## ADMINISTRATIVE INFORMATION

The Hoffmann-La Roche Industrial Pharmacy Residency Program – Specialty in Global Product Development Regulatory is coordinated jointly with the Faculty of Pharmacy, University of Toronto. The Resident receives insight and direction from the Faculty of Pharmacy Liaison and the Roche Residency Program Director. Together, these individuals cooperate to maximize the Resident's experiences at Hoffmann-La Roche Limited.

This program is not suited for individuals with advanced academic degrees and research experience or with extensive related work experience.

Applications and further information about the Industrial Pharmacy Residency Programs can be obtained by contacting the:

Leslie Dan Faculty of Pharmacy
University of Toronto
144 College Street
Toronto, ON M5S 3M2
Tel: 416-978-2889
Fax: 416-978-8511

https://pharmacy.utoronto.ca/programs-and-admissions/residency-programs/industrial-pharmacy-residency-program

## HOFFMANN-LA ROCHE LIMITED

Founded in 1896 in Basel, Switzerland, Hoffmann-La Roche Limited, also known as Roche, has grown from a small drug laboratory into one of the world's leading research-based healthcare companies.

Celebrating more than 75 years of business in Canada, Roche enjoys a global perspective on research, drug development and marketing.

Roche is one of the few companies in Canada that combine the disciplines of pharmaceuticals and diagnostics. Together, they enable us to cover the entire healthcare spectrum, from predisposition and screening, to prevention and diagnosis, to therapy and monitoring. Our operations are centered in Mississauga, Ontario (pharmaceuticals) and Laval, Quebec (diagnostics).

At Roche, we believe that innovation is the key to success in today's highly competitive pharmaceutical market and the company values a performance culture that sets ambitious goals and rewards achievement. Roche encourages courageous leadership and cooperative teamwork that demonstrates respect for people and a commitment to ethical business practices.

Hoffmann-La Roche Limited is located at:
7070 Mississauga Road
Mississauga, ON
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Fax: (905) 542-7130

www.rochecanada.com

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.



Hoffmann-La Roche Limited
Mississauga, ON L5N 5M8

PDS 02/19

# Hoffmann-La Roche Industrial Pharmacy Residency Program

## *Specialty in Product Development Regulatory (PDR)*

## INDUSTRIAL PHARMACY RESIDENCY PROGRAM

Hoffmann-La Roche offers specialty residencies in Medical Affairs and Global Product Development Regulatory.

The specialized Industrial Pharmacy Residency Program in Global Product Development Regulatory Affairs is targeted towards recent graduates of pharmacy programs and is designed to be exploratory, project based and self-directed. The Resident will focus on Global Product Development Regulatory Affairs to develop an in-depth knowledge and experience in this discipline.

## OBJECTIVES

Upon completion of the program, the Resident will have sufficient knowledge and experience in Global Product Development Regulatory Affairs to enable him/her to pursue future career entry opportunities in this practice setting of the pharmaceutical industry. Key objectives of the program include:

- Understand the importance of the role of the global pharmaceutical industry in the provision and improvement of health care
- Understand the role of the Global Product Development Regulatory Affairs Department within the company
- Recognize the variety of opportunities available to pharmacists in industry
- Strengthen communication skills and problem-solving skills

## PROGRAM CONTENT

Fulfillment of the objectives will be facilitated through completion of multiple projects and activities within one of the four Product Development Regulatory Affairs departments: Regulatory Documentation; Labelling; Program Management; and Operations: and some of which will allow the Resident to have cross functional exposure with other departments within the company.

Examples of projects and activities include:

- Using effective oral and written communication skills
- Interpreting and analyzing clinical and safety drug information for Roche products
- Evaluating and critiquing published medical literature

### Product Development Regulatory Documentation (PDRD)

- Scheduling, writing, editing, publishing and distribution of Medical (Clinical and Safety) documentation for submission to global regulatory agencies
- Participation in the resourcing/outsourcing activities of clinical and safety documents in accordance with approved vendors
- Actively support the project management of report deliverables, assisting in tracking and overseeing key milestones

### Product Development Regulatory Labelling (PDRL)

- Participate in the development and update of Core Data Sheets (CDS) in partnership with Regulatory Program Management and cross-functional experts
- Provide regulatory labelling guidance and advise Life Cycle Team (LCT)/Established Products Team (EPT) and internal working groups on CDS content
- Ensure changes and safety signals from CDS updates are implemented into local product labels
- Participate in the development of general and issue related label strategies with a focus on USPI, EU SmPC and Key Claims documents

### Product Development Regulatory Program Management (PDRP)

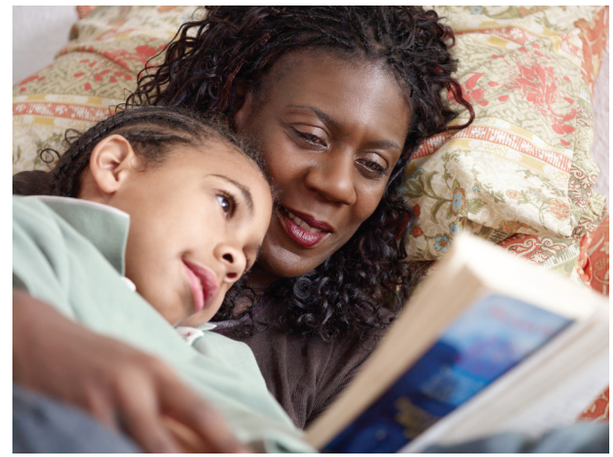
- Participate in the development and implementation of global and local innovative regulatory strategies for the development and maintenance of Established Products
- Providing guidance on regulatory procedures and requirements
- Research and support development of regulatory strategic options and assessments of risk for business critical decisions
- Participate in new filings (e.g. new indications, new formulations) based on business needs and/or global Health Authority requirements as appropriate

### Product Development Regulatory Operations (PDRO)

- Provides coordination, compilation, publishing, and submission expertise in preparation of new and existing regulatory applications.
- Working closely with Regulatory and cross-functional colleagues, the team supports the preparation of high-quality dossiers that meet the requirements of health authorities worldwide.
- Provides effective and efficient management of regulatory information and standards through planning, tracking, submission, and archiving of the information within our systems

The Resident is also required to complete a major research-based project that supports Roche business and/or departmental objectives and that is satisfactory to the University of Toronto, Faculty of Pharmacy.

The duration of the program is 52 weeks (one year).



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