HLTH 5816 for Fall 2026
Government Regulatory Processes

Course Instructor: Scott Sawler

Student Hours: by appointment

Office Location: Online Via Zoom

Class Location:

Class Times:

Department/Unit: Health Sciences

Topics Covered and Learning Outcomes

Topics to be Covered

Important dates and deadlines can be found here: https://calendar.carleton.ca/academicyear/, including class suspension for fall, winter breaks, and statutory holidays.

Course level learning outcomes:

Upon successful completion of the course, students will be able to:

- Identify the legal and institutional authority for a health-product regulatory decision and distinguish binding requirements from guidance, policy, and practice.
- Classify health products and regulatory problems accurately and identify the pathway, evidence, authorization, and lifecycle consequences that follow.
- Explain Canadian drug clinical-investigation and market-authorization processes and assess how evidence, uncertainty, benefit-risk, labelling, and conditions interact.
- Analyze post-market safety, risk-management, compliance, inspection, recall, and enforcement issues using a proportionate lifecycle approach.
- Evaluate priority, conditional, exceptional-access, and other flexibility mechanisms without conflating faster review, lower evidence, special access, and market authorization.
- Compare Health Canada, FDA, EMA, ICH, collaborative, and reliance approaches while preserving the distinction between common science and jurisdiction-specific legal decisions.
- Locate, interpret, protect, and communicate regulatory information using appropriate public databases, transparency mechanisms, confidentiality rules, and access routes.
- Create defensible regulatory documentation that states authority, facts, evidence, uncertainty, analysis, recommendations, commitments, and legal effect with precision.
- Evaluate emerging regulatory reforms by distinguishing enacted rules, commencement dates, draft guidance, policy expectations, and implementation implications.

Core reference set

These sources form the recurring reference base for the course. Assigned excerpts should be identified in Brightspace before each class; students are not expected to read every source in full every week.

- Food and Drugs Act, RSC 1985, c F-27. Link
- Food and Drug Regulations, CRC, c 870. Link
- Health Canada. Guidance on management of drug submissions and applications, effective 1 October 2025. Link
- Health Canada. GUI-0100, Part C, Division 5 clinical-trial guidance, Version 4, 14 August 2026. Link
- ICH. E6(R3), Good Clinical Practice, consolidated final version adopted 16 June 2026. Link
- Health Canada. Regulatory Transparency and Openness Framework. Link

- Health Canada. Compliance and Enforcement Policy for Health Products (POL-0001). Link
- Health Canada. Ministerial Reliance Order - About the Order, in force 15 July 2026. Link

Course-wide additional reading

- ICH. Harmonised Guidelines index - quality, safety, efficacy and multidisciplinary standards. Link
- WHO. Good reliance practices in the regulation of medical products, TRS 1033, Annex 10 (2021). Link
- Health Canada. Drug Product Database, Regulatory Decision Summaries and Summary Basis of Decision resources. Link
- Health Canada. Canada Vigilance and Summary Safety Reviews. Link
- ICMRA. International regulatory collaboration and communication initiatives. Link

Lecture	***Topic***	***Organizing question***
1	Regulatory Method: Authority, Evidence, Risk and Decision-Making	What makes a regulatory decision lawful, evidence-based, proportionate and defensible?
2	Canadian Regulatory Architecture and Comparative Regulators	Who makes health-product regulatory decisions, and how do Health Canada, FDA and EMA systems differ?
3	Product Classification and Regulatory Pathway Selection	What is the product, which regulatory framework applies, and what follows from that classification?
4	Drug Market Entry, Evidence and Authorization	What evidence and submission architecture are required before a new drug may enter the Canadian market?
5	Clinical Investigation	What makes a clinical trial lawful, ethical, credible and capable of regulatory use?
6	Lifecycle Regulation, Pharmacovigilance and Post-Market Risk	How does the regulatory system continue to learn, reassess and intervene after authorization?
7	Regulatory Flexibility, Conditional Pathways and Exceptional Access	How can regulators permit earlier or exceptional access without abandoning evidence, safety and accountability?
8	International Harmonization, Reliance and Comparative Regulation	How do common standards, foreign regulator work and domestic law interact?
9	Compliance, Inspection and Enforcement	How does a regulator verify that regulated activity in the real world matches the law, authorization and quality system?
10	Transparency, Confidentiality and Access to Regulatory Information	What should be public, what may remain confidential, and how do you find and interpret the regulatory record?
11	Regulatory Documentation and Communication	How should sponsors, regulators and professionals write, organize and communicate records so they can be understood and defended?
12	Regulatory Reform, Emerging Issues and Course Integration	How should regulatory professionals evaluate change without losing the discipline of authority, evidence, risk, records and communication?

