

Master of Science in Regulatory Affairs

Quarter to Semester Program Comparison

Degree Requirements	Current Quarter Hours	Semester Hours - Fall 2026
Core Courses + Capstone	23	18
Electives	3-6	
RGA Electives	4-8	4
Concentrations	14-18	12
Total Degree Hours	45	34

Quarter Format

Campus:
Toronto

Semester Format

Core Courses: 23 Quarter Hours (QH)

Complete all the required courses:

RGA 6002 Introduction to Regulatory Compliance and Practice (2)

RGA 6463 Regulatory Strategy for Product Development and Life-Cycle Management (4)

RGA 6212 Introduction to Safety Sciences (4)

BTC 6210 Human Experimentation: Methodological Issues Fundamentals (4)

RGA 6203 Pharmaceutical and Medical Device Law: Topics and Cases (5)

or RGA 6204 Legal Issues in International Food, Drug, and Medical Device Regulation (5)

RGA 6300 Capstone: Practical Applications in Global Regulatory Affairs (4)



Core Courses: 18 Semester Hours (SH)

Complete all the required courses:

RGA 6105 Introduction to Regulatory Compliance and Practice (3)

RGA 6150 Regulatory Strategy for Product Development and Life-Cycle Management (3)

RGA 6208 Introduction to Safety Sciences (3)

RGA 6238 Human Experimentation Methodological Issues Fundamentals (3)

RGA 6308 Pharmaceutical and Medical Device Law: Topics and Cases (3) or

RGA 6350 Legal Issues in International Food, Drug, and Medical Device Regulation (3)

RGA 6980 Capstone: Practical Applications in Global Regulatory Affairs (3)

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General Elective Courses: 3-6 Quarter Hours (QH)

RGA 6205 Emerging Trends and Issues in the Medical Device Industry (4)

RGA 6210 Strategic Planning and Project Management for Regulatory Affairs (4)

RGA 6215 Project Management in Early Drug Discovery and Development (4)

RGA 6217 Biomedical Product Development: From Biotech to Boardroom to Market (4)

RGA 6219 Advanced Topics in Advertising and Promotion of Drugs and Medical Devices (4)

RGA 6255 Global Convergence of Regulatory Science and Reimbursement/Market Access (2)

RGA 6461 Cybersecurity and Regulation of Digital Health Technologies by the FDA (2)

Other Approved Electives:

COP 6940; EDU 6184; INT 6943

RGA Elective Courses: 4-8 Quarter Hours (QH)

Regulatory Affairs of Food:

GST 6350 Global Economics of Food and Agriculture (4)

GST 6610 Sustainable Development (4)

GST 6102 Global Corporate Social Responsibility (4)

RFA 6220 Food Safety and Surveillance: Concepts and Applications (3)

International Regulatory Affairs:

RGA 6221 European Union Compliance Process and Regulatory Affairs (4)

RGA 6222 European Medical Device Regulations (4)

RGA 6223 Introduction to Australian, Asian, and Latin American Regulatory Affairs (4)

RGA 6224 Regulation of Biomedical Product Commercialization by Health Canada (4)

RGA 6228 Managing International Clinical Trials (4)

RGA 6243 Medical Device Product Development in CAN (4)

RGA 6244 Therapeutic Product Development in CAN (4)

The remaining quarter hours may be completed by selecting a combination of a concentration and additional electives or selecting any courses listed in the concentrations and electives lists.

Elective Courses: 4 Semester Hours (SH)

RGA 6400 Medical Device Product Development and Process Validation (2)

RGA 6415 Fundamentals of CMC Regulations and Methods (2)

RGA 6435 Medical Device Cybersecurity and Digital Health (2)

RGA 6440 Advanced Topics in Advertising and Promotion of Drugs and Medical Devices (2)

RGA 6450 Financing and Reimbursement in Biomedical Product Development (2)

RGA 6465 Nonclinical Regulations in Biomedical Product Commercialization (2)

RGA 6475 Strategic Planning and Project Management for Regulatory Affairs (2)

RGA 6480 Real-World Evidence and Patient-Reported Outcomes in Regulatory Decision Making (2)

RGA 6490 Emerging Trends and Challenges in Regulatory Affairs (2)

RGA 6500 Biomedical Product Development: Regulatory Affairs in a Market-Based Setting (2)

Elective Option:

Complete courses from concentrations below or from the unused electives options in the restricted electives of the major.



