Hoffmann-La Roche Industrial Pharmacy Residency Program

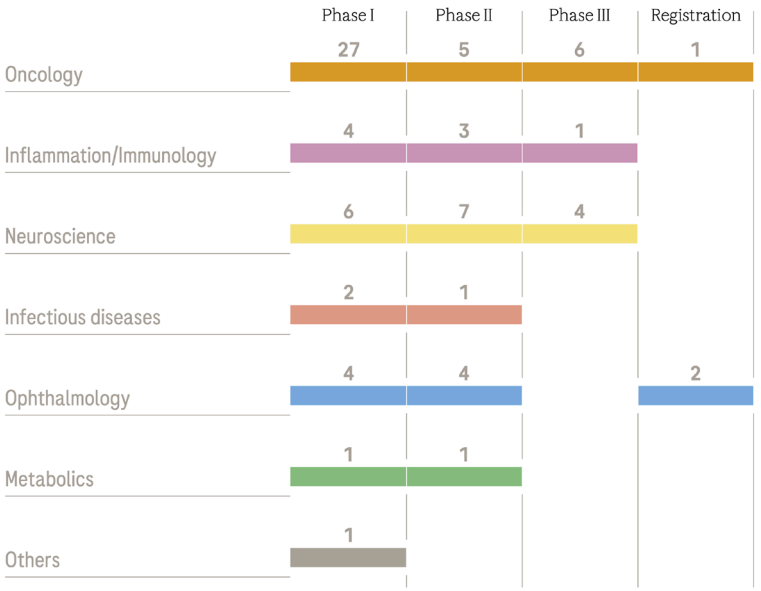
Specialty in Product Development Regulatory (PDR)

Our Purpose

We believe it's urgent to deliver medical solutions right now – even as we develop innovations for the future. We are passionate about transforming patients' lives. We are courageous in both decision and action. And we believe that good business means a better world.

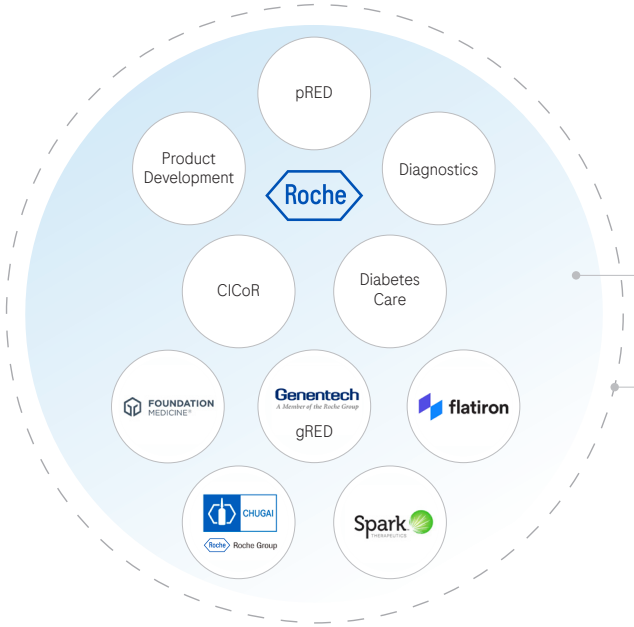
That is why we come to work each day. We commit ourselves to scientific rigor, unassailable ethics, and access to medical innovations for all. We do this today to build a better tomorrow.

We are proud of who we are, what we do, and how we do it. We are many, working as one across functions, across companies, and across the world.



Our pipeline of 80 new molecular entities covers a broad range of diseases, and highly innovative technologies are applied to create and produce the active molecules.

*Adapted from 2021 Roche Annual Report



Roche **Group** Innovation Engines

> 250 Partners

pRED -
Roche Pharma Research & Early Development

gRED -
Genentech Research & Early Development

CICoR -
China Innovation Centre of Roche

*Adapted from www.roche.com/innovations

ROCHE		GENENTECH
	1985	Protropin
	93	ACTIVASE ALTEPLASE
	93	Pulmozyme dornase alfa
		Nutropin®
CellCept (mycophenolate mofetil)	95	
	96	NutropinAQ NuSpin (somatropin (rDNA origin) injection)
	97	Rituxan Rituximab
Xeloda capecitabine	98	Herceptin trastuzumab
Tamiflu	99	
	2000	TNKase
Valcyte	01	Cathflo Activase (alteplase)
PEGASYS peginterferon alfa-2a (40KD)	02	
	03	Xolair Omalizumab
	04	AVASTIN bevacizumab
		Tarceva erlotinib tablets
	06	LUCENTIS RANIBIZUMAB INJECTION

