

Area of Interest: Environmental and Applied Sciences

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

Ontario College Graduate Certificate

Program Code: 1523X01FPM

1 Year

Pembroke Campus

### **Our Program**

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

In this one-year Regulatory Affairs - Sciences Ontario College Graduate Certificate program, you build on your existing science, engineering, or technology education to learn how pharmaceuticals, medical devices, agrochemicals, and industrial chemicals are regulated for public health and environmental protection. You also have an opportunity to choose specific areas of focus though project topic selection. The program prepares well-rounded regulation professionals who are knowledgeable about the regulatory life-cycle management of science-based products.

As a regulatory affairs professional, you develop the skills and knowledge necessary to work in the field through practical, hands-on applications. You research and analyze the requirements of applicable regulations, prepare regulatory submissions, identify strategies to support pre-market product approval, identify and apply best practices for regulatory compliance and post-market surveillance, and provide stakeholders with clear and concise guidance and communications.

The breadth of the program means that your knowledge and skills are applicable in large industrial sectors involving pharmaceuticals, medical devices, agrochemicals, and industrial chemicals. Governments and industries require your expertise to capture the benefits of these products for the economy and society while ensuring their safety and efficacy for public health and the environment.

You 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. Admission to the co-op program does not guarantee a co-op placement.

After graduating from this program, you are prepared to respond to employer needs at various product life cycle stages, such as:

- pre-market risk assessment processes
- management of post-market regulatory compliance systems
- surveillance and monitoring of products on the market
- public risk communications and consultations
- industry regulation strategies for product development
- regulation design
- regulation policy analysis

#### SUCCESS FACTORS

This program is well-suited for students who:

- Are motivated to protect public health and the environment.



- Have an interest in research and analysis.
- Are adept at critical thinking and problem-solving.
- Enjoy teamwork and the challenge of leadership.
- Have strong attention to detail.

#### Employment

Graduates may find employment in government, industry, and consulting under a wide range of job titles, such as regulatory affairs officer, regulatory compliance officer, regulatory specialist, regulatory analyst, clinical administration officer, clinical research assistant, pharmacovigilance officer, regulatory affairs consultant, regulatory affairs coordinator, quality control officer, program support officer, environmental policy officer, environmental health and safety officer, and policy analyst.

#### **Learning Outcomes**

The graduate has reliably demonstrated the ability to:

- Apply regulatory theories, concepts, and methodologies to assess the role of regulatory affairs and optimize regulatory processes and practices.

- Assess the roles and responsibilities of regulation professionals in lifecycle management of hazardous products.

- Interpret legislation, regulations and standards in Canada and the jurisdictions of significant trading partners to support international cooperation and harmonization.

- Assess and establish compliance with legislation and regulation by applying compliance promotion and enforcement policies and post-market surveillance techniques consistent with professional standards.

- Prepare and evaluate regulatory submissions and supplemental documentation requirements for pharmaceuticals, medical devices, agrochemicals, and industrial chemicals throughout their lifecycle.

- Analyze scientific and socioeconomic data to inform government, industry and other stakeholders of risk assessment and management approaches and strategies.

- Anticipate impacts of government regulations on product design and economics in industry to support risk management strategies.

- Assess information needs and analysis methods in science and socioeconomics to inform government decision-making for regulatory design and approval.

- Apply collaborative project management principles, leadership techniques and effective communication to implement and improve systems for regulatory compliance in government and industry.

- Organize and compose communications for public policy, public risk communications, consultations, and regulatory compliance to inform and mobilize risk avoidance actions for organizations and the public.