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Concentrations: 14-18 Quarter Hours (QH)

Biopharmaceutical Regulatory Affairs

RGA 6000 Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation (2)

RGA 6101 Therapeutic Product Development: A Regulatory Overview (4)

RGA 6207 Global Impact of Electronic Common Technical Document (eCTD) Submissions (4)

RGA 6380 Advanced Regulatory Writing: New Drug Applications (4)

Complete 4 quarter hours from one of the following:

RGA 6217 Biomedical Product Development: From Biotech to Boardroom to Market (4)

RGA 6235 Emerging Product Categories in the Regulation of Drugs and Biologics (4)

Clinical Research Regulatory Affairs

BTC 6211 Validation and Auditing of Clinical Trial Information (4)

BTC 6213 Clinical Trial Design Optimization and Problem Solving (4)

RGA 6101 Therapeutic Product Development: A Regulatory Overview (4) or

RGA 6202 Medical Device Development: A Regulatory Overview (4)

Complete 4 quarter hours from one of the following:

RGA 6217 Biomedical Product Development: From Biotech to Boardroom to Market (4)

RGA 6228 Managing International Clinical Trials (4)

Nonclinical Biomedical Product Regulation

RGA 6207 Global Impact of Electronic Common Technical Document (eCTD) Submissions (4)

RGA 6233 Application of Quality System Regulation in Medical Device Design and Manufacturing (4)

RGA 6405 Nonclinical Regulations in Biomedical Product Commercialization (4)

RGA 6420 Global IVD Regulations and Submissions (4)



Concentrations: 12 Semester Hours (SH)

Biopharmaceutical Regulatory Affairs

RGA 6600 Introduction to Food and Drug Administration Pharmaceutical Regulation (3)

RGA 6660 Therapeutic Product Development: A Regulatory Overview (3)

RGA 6670 Global Impact of Electronic Common Technical Document (eCTD) Submissions (3)

RGA 6680 Project Management in Early Drug Discovery and Development (3)

Clinical Research Regulatory Affairs

RGA 6285 Validation and Auditing of Clinical Trial Information (3)

RGA 6290 Clinical Trial Design Optimization and Problem Solving (3)

RGA 6295 Managing International Clinical Trials (3)

RGA 6600 Introduction to Food and Drug Administration Pharmaceutical Regulation (3) or

RGA 6610 Introduction to Food and Drug Administration Medical Device Regulation (3)

Global Regulatory Affairs

RGA 6650 Medical Device Product Development in Canada (3)

RGA 6675 Therapeutic Product Development in Canada (3)

RGA 6685 European Medical Device Regulations (3)

RGA 6690 Global In Vitro Diagnostic Regulations and Submissions (3)

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Concentrations: 14-18 Quarter Hours (QH)

Medical Device Regulatory Affairs

RGA 6001 Introduction to Food and Drug Administration (FDA) Medical Device Regulation (2)

RGA 6202 Medical Device Development: A Regulatory Overview (4)

RGA 6233 Application of Quality System Regulation in Medical Device Design and Manufacturing (4)

Complete one of the following:

RGA 6205 Emerging Trends and Issues in the Medical Device Industry (4)

RGA 6222 European Medical Device Regulations (4)

RGA 6243 Medical Device Product Development in Canada (4)

RGA 6275 Product Development and Process Validation (2)

RGA 6370 Advanced Regulatory Writing: Medical Device Submissions (4)

Quality Assurance Compliance

Complete one of the following:

RGA 6000 Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation (2)

RGA 6001 Introduction to Food and Drug Administration (FDA) Medical Device Regulation (2)

RGA 6461 Cybersecurity and Regulation of Digital Health Technologies by the FDA (2)

Complete the following:

RGA 6233 Application of Quality System Regulation in Medical Device Design and Manufacturing (4)

RGA 6234 Risk Management: Compliance and Processes (4)

RGA 6275 Product Development and Process Validation (2)

Choose from the following to reach 16 quarter hours:

RGA 6221 European Union Compliance Process and Regulatory Affairs (4)

RGA 6410 Fundamentals of CMC Reg. and Methods (4)

RFA 6220 Food Safety and Surveillance: Concepts and Applications (3)

Concentrations: 12 Semester Hours (SH)

Medical Device Regulatory Affairs

RGA 6610 Introduction to Food and Drug Administration Medical Device Regulation (3)

RGA 6620 Medical Device Development: A Regulatory Overview (3)

RGA 6630 Medical Device Quality Management System: Principles and Applications (3)

RGA 6640 Risk Management: Compliance and Processes (3)

Elective Option / Custom Concentration

A concentration is not required. Students may complete the electives option in lieu of a concentration.