Student Expectations

- Preparation: complete the assigned statutory, regulatory, guidance, policy, or case materials before class. The goal is not memorization; students should be able to locate the governing source and explain what it does.

- Source hierarchy: always distinguish binding law from regulations, orders, incorporated material, guidance, policy, public databases, and informal regulator practice. A webpage summary does not override the governing instrument.
- Currency: regulatory requirements change. When a question turns on a current rule, students are expected to check the effective date, commencement provision, version history, and whether a source is final, draft, or under consultation.
- Analysis: identify the product, actor, regulated activity, legal authority, facts, evidence, uncertainty, available controls, decision, and reasons. Do not jump directly to a conclusion.
- Communication: use precise regulatory language. Distinguish authorization from access, approval from evidence generation, suspected adverse events from proven causality, and foreign decisions from Canadian legal effect.
- Participation: contribute actively to regulatory scenarios and class discussion. Students should be prepared to defend a conclusion, revise it when a stronger source is identified, and acknowledge uncertainty.
- Attendance: consistent attendance and punctual participation are expected because case analysis and comparative discussion are central to the course. Students who miss a class are responsible for obtaining the material and any announced changes.
- Professional writing: assignments should be concise, structured, source-traceable, and written for a decision-maker. Conclusions must be proportionate to the record and clearly separate facts from assumptions or recommendations.
- Academic integrity and confidentiality: submitted work must comply with Carleton's Academic Integrity Policy. Course cases, client-like exercises, and any materials identified as confidential or restricted must not be distributed outside the course.
- Respectful learning environment: disagreement about regulatory policy, evidence, or risk is expected. Debate should focus on sources, reasoning, and consequences rather than on individuals.

Lecture-by-Lecture Content

The following material is designed to be transferred directly into the weekly syllabus schedule or Brightspace modules. "Primary references" are authoritative or foundational sources; "additional reading" is recommended enrichment and may be selectively assigned.

Lecture 1 — Regulatory Method: Authority, Evidence, Risk and Decision-Making

What makes a regulatory decision lawful, evidence-based, proportionate and defensible?

Establishes the method used throughout the course: identify legal authority, classify the product and problem, identify the required evidence, assess benefit-risk and uncertainty, select an appropriate regulatory control, document reasons, and communicate the legal effect of the decision. The lecture also distinguishes legislation, regulations, orders, incorporated materials, guidance, policy, and regulator practice.

Learning objectives

- Distinguish legislation, regulations, orders, incorporated-by-reference materials, guidance, policy, and operational practice by legal status.
- Use a structured method to move from authority and facts to evidence, uncertainty, controls, decision, and reasons.
- Explain why regulatory decisions are not equivalent to scientific conclusions or clinical recommendations.
- Recognize when a regulatory question requires current-source verification rather than reliance on memory or precedent.

Primary references

- Food and Drugs Act, RSC 1985, c F-27. Link
- Food and Drug Regulations, CRC, c 870. Link
- Department of Health Act, SC 1996, c 8. Link
- Health Canada. Regulating health products. Link

Additional reading

- Constitution Act, 1867, ss 91-92 - orientation to federal/provincial authority. Link
- Health Canada. Regulatory Transparency and Openness Framework. Link

Lecture 2 — Canadian Regulatory Architecture and Comparative Regulators

Who makes health-product regulatory decisions, and how do Health Canada, FDA and EMA systems differ?
Maps the Canadian federal health-product regulatory system and positions Health Canada within government, then compares institutional design and legal outputs with the U.S. FDA and the European medicines system. Students learn to compare regulators without assuming equivalent terminology, authority, or decision pathways.