- 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**

# ALGONQUIN

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

Level: 01	Courses	Hours
ENL7074	Communication for Regulation Professionals	56.0
RGL7301	Law and Policy Governing Chemicals and Medical Devices	42.0
RGL7401	Science and Risk Assessment in Regulation	42.0
RGL7501	Theories, Concepts and Definitions in Regulation	42.0
RGL7601	Regulation Design and Approval Processes in Government	56.0
RGL7800	Pre-Market Regulatory Processes	56.0
Level: 02	Courses	Hours
RGL7402	Post-Market Surveillance, Analytics and Monitoring	42.0
RGL7502	Managing Life-Cycle Regulatory Compliance for Pharma and Medical Device	56.0
RGL7602	Managing Life-Cycle Reg.Compliance for Agrochemicals and Industrial Chemicals	56.0
RGL7700	Regulation and Industry Product Development Processes	42.0
RGL7801	Public Risk Communications and Consultations	42.0
RGL7900	Regulatory Affairs Applied Project	56.0
Co-op: 01	Courses	Hours

# Fees for the 2024/2025 Academic Year

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

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

Fees are subject to change.

Additional program related expenses include: Books and supplies cost approximately \$500.

# Admission Requirements for the 2025/2026 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; OR Duolingo (DET) - Overall 120, minimums of 120 in Literacy and 105 in Production.

# Admission Requirements for 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; OR Duolingo English Test (DET) Overall 120, minimum of 120 in Literacy and no score below 105.

#### **Application Information**

#### REGULATORY AFFAIRS - SCIENCES (CO-OP AND NON CO-OP VERSION) Program Code 1523X01FPM

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 https://%20www.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://algonguincollege.force.com/myACint/ or by contacting the Registrar`s Office.

For further information on the admissions process, contact:

Registrar's Office Algonquin College in the Ottawa Valley 1 College Way Pembroke, ON K8A 0C8 Local: 613-735-4700 Toll-free: 1-800-565-4723 TTY: 1-866-620-3845 Fax: 613-735-4739 https://www.algonquincollege.com/pembroke

#### **Additional Information**

#### **CO-OP INFORMATION:**

**The Regulatory Affairs - Sciences co-op program is open to domestic students only and not available to international students.** All applicants apply directly to the non-co-op version of this program through <u>https://www.ontariocolleges.ca/</u>. 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 realworld 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.

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 <u>https://www.algonquincollege.com/coop</u>.

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

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)

- Jamie MacDonald, <u>mailto:macdonj6@algonquincollege.com</u>, 613-735-4700, ext. 2743

#### **Course Descriptions**

#### **ENL7074** Communication for Regulation Professionals

Refining writing skills is a lifelong endeavor, even for the most sophisticated professional writers. For regulation professionals, continuous improvement in science and policy written communications is vital for a successful career path. Students review the fundamentals of effective writing by completing short written pieces typical of the regulatory affairs profession, including fact sheets, briefing notes, short research reports, and public awareness communications.

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

#### **RGL7301 Law and Policy Governing Chemicals and Medical Devices**

Regulation professionals involved in the regulation of pharmaceuticals, medical devices, agrochemicals, and industrial chemicals must be able to identify and interpret government policy, legislation, regulations, and international agreements applicable to these products. Students survey these policies, laws, and agreements to interpret content, function, and relationships. Comparative methods are used to examine similarities and differences between Canada's policies, laws, and international agreements trading partners.

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

#### **RGL7401 Science and Risk Assessment in Regulation**

Science plays a vital role in the risk assessment and life cycle management of hazardous products. Students assess the evolution of scientific methods in risk assessment; data types used in risk assessments; data collection methods; data quality assurance procedures; and data analysis techniques. Case studies illustrate science's contributions to robust risk assessments. Students explore debates in risk assessment literature regarding the potential for innovation in scientific methods and technologies to improve assessments of current and emerging risks.

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



#### **RGL7402** Post-Market Surveillance, Analytics and Monitoring

Post-market surveillance is a vital component of regulatory life-cycle management to protect public health and the environment. Students explore the risk monitoring objectives, technologies, and techniques of post-market surveillance, including reporting systems such as pharmacovigilance, and data gathering methods such as biomonitoring and ecosystem monitoring. Through case studies and comparative research, students assess how post-market surveillance relates to compliance promotion and enforcement of regulations, product advisories and recalls, and reversals or amendments to regulatory decisions.