ROCHE		GENENTECH
(Continued)		
ACTEMRA tocilizumab	10	
ZELBORAF (vemurafenib) tablets	11	
	12	PERJETA pertuzumab
		Erivedge (vismodegib) capsules
GAZYVA obinutuzumab injection	13	Kadcyla ado-trastuzumab emtansine for injection
Esbriet (pirfenidone) capsules	14	
ALECENSA alectinib	15	COTELLIC (cobimetinib) tablets
	16	VENCLEXTA venetoclax tablets
		TECENTRIQ atezolizumab
HEMLIBRA emicizumab	17	OCREVUS ocrelizumab
xofluza (baloxavir marboxil)	18	
ROZLYTREK entrectinib	19	POLIVY polatuzumab vedotin
ENSPRYNG satralizumab-mwge	20	PHESGO pertuzumab/trastuzumab/hyaluronidase-zzxf
Evrysdi risdiplam	21	SUSVIMO ranibizumab injection
GAVRETO pralsetinib		
VABYSMO faricimab-svoa injection	22	

Industrial Pharmacy Residency Program

Hoffmann-La Roche offers specialty residencies in 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 the 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 and promote the value of a clinically-trained pharmacist within the pharmaceutical industry.

Develop highly marketable skills for employment opportunities within the pharmaceutical industry.

Regulatory Affairs

Overview

Successful drug development within the pharmaceutical industry requires compliance with global regulations and collaboration with global health authorities. Regulatory professionals provide the interpretation of global regulations within their companies to facilitate drug development that meets the needs of Health Authorities, patients, and prescribers. Regulatory professionals are responsible for the design and implementation of regulatory strategies to optimally develop, license, and market products globally.

At Roche, Regulatory Affairs Residents will receive individual guidance from regulatory professionals and obtain an understanding of the regulatory roles and responsibilities in the drug development process. Each Resident will learn how to apply regulations and health authority guidances in the drug development process, develop regulatory strategies in collaboration with global project teams, and interact with Health Authorities.

Fulfillment of the objectives will be facilitated through completion of multiple projects and activities within our Product Development Regulatory Affairs department. The following areas will allow the Resident to have cross functional exposure within the department.

Documentation

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.

Labelling

Participate in the development and update of Core Data Sheets (CDS), USPI and EU PI in partnership with Regulatory Program Management and cross-functional experts

- Participate in the assessment and development of general and issue related label strategies
- Provide regulatory labelling guidance and advise Life Cycle Team (LCT)/Established Products Team (EPT) and internal working groups on CDS, USPI and EU PI content
- Ensure changes and safety signals from CDS updates are implemented into local product labels
- Participate in the development of Key Claims documents

Program Management

- Participate in the development and implementation of global and local innovative regulatory strategies for the development of Roche 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

Operations

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

Residency Components

Mentorship Program

The mentorship program pairs Residents with experienced mentors currently on their team. This provides the Residents with additional support in their day-to-day activities outside of their co-residents and managers. The mentorship program aims to give Residents continued career guidance and professional development.

Networking Opportunities

- **Pharmacy Network**
  - Network with other pharmacists within and outside the department at Roche
  - Network and seek guidance from past U of T Pharmacy Residency alumni
- **Roche Canada Health Care Professionals (HCP) Network**
  - Network with other HCPs working within the Canadian organization
- **Roche/Genentech Residents/Fellows/Interns Network**
  - Network with professionals completing training programs at Roche/Genentech at other global sites in South San Francisco, Basel, and Welwyn

Rotation Opportunity

At Roche, we prioritize the development of each Resident. Our residency is structured to maximize exposure to various roles within industry, specifically within regulatory affairs. We offer a rotational opportunity during the Resident's second year in order to gain hands-on experience in an additional functional area of interest outside of PDR.

Residency Project

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.

Regulatory Affairs Certification (RAC)

Regulatory Affairs Certification (RAC) is the professional credential for regulatory professionals in the healthcare product sector. It is intended for individuals employed in regulatory agencies, industry, consultancies and other settings involved with the regulation of healthcare products. Upon passing the Regulatory Affairs Certification test, the individual will be recognized by the RAC and eligible to put 'RAC' after their name. Roche is fully supportive for residents to pursue the RAC certification during their residency term.

The duration of the program is 104 weeks (two years).

Roche Residency Alumni Careers

- Senior Documentation Scientist, Product Development Regulatory, Roche
- Program Manager, Program Management, Product Development Regulatory, Roche
- Associate Director, Program Management, Product Development Regulatory, Roche
- Labeling Program Manager, Product Development Regulatory, Roche
- Senior Associate Labeling Manager, Product Development Regulatory, Roche
- Program Manager, Program Management, Global Product Technical Regulatory, Roche
- Clinical Project Manager, Product Development Regulatory, Roche
- Lead Clinical Scientist, Product Development Neuroscience, Roche
- Associate Regulatory Submissions Manager, Product Development Regulatory, Roche
- Quality Solutions Leader, Product Development Quality, Roche
- Patient Experience - Patient Support Programs, Roche
- Evidence Generation & Strategic Collaborations, Roche
- Engagement Manager, Clearview Healthcare Partners
- Medical Science Liaison, Takeda
- Medical Science Liaison, Boehringer Ingelheim
- Medical Science Liaison, Lundbeck
- Medical Science Liaison, Ferring
- Field Medical Advisor, Pfizer
- Medical Director, Sanofi
- Scientific Evaluator, Health Canada

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

Who We Are

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:

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www.rochecanada.com

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

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