Learning objectives

- Map the main Canadian institutions and branches involved in pre-market review, post-market oversight, compliance, and enforcement.
- Compare the institutional roles of Health Canada, U.S. FDA, and EMA/European Commission at a high level.
- Distinguish a regulatory agency, a legal authority, a review process, and a final authorization output.
- Construct a comparative regulatory table that identifies authority, evidence, decision-maker, output, and lifecycle controls rather than relying on label-equivalence.

Primary references

- Health Canada. Regulating health products. Link
- Health Canada. Guidance on management of drug submissions and applications (effective 1 October 2025). Link
- U.S. FDA. What We Do. Link

- European Medicines Agency. Human medicines: regulatory overview. Link

Additional reading

- ICH. Members and harmonised guidelines. Link
- International Coalition of Medicines Regulatory Authorities (ICMRA). Link

Lecture 3 — Product Classification and Regulatory Pathway Selection

What is the product, which regulatory framework applies, and what follows from that classification?
Examines classification as a threshold regulatory decision. Students work through drugs, biologics, medical devices, natural health products, combination products, and borderline products, with emphasis on how classification changes evidence, licensing, labelling, manufacturing, and lifecycle obligations.

Learning objectives

- Classify a proposed health product at a high level under the Food and Drugs Act framework and identify the governing regulatory instrument.
- Explain how product composition, intended use, mechanism, claims, presentation, and risk can affect classification.
- Identify downstream consequences of classification for submission pathway, evidence, labelling, licensing, and compliance.
- Recognize borderline and combination-product issues that require a formal classification analysis or regulator engagement.

Primary references

- Food and Drugs Act and Food and Drug Regulations. Link
- Health Canada. Guidance on management of drug submissions and applications - pre-application and filing: classification of therapeutic products. Link
- Medical Devices Regulations, SOR/98-282. Link
- Natural Health Products Regulations, SOR/2003-196. Link

Additional reading

- Health Canada. Drug-medical device combination products policy. Link
- Health Canada. Guidance on management of drug submissions and applications - current classification and filing resources. Link

Lecture 4 — Drug Market Entry, Evidence and Authorization

What evidence and submission architecture are required before a new drug may enter the Canadian market?
Covers the transition from development evidence to a Canadian new drug submission, review, regulatory questions, labelling, decision, Notice of Compliance, and Drug Identification Number. Students distinguish evidence requirements from administrative process and learn the relationship between dossier structure, benefit-risk assessment, product monograph, and authorization.

Learning objectives

- Describe the Canadian NDS review pathway from pre-submission planning through screening, review, decision, NOC, DIN, and public information.
- Explain how quality, nonclinical, and clinical evidence are organized and integrated for regulatory review.
- Use CTD/eCTD concepts to locate the type of information needed to answer a regulatory question.
- Distinguish authorization, product labelling, regulatory reasons, and post-authorization commitments as different outputs of the review process.

Primary references

- Food and Drug Regulations, Part C, Division 8. Link
- Health Canada. Guidance on management of drug submissions and applications, effective 1 October 2025. Link
- ICH. Common Technical Document (CTD), M4 family. Link
- Health Canada. Guidance document: Product Monograph, effective 23 December 2024. Link

Additional reading

- Health Canada. How drugs are reviewed in Canada. Link
- Health Canada. Notice of Compliance database and Drug Product Database. Link

Lecture 5 — Clinical Investigation

What makes a clinical trial lawful, ethical, credible and capable of regulatory use?
Treats clinical investigation as regulated evidence generation. The lecture focuses on Canadian Division 5 authorization, GCP, sponsor and investigator obligations, site activation, protocol amendments, safety reporting, records, inspection, and the interface with research ethics. It builds on HLTH 5812 by emphasizing regulatory control rather than introductory trial design.

Learning objectives

- Explain the legal function of Canadian clinical-trial authorization and the role of Part C, Division 5.
- Connect GCP requirements to participant protection, scientific validity, data reliability, and inspectability.
- Identify regulatory triggers for CTA amendments, serious unexpected adverse drug reaction reporting, discontinuance, suspension, or cancellation.
- Analyze a clinical-trial scenario by separating federal authorization, REB review, institutional governance, and professional accountability.

