Pharmaceutical Regulatory Affairs Certificate (Online)

Certificate Program Overview

AAPS' Regulatory Affairs Certificate Program focuses on introducing the basic requirements for regulatory affairs professionals applicable to the Canadian, U.S. and international pharmaceutical, cosmetic and food industries.

Apart from an overview of the regulatory affairs terms, basic principles and regulatory pathways for product licensures, students will dive into the Good Manufacturing Practices (GMP) and learn how these standards contribute to the manufacturing of safe, effective and regulation compliant pharmaceuticals. This online certificate will also cover the Chemistry, Manufacturing and Control (CMC) requirements for both the product substance and drug product in accordance with the ICH guidelines. Students will also get a deep understanding of preclinical and clinical submissions, such as Clinical Trial Applications (CTA), New Drug Submissions (NDS), and Abbreviated New Drug Submissions (ANDS), they will get some hands-on training on the Common Technical Document (CTD) format, as well as labelling and product summary requirements, including Product Monographs, Package Inserts and Summaries of Product Characteristics.

Certificate Program Outline

- Introduction to Regulatory Affairs
- Good Manufacturing Practices (GMP) (Level I)
- Regulatory Submissions and Preclinical – Drugs
- Chemistry, Manufacturing and Controls (CMC)
- Labelling and Product Summaries

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Program Details

Program Tuition Fees	Duration	Mode
CAD $3,950	11 Weeks	Online

Course Outline

	Course	Code	Cost
1	Introduction to Regulatory Affairs	PRA101	CAD $945
2	Good Manufacturing Practices (Level I)	GMP1001	CAD $895
3	Pharma Regulatory Submissions, Labeling and Product Summaries	PRA201	CAD $995
4	Regulatory Affairs for Clinical Research and Preclinical - Drugs	PRA202	CAD $850
5	Chemistry, Manufacturing and Control (CMC)	PRA304	CAD $850