Prerequisite(s): RGL7401 and RGL7501 Corerequisite(s):none

#### **RGL7501** Theories, Concepts and Definitions in Regulation

Regulation theories, concepts, and definitions are foundational intellectual tools for regulation professionals. Students investigate how theories inform the study of regulation in the public interest. Essential concepts and definitions in the regulation of science are identified, explained, and applied by students. Case studies, class discussions and research reports are used to practice effective use of foundational tools in analysis and communications.

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

#### RGL7502 Managing Life-Cycle Regulatory Compliance for Pharma and Medical Device

Regulation professionals working in the pharmaceutical and medical device sectors, whether in government regulatory departments or private sector companies, must be aware of required regulatory compliance submissions throughout the product life cycle. Students explore guidance documents for the diverse types of pharmaceutical pre-market submissions, post-market pharmacovigilance reporting, and establishment licensing for Good Manufacturing Practices. Students also assess guidance for pre- and post-market submissions for Class II, III and IV medical devices. Finally, students explore the Electronic Common Technical Document (eCTD) submission standard adopted in Canada and other trading partners.

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

#### **RGL7601 Regulation Design and Approval Processes in Government**

Understanding how regulations are prioritized, designed, and approved by governments is essential for regulation professionals. Through a review of official documents and case studies, students analyze the features and stages of regulation design and approval processes. Students explore case studies illustrating how regulation design considerations vary for different harm reduction scenarios. Finally, students survey process and procedural requirements for approval of new and amended regulations in the Government of Canada.

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

#### RGL7602 Managing Life-Cycle Reg.Compliance for Agrochemicals and Industrial Chemicals

Regulation professionals responsible for the regulatory management of agrochemicals and industrial chemicals, whether in government regulatory departments or private sector companies, must be aware of required regulatory compliance submissions throughout the life cycle of these products. To inform risk assessment and risk management priorities, students explore guidance documents for pesticides, industrial chemicals, and polymers, such as requirements for pre-market submissions; pesticide incidence reporting; reevaluation of pesticides; new substances notifications; new activity notifications; and post-market reporting.

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



#### **RGL7700 Regulation and Industry Product Development Processes**

Companies that undertake new product development increase likelihood of success by anticipating the effects of regulatory requirements on a product's functionalities and design characteristics. Students assess the impacts of regulations on industry product development decision-making. They explore the components of company regulatory strategies, including when and how regulation professionals must work with science and legal perspectives to protect the company's interests. Case studies addressing pharmaceuticals, agrochemicals, industrial chemicals, and medical devices illustrate the similarities and differences in regulatory impacts on product development.

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

#### **RGL7800 Pre-Market Regulatory Processes**

Most national regulatory regimes require pre-market regulatory assessments and approvals for pharmaceuticals, medical devices, agrochemicals, and industrial chemicals. Students use official guidance documents to analyze these regulatory processes for each product category. Canada's pre-market regulatory processes are compared with major trading partners. Processes for new or modified uses of regulated products already on the market are also analyzed and compared.

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

#### **RGL7801 Public Risk Communications and Consultations**

Companies that undertake new product development increase likelihood of success by anticipating the effects of regulatory requirements on a product's functionalities and design characteristics. Students assess the impacts of regulations on industry product development decision-making. They explore the components of company regulatory strategies, including when and how regulation professionals must work with science and legal perspectives to protect the company's interests. Case studies addressing pharmaceuticals, agrochemicals, industrial chemicals, and medical devices illustrate the similarities and differences in regulatory impacts on product development.

Prerequisite(s): RGL7401 and RGL7501 Corerequisite(s):none

#### **RGL7900 Regulatory Affairs Applied Project**

Designing and completing projects is a common task for regulation professionals. Students synthesize, integrate, and apply their knowledge to complete a self-driven project in a chosen specialization area consistent with the scope of the regulatory affairs program. Students identify a project, defend its relevancy, prepare a project workplan, and complete it through stages appropriate to the subject matter's demands. Students deliver documentation and presentations for guidance and approval at each project stage simulating a workplace scenario.

Prerequisite(s): RGL7401 and RGL7501 and RGL7800 Corerequisite(s):none

#### WKT7300 Work Term

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