Primary references

- Food and Drug Regulations, Part C, Division 5. Link
- Health Canada. GUI-0100, Version 4, issued and implemented 14 August 2026. Link
- ICH. E6(R3), Good Clinical Practice, consolidated final version adopted 16 June 2026. Link

- TCPS 2 (2022), Chapter 11: Clinical Trials. Link

Additional reading

- Health Canada. Guidance on registration of clinical trials and public disclosure of results, effective 29 July 2026. Link
- World Medical Association. Declaration of Helsinki, revised 2024. Link

Lecture 6 — Lifecycle Regulation, Pharmacovigilance and Post-Market Risk

How does the regulatory system continue to learn, reassess and intervene after authorization?
Moves from the pre-market decision to lifecycle oversight: adverse reaction reporting, signal detection, safety assessment, risk management plans, product-monograph changes, safety communication, post-authorization evidence, recalls, and regulatory powers introduced or strengthened through Vanessa's Law and agile modernization.

Learning objectives

- Explain why market authorization is a point in a regulatory lifecycle rather than the end of review.
- Differentiate spontaneous reporting, signal detection, signal assessment, safety review, risk minimization, and regulatory action.
- Describe the role of risk management plans and distinguish routine pharmacovigilance from additional risk-minimization measures.
- Select proportionate post-market regulatory responses to a hypothetical new safety signal while stating residual uncertainty.

Primary references

- Food and Drugs Act - therapeutic product safety powers and lifecycle provisions. Link
- Health Canada. Canada Vigilance Adverse Reaction Online Database and reporting resources. Link
- Health Canada. Summary Safety Reviews. Link
- Health Canada. Agile regulatory provisions and updated guidance for risk management plans (RMP provisions come into force 1 April 2027). Link

Additional reading

- ICH. E2E, Pharmacovigilance Planning. Link
- Health Canada. MedEffect Canada - safety information and risk communications. Link

Lecture 7 — Regulatory Flexibility, Conditional Pathways and Exceptional Access

How can regulators permit earlier or exceptional access without abandoning evidence, safety and accountability?
Compares review acceleration, conditional authorization, patient-specific special access, urgent public-health access, exceptional importation, and related international pathways. Students

separate speed, evidence threshold, legal output, population, and lifecycle controls. The lecture also identifies 2027 agile reforms that are not yet in force during Fall 2026.

Learning objectives

- Distinguish priority review, NOC/c, Special Access Program, exceptional importation, and other access tools by legal output and purpose.
- Explain why review speed, evidentiary uncertainty, and authorization status must be analyzed separately.
- Assess whether conditions, commitments, monitoring, communication, and supply-chain controls are adequate for residual uncertainty.
- Compare Canadian flexibility tools with FDA expedited/expanded-access programs and EMA PRIME/conditional authorization without treating them as direct equivalents.

Primary references

- Health Canada. Guidance for Industry - Priority Review of Drug Submissions. Link
- Health Canada. Guidance Document: Notice of Compliance with Conditions (NOC/c). Link
- Health Canada. Special Access Program for drugs: Guidance document for industry and practitioners. Link
- Health Canada. Guide to exceptional importation and sale of drugs in response to drug shortages (GUI-0148). Link

Additional reading

- Health Canada. Draft guidance on promising evidence and terms and conditions; new broad T&C authorities take effect 1 April 2027. Link
- U.S. FDA. Expedited Programs for Serious Conditions - Drugs and Biologics. Link
- U.S. FDA. Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers. Link
- European Medicines Agency. PRIME and Conditional Marketing Authorisation. Link

Lecture 8 — International Harmonization, Reliance and Comparative Regulation

How do common standards, foreign regulator work and domestic law interact?
Explores harmonization through ICH and common technical standards, regulatory collaboration, information sharing, reliance, work-sharing, and comparative analysis. Particular attention is given to Canada's Ministerial Reliance Order, in force since 15 July 2026, and to the difference between using foreign regulatory work and surrendering domestic legal responsibility.

Learning objectives

- Differentiate harmonization, convergence, collaboration, work-sharing, recognition, and reliance.
- Explain how ICH standards and the CTD create shared technical language without creating identical national law.

