Professional Regulatory Affairs

Post-Graduate Program

AAPS

Who We Are

IN CLASS & ONLINE LEARING

CERTIFICATION UPON COMPLETION

About Us

AAPS is a registered college by the Ministry of Colleges and Universities since 2003 and recognized and approved by the International Association of Continuing Education and Training (IACET) – USA since 2011.

AAPS is a leader in training and professional development in the Food, Nutrition, Healthcare, Cosmetics, Clinical, Pharmaceutical, Cannabis, and Medical Device Industries.

We have developed an excellent reputation, strong track record, high student satisfaction and employment rating with domestic and international students. Our faculty is comprised of industry experts administering the latest curricula in modern classrooms and fully equipped laboratories. AAPS offers certificate and diploma programs in-class as well as online. Our program is comprehensive and cost effective with flexible payment plans and OSAP available for students (international and domestic).

Professional Regulatory Affairs Program

Program Outline

The AAPS Regulatory Affairs program includes courses on; International, Health Canada, and FDA's laws, regulations, and Guidelines, investigational and marketing applications, technical writing, negotiation skills, development of New Drug Application (NDA) submissions, labeling and drug Information, Electronic Common Technical Documents (eCTD), Notice of Compliance (NOC), Good Clinical Practices (GCPs), requirements for ongoing post-marketing surveillance and post-marketing changes, communication and management skills essential for the successful regulatory affairs professional in an industry work environment.

Program Details

- Certifications Awarded: Post-Graduate Diploma
- Duration: 28 Weeks
- Admission Requirement: BSc. (or equivalent) or higher level of education

Professional Regulatory Affairs Post-Graduate Diploma Program

PRA101 Introduction to Regulatory Affairs
This course is designed to provide students with an overview of the regulatory requirements and processes involved in the development, approval, and post-marketing surveillance of pharmaceutical products.

GMP1001 Introduction to Good Manufacturing Practices (GMP) Level I
This course provides an introduction to Good Manufacturing Practices (GMP) for individuals interested in working in the pharmaceutical, biotech, or food industries.

MFG1007 Introduction to Pharmaceutical Manufacturing Methods
Using step-by-step examples and interactive exercises, this course develops participants' knowledge of pharmaceutical mixing, mixers, excipients, solutions, ointments and creams.

GMP2001 Intermediate Good Manufacturing Practices (GMP) Level II
This intermediate course provides an in-depth examination of Quality Management System (QMS) in the pharmaceutical, biopharmaceutical, and medical devices industries.

PRA201 Pharma Regulatory Submissions, Labeling and Product Summaries
This course provides an in-depth understanding of the regulatory requirements and processes for pharmaceutical products involved in the submission, labeling, and approval of pharmaceutical products.

IN CLASS

ONLINE

IN CLASS

ONLINE

Professional Regulatory Affairs Post-Graduate Diploma Program

PRA303 Intellectual Property
This course provides a comprehensive understanding of Intellectual Property (IP) in the pharmaceutical industry, including the cost of research and development, product-to-market timelines, patents, data exclusivity, and other related topics.

PRA202 Regulatory Affairs for Clinical Research and Preclinical - Drugs
The Regulatory Affairs for Preclinical and Clinical course provides a comprehensive overview of drug development and regulatory compliance for professionals involved in preclinical and clinical research.

PRA301 Post Approval Activities and Compliance
Post-Approval and Marketing Activities is a comprehensive course that covers the essential aspects of pharmacovigilance, safety reporting regulations, and requirements for post-approval drug and medical device marketing activities.

TWR3009 Technical Writing and Scientific Communication
This course focuses on the technical writing skills required to prepare and review pharmaceutical documents such as Standard Operating Procedures (SOPs), change control documents, deviation reports, and other Good Manufacturing Practices (GMP) documents.

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PRA304 Chemistry, Manufacturing and Control
This course provides a comprehensive understanding of Chemistry, Manufacturing, and Controls (CMC) in the pharmaceutical industry, including the product life cycle, manufacturing processes and controls.

PRA305 Global Regulatory Affairs
This comprehensive course on Global Regulatory Strategies will provide participants with a thorough understanding of the regulatory requirements and processes for bringing products to market in various regions around the world.

CR010 Introduction to Clinical Research and Drug Safety
This activity is designed to orient students to the Drug Development Process, clinical research process, and how clinical safety and pharmacovigilance functions within the corporate and regulatory context from Canadian and international perspectives.

GMP3001 Advanced – Good Manufacturing Practices (GMP) Level III
This activity is designed to orient students to the Drug Development Process, clinical research process, and how clinical safety and pharmacovigilance functions within the corporate and regulatory context from Canadian and international perspectives.

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PRA302 Regulatory Affairs Generic Drugs
This course provides a comprehensive overview of the regulatory requirements for generic drugs including the development, submission process, and approval of generic drugs.

PRA205 Regulatory Affairs for Natural Health Products
This course on Regulatory Affairs (RA) for Natural Health Products (NHPs) will cover the essential aspects of the regulatory process for NHPs, including timelines and Quality Assurance (QA) requirements.

PRA203 Regulatory Affairs Biotech/Biologics
This course on Regulatory Affairs (RA) for Biologics and Biotechnology Products will provide an in-depth understanding of the regulatory framework and drug approval process for biologics.

PRA204 Regulatory Affairs Medical Device
This course on Medical Device Regulation will provide participants with an in-depth understanding of the regulatory requirements for medical devices. The course will cover Medical Device Classification and Quality Management, including Quality Management Systems (QMS) and the International Organization for Standardization (ISO) standards.

Career Services & Co-Op

Career Services & Co-Op

AAPS offers a dedicated Career Services Department for your career development as well as co-op job placements. We have worked diligently to develop partnerships with companies leading pharmaceutical, food and clinical companies across the GTA and Canada to provide direct industry experience to our graduates. In addition, we offer you one-on-one career management meetings with a Student Affairs Councilor, providing career advice and assistance in resume writing and honing your interview skills.

We also work collaboratively with companies to provide referral and placement services exclusive to AAPS students and graduates placing hundreds of prospective employees with leading companies!

Job Opportunities

Job Opportunities

Graduates of the Professional Regulatory Affairs Post-Graduate Diploma Program may work for pharmaceutical, biotechnological, medical device or natural health product companies. Trained and qualified RA professionals are in demand for pharmaceutical, biotech, medical device and natural health product companies as they are needed to navigate the intricacies of regulatory submissions for new products. Job opportunities upon graduation may include:

- Document Control
- Regulatory Affairs Associate
- Regulatory Affairs Assistant
- Project Coordinator
- QA Associate
- Manufacturing Auditor
- Quality Auditor

Organizations who have hired AAPS Graduates


gsk
GlaxoSmithKline


APOTEX
Innovating for
patient affordability


AstraZeneca


Pfizer


calea.


AGRISAN
Specialty Chemical
and Pharmaceutical


Health
Canada


SANOFI PASTEUR


Roche


ThermoFisher
SCIENTIFIC


SGS


Baxter

Contact Us

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