Canada. Interested applicants should explore the minimum credential requirements for the career in their desired sector.

Graduates with degrees are encouraged to apply for Federal Student Work Experience Program (FSWEP) opportunities.

## Contact Information

### Program Coordinator(s)

- Thomas Conway, <mailto:conwayt@algonquincollege.com>, 613-727-4723, ext. 6002

## Course Descriptions

### MGT4501 Project Management

Project management and leadership skills are critical for professionals in both the public and private sectors. Students investigate principles, tools and techniques of project management and learn to mitigate common issues to ensure project success and stakeholder satisfaction. Through case studies and team work, students explore leadership and team dynamics.

Prerequisite(s): none  
Corerequisite(s):none

### QUA3000 Critical Data Analysis in Regulation

Regulatory decisions require not only an understanding of statistical data and processes, but also the ability to think critically about their application. Students investigate how statistical information is used to make regulatory decisions, explore the type of statistical analyses that are most appropriate in the various regulatory sectors, and describe how regulatory methodology can affect risk mitigation, and compliance. Students apply basic statistical concepts to data and explain their utility in regulatory decision-making. Using published literature, students examine data to understand the design, accuracy, and effectiveness of studies for use in regulatory processes.

Prerequisite(s): SCI4100  
Corerequisite(s):none

**RGL2000 Governance and Policy Instruments**

An understanding of the regulatory framework in Canada and familiarity with international regulatory regimes is of paramount importance to professionals in regulatory affairs. Students examine and discuss legislation, policies and acts that shape regulations in Canada, and explore the relationships between regulations and policy instruments available to government. Using case studies, students situate regulations in the wider framework of governance across various sectors. Students work independently and in small groups to research, summarize and present comparisons of different regulatory regimes internationally and discuss the history, scope and potential impacts of the harmonization of those regimes.

Prerequisite(s): none

Corerequisite(s):none

**RGL2100 Regulation Theory**

Regulatory professionals must understand the role of regulation in serving the public interest. Students explore the purpose and impact of both pre- and post-market regulations, examine risk management strategies and discuss the roles of regulatory professionals. Through case studies and discussion, students develop a sound understanding in regulation theory and both the ethical and socioeconomic implications of regulatory practice.

Prerequisite(s): none

Corerequisite(s):none

**RGL2200 Regulation Design**

The design of a regulation has extensive implications for both government and industry stakeholders. Students explore performance-based and prescriptive regulations and discuss the impact on the roles and responsibilities of stakeholders, as well as concerns for compliance and enforcement. Students examine how patents, trademarks and copyrights relate to regulatory issues. Using case studies, students classify regulations, relate regulations to pertinent legislation and investigate the implications of a new or evolved technology, performance or process standard.

Prerequisite(s): none

Corerequisite(s):none

**RGL3000 Socioeconomics of Regulation Design**

Changes to regulations often have far-reaching consequences for all stakeholders. Students examine the role of relevant risk-management and socioeconomic principles in the regulatory process. Using case studies, students analyze the impacts of regulatory changes, the use of cost-benefit analysis and propose impact-mitigating strategies. Working independently and in groups, students examine Regulatory Impact Analysis Statements (RIAS) and Strategic Environmental Assessments (SEA).

Prerequisite(s): RGL2100 and RGL2200

Corerequisite(s):none

**RGL3100 Regulatory Processes**

The regulatory processes in the pharmaceutical, agrochemical and industrial chemical industries vary widely. Students explore the regulatory processes and the roles of regulatory professionals in these three key industries and investigate how the regulations impact product development. Students consider the life cycle components of regulations in each industry, including stakeholders, risk assessments and pre- and post-market perspectives. Students analyze the agrochemical sector in detail.

Prerequisite(s): RGL2200

Corerequisite(s):none

**RGL3200 Pre-Market Regulatory Submission**



Regulatory submissions are critical components of the regulatory process for both government and industry. Students work with industry to complete a regulatory submission from one of the following areas: pharmaceuticals, medical devices, biotechnology, natural health products, agrochemicals and/or industrial chemicals. Students delineate the appropriate sequence and processes required for new product approval, including the selection of appropriate guidance documents.

Prerequisite(s): MGT4501 and SCI4003  
Corerequisite(s):none

### **RGL3300 Submission Evaluation and Post-Market Analysis**

The regulatory requirements for a new product continue beyond the regulatory submission, to its evaluation and continued regulatory control once the product is on the market. Students consider the submission approval process and investigate the regulatory concerns for products once they are on the market. Using case studies, students apply the regulatory requirements at various stages in the evaluation of a new drug submission and determine the factors that contribute to approval or rejection.

Prerequisite(s): MGT4501  
Corerequisite(s):none

### **SCI4003 Scientific Communication for Public Policy**

Clear, concise and effective communication is required for success in this industry. Students explore and apply industry-specific technical writing strategies, such as assessing scientific procedures and clearly articulating complex technological problems. Through written assignments, presentations and simulating briefing activities, students develop written and spoken communication skills essential for professionals in this sector.

Prerequisite(s): none  
Corerequisite(s):none

### **SCI4100 Science and Risk Assessment in Regulation**

Risk assessment using scientific data is critical for making sound regulatory decisions. However, the science used to assess risk varies widely across industries. Students investigate how scientific data is used in different fields and compare the risk assessment strategies used in different industries. Using case studies, students explore the validity of claims supported by different types of scientific data and discuss how risk assessment leads to effective risk management. In addition, students enhance research skills and the ability to assess the credibility of sources.

Prerequisite(s): none  
Corerequisite(s):none

### **WKT2300 Work Term I**

Students complete a paid full-time work term with an employer off campus. The placement is monitored by the College and assignments, including a final report, must be completed. The College provides assistance in finding a placement.

Prerequisite(s): none  
Corerequisite(s):none