- Describe the purpose and current scope of Canada's Ministerial Reliance Order and the concept of deeming based on foreign regulatory decisions or documents.
- Prepare a comparative regulatory analysis that identifies authority, evidence, output, controls, local requirements, and residual uncertainty.

Primary references

- Health Canada. Health products international activities. Link
- ICH. Guidelines overview. Link
- WHO. Good reliance practices in the regulation of medical products, TRS 1033, Annex 10 (2021). Link
- Health Canada. Ministerial Reliance Order - About the Order (in force 15 July 2026). Link
- Health Canada. Draft guidance on the Ministerial Reliance Order, published 15 July 2026. Link

Additional reading

- Health Canada. Access Consortium. Link
- U.S. FDA. Project Orbis. Link
- ICMRA. Strategic initiatives and regulatory collaboration. Link

Lecture 9 — Compliance, Inspection and Enforcement

How does a regulator verify that regulated activity in the real world matches the law, authorization and quality system?

Examines compliance promotion, monitoring, inspection, establishment and activity controls, GMP, observations, risk classification, corrective and preventive action, recalls, enforcement tools, and the evidentiary record needed to demonstrate compliance. Students learn to treat inspection as verification of an operating system, not merely review of documents.

Learning objectives

- Distinguish compliance promotion, compliance monitoring, inspection, investigation, and enforcement.
- Explain how GMP and other GxP requirements become verifiable records, controls, and operating practices.
- Analyze an inspection observation by identifying the requirement, factual evidence, risk, root cause, corrective action, preventive action, and effectiveness check.
- Select proportionate regulatory responses to non-compliance and explain how risk, history, conduct, and public-health impact affect escalation.

Primary references

- Health Canada. Compliance and Enforcement Policy for Health Products (POL-0001). Link
- Health Canada. Good manufacturing practices guide for drug products (GUI-0001). Link
- Food and Drugs Act - inspection and enforcement authorities. Link
- Health Canada. Drug, natural health product and biocide recall guide (GUI-0039), issued 13 December 2024. Link

Additional reading

- Health Canada. Drug and Health Products Inspections Database. Link
- PIC/S. Guide to Good Manufacturing Practice for Medicinal Products. Link

Lecture 10 — Transparency, Confidentiality and Access to Regulatory Information

What should be public, what may remain confidential, and how do you find and interpret the regulatory record?

Maps the public regulatory record across authorization, clinical evidence, safety, recalls, and inspections, then distinguishes public information, confidential business information, personal information, third-party information, and access routes. Students learn source selection and the limits of what public databases can prove.

Learning objectives

- Map a regulatory question to the most appropriate public source, record holder, confidentiality rule, and access pathway.
- Differentiate regulatory decision summaries, Summary Basis of Decision documents, product monographs, PRCI clinical information, safety databases, and inspection records by purpose and evidentiary limits.
- Explain the relationship between Food and Drugs Act clinical-information disclosure powers, PRCI, the Access to Information Act, and privacy protections at a high level.
- Communicate public regulatory information precisely without treating absence of public evidence as proof that an issue was not considered.

Primary references

- Health Canada. Regulatory Transparency and Openness Framework. Link
- Food and Drugs Act, including s 21.1 clinical-information disclosure authority. Link
- Health Canada. Public Release of Clinical Information (PRCI): Guidance document. Link
- Access to Information Act, including third-party information rules. Link
- Privacy Act. Link

Additional reading

- Health Canada. Drug Product Database. Link
- Health Canada. Regulatory Decision Summaries. Link
- Health Canada. Summary Basis of Decision documents. Link
- Health Canada. Canada Vigilance, Summary Safety Reviews, Recalls and Drug and Health Products Inspections Database. Link

Lecture 11 — Regulatory Documentation and Communication

How should sponsors, regulators and professionals write, organize and communicate records so they can be understood and defended?

Turns from accessing the regulatory record to building it. Students examine the functions of submission documents, cover letters, regulator questions and responses, meeting records, commitments, product monographs, decision summaries, internal regulatory memos, and public risk communications. The emphasis is traceability, precision, decision usefulness, and defensibility.

Learning objectives

- Identify the purpose, audience, authority, evidence base, and decision requested for a regulatory document before drafting it.
- Structure a regulatory memo or response so that facts, authority, analysis, uncertainty, recommendation, commitments, and next steps are traceable.
- Distinguish advocacy from accurate regulatory communication and avoid language that overstates safety, efficacy, causality, authorization, or certainty.
- Evaluate whether a meeting record, response package, or product communication creates a defensible and auditable record of the decision.

Primary references

- Health Canada. Guidance on management of drug submissions and applications, effective 1 October 2025. Link
- Health Canada. Guidance document: Product Monograph, effective 23 December 2024. Link
- ICMRA. Regulators as communicators: strengthening regulatory communication for public health, 14 January 2026. Link
- Health Canada. Regulatory Decision Summaries and Summary Basis of Decision resources. Link

Additional reading

- ICH. Common Technical Document (CTD) and eCTD resources. Link
- Health Canada. Public Release of Clinical Information guidance - redaction, anonymization and public-facing records. Link

Lecture 12 — Regulatory Reform, Emerging Issues and Course Integration

How should regulatory professionals evaluate change without losing the discipline of authority, evidence, risk, records and communication?

A capstone on how regulatory method survives rapid change. Students apply the course framework to agile licensing, terms and conditions, RMP reforms, clinical-trial modernization and transparency, reliance, digital and machine-learning-enabled products, and institutional pressures for speed and efficiency. The goal is not to predict every reform, but to develop a repeatable method for advising while law and policy are moving.

Learning objectives

- Evaluate a regulatory reform by identifying its legal authority, commencement date, scope, affected processes, evidence implications, records, controls, and implementation burden.
- Distinguish enacted law, provisions not yet in force, draft guidance, consultation proposals, and policy expectations when advising on emerging changes.

- Apply the course method to a new regulatory problem involving innovation, reliance, lifecycle uncertainty, transparency, or technological change.
- Synthesize the course into a professional standard: state the authority, classify the problem, assess evidence and uncertainty, choose controls, document reasons, and communicate without overclaiming.

Primary references

- Health Canada. New agile regulatory provisions and updated guidance for risk management plans (18 December 2024; RMP provisions effective 1 April 2027). Link
- Health Canada. Draft guidance on promising evidence and terms and conditions (12 December 2025; relevant authorities effective 1 April 2027). Link
- Health Canada. Guidance on registration of clinical trials and public disclosure of results, effective 29 July 2026. Link
- Health Canada. Ministerial Reliance Order and draft guidance, 15 July 2026. Link
- ICH. E6(R3), Good Clinical Practice, consolidated 16 June 2026. Link

Additional reading

- Health Canada. Consultation: Modernizing the framework for clinical trials (closed 19 April 2026). Link
- Health Canada. Pre-market guidance for machine learning-enabled medical devices, 1 April 2026. Link
- Health Canada. Regulatory Transparency and Openness Framework. Link

Assessments

Component	***Grade Value***	***Date***
Assignment 1	30%	After week 2
Assignment 2	30%	After week 5
Assignment 3	30%	After week 8
In Class Participation	10%	Throughout

Late and Missed Work Policies

Late Work

Insert statement about late work penalties (indicate percentage and/or grade point deduction, as well as the maximum number of days something may be submitted after the initial deadline), and course-related policy regarding use of the academic considerations form.

Missed Work

Short-term (5 days or less): Insert statement about course-related policy for missed work, and a link to the academic considerations form. You may state whether there is a limit to the number of times the student can submit the form for your course.

Long-term (> 5 days): Insert statement about course-related policy for longer-term accommodation .

We strongly encourage you to use the Academic Considerations Form for any circumstances where you either require or permit students to hand in late or missed work so that a record is captured in the Registrar's Office of how often students use the form. The link to the form is at the end of the URL above: https://sarms.carleton.ca/registrar/academic-consideration

Learning Material(s) and Other Course/Lab-Related Resources

Students are not required to purchase textbooks or other learning materials for this course.

Academic Accommodations and Regulations

Carleton is committed to providing academic accessibility for all individuals. You may need special arrangements to meet your academic obligations during the term. The accommodation request processes, including information about the Academic Consideration Policy for Students in Medical and Other Extenuating Circumstances, are outlined on the Academic Accommodations website (https://students.carleton.ca/course-outline/).

Statement on Generative Artificial Intelligence (GenAI) Usage:

Generative artificial intelligence (GenAI) tools may be used in this course as research-support, drafting-support, and professional productivity tools, subject to the limitations below. Their use does not transfer responsibility for regulatory analysis, legal interpretation, evidentiary judgment, or professional recommendations from the student to the AI system.

Permitted uses may include using GenAI to:

- brainstorm regulatory questions or analytical frameworks;
- organize research or develop an initial outline;
- identify issues that warrant further investigation;
- summarize material for the student's own preliminary understanding, provided the original source is subsequently reviewed;
- compare ways of structuring an argument or communicating a regulatory conclusion;
- improve the clarity, organization, or concision of student-authored material; and
- simulate questions, counterarguments, or regulatory-review perspectives for learning purposes.

Students may not rely on GenAI as the authority for a statement of law, regulation, regulatory policy, guidance, scientific evidence, or agency practice. Regulatory conclusions must be supported by the underlying legislation, regulations, guidance, regulatory decisions, case law, scientific literature, or other appropriate primary and authoritative sources.

Where GenAI materially contributes to graded work, students must disclose its use. The disclosure should identify the tool and describe its role with sufficient specificity to distinguish the student's work from the assistance provided by the tool. For example: *"ChatGPT was used to identify potential counterarguments and to review the organization of the memorandum. The statutory interpretation, source research, analysis, conclusions, and final wording were completed and verified by the author."* More detailed disclosure requirements may be specified for individual assignments.

The rationale for permitting limited GenAI use is that regulatory professionals increasingly work in environments where AI-assisted research, drafting, information retrieval, and analysis are available. Competent regulatory practice therefore includes knowing how to use these tools efficiently while recognizing their limitations. A central objective of HLTH 5816, however, is the development of independent regulatory judgment: students must be able to identify the governing authority, distinguish law from guidance and policy, assess evidence and uncertainty, develop a defensible position, and communicate the basis for that position. GenAI may assist that process but may not substitute for it.

Students are responsible for the accuracy, currency, traceability, originality, and professional defensibility of all submitted work. AI-generated statements must be independently verified, particularly where they concern legislation, regulations, government guidance, regulatory decisions, dates, jurisdictional differences, or scientific evidence.

The following uses are not permitted unless expressly authorized by the instructor:

- submitting GenAI-generated regulatory analysis, legal interpretation, recommendations, or conclusions as the student's own work;
- citing a GenAI tool as the substantive authority for a regulatory or legal proposition;
- using citations, quotations, cases, guidance documents, regulatory decisions, or scientific references generated by AI without verifying the underlying source;
- using GenAI during an examination, quiz, or individually assessed exercise where its use has not been authorized;
- fabricating or altering evidence, regulatory records, quotations, references, data, or government positions;
- entering confidential, proprietary, personal, client, patient, sponsor, or otherwise protected information into a public GenAI platform; or
- using GenAI in a manner that prevents meaningful assessment of the student's own regulatory reasoning and professional judgment.

Failure to disclose material GenAI use when disclosure is required may constitute a breach of academic integrity.

Statement on Academic Integrity

Students are expected to uphold the values of academic integrity, which include fairness, honesty, trust, and responsibility. Examples of actions that that compromise these values include but are not limited to plagiarism, accessing unauthorized sites for assignments or tests, unauthorized collaboration on assignments or exams, and using Generative Artificial Intelligence (GenAI) tools when course assessment instructions indicate such use is not permitted.

Misconduct in scholarly activity will not be tolerated and will result in consequences as outlined in Carleton University's Academic Integrity Policy. A list of standard sanctions in the Faculty of Science can be found here.

Additional details about this process can be found on the Faculty of Science Academic Integrity website.

Students are expected to familiarize themselves with and abide by Carleton University's Academic Integrity Policy.

Student Rights & Responsibilities

Students are expected to act responsibly and engage respectfully with other students and members of the Carleton and the broader community. See the 7 Rights and Responsibilities Policy for details regarding the expectations of non-academic behaviour of students. Those who participate with another student in the commission of an infraction of this Policy will also be held liable for their actions.