Regulatory Affairs
Postgraduate Training Program
Regulatory Affairs Postgraduate Training Program

Regulatory Affairs (RA) Postgraduate Training Program will enable you to gain more regulatory relevant knowledge and gain first hand experience, contributing in a number of cross-functional areas in our dynamic RA network. The diversity of the Novartis research and development portfolio provides a great opportunity for gaining broad experience of RA activities.

“The Regulatory Affairs (RA) Postgraduate Training Program is an opportunity to discover the global functions of Regulatory Affairs.”

Susan Longman
Head RA, Region Europe

“The Regulatory Affairs Postgraduate Training Program is a unique opportunity to elaborate on a strong foundation in Regulatory Affairs to build your future career. It will not only enable you to transfer your theoretical know-how into practice but also to grow your internal network by working on different assignments and rotating through different functional areas to gain a wide perspective and solid foundations in Regulatory Affairs.”

Robert Kowalski
Global Head RA

“The Regulatory Affairs Postgraduate Training Program will enable you to expand your regulatory knowledge, getting familiarized with dossier content and acquire a significant practical experience through cross-functional projects in different areas in a dynamic environment to build on your potential future career at Novartis.”

Diane Zezza
Global Head Regulatory RA CMC
Mission of Regulatory Affairs (RA)

RA aims to secure industry best approval times with commercially attractive labeling and ensures compliance with company policy, national regulations and laws through development, registration and approval/post-approval phase. RA also aims to provide strategic input and tactical support for global development projects and throughout product life-cycle.

The RA organisation is structured around Development Units representing a number of therapeutic areas such as Oncology or Cardio Metabolic, as well as CMC (Chemistry, Manufacturing and Controls), Regional and Global Strategy and Excellence Groups (line functions).

RA has an impact on business by advising on clinical development plans, achieving competitive new product registrations, supporting maintenance and executing regulatory compliance.
Activities covered by RA and/or RA CMC:

- Interact globally with interdisciplinary project teams to provide strategic input and tactical support to expedite the development, submission, and regulatory approval of new drug or biologic products.
- Prepare high quality dossiers, drug substance and/or drug product quality documentation to support global regulatory submissions (e.g. Clinical Trial applications, MAA Applications, post-approval variations, etc.).
- Serve as the primary liaison between Novartis and Health Authorities worldwide for regulatory activities and submissions.
- Lead submission and response activities (planning, preparation, review, coordination, submission) as key Health Authority (HA) contact.
- Develop and globally maintain consistent product information.
- Ensure regulatory compliance by creating awareness of requirements and guidelines, facilitating timely variations submissions and participation in the change control operations.
- Lead Intelligence Networks and comment on draft regulatory guidelines and legal framework.
- Prepare adequate training documentation.

Program concept

RA Postgraduate Training Program

The RA Postgraduate Program will enable you to grow professionally and gain practical experience by rotating through different groups. It will provide a solid foundation for your future career in RA.
Qualification and minimum requirements

- Strong interest in Regulatory Affairs and Drug Development

- Completion of an MSc, PhD or Post-doctoral qualification in Pharmaceutical Sciences/Pharmacy/Life Science or equivalent and in Regulatory Affairs (desirable) within the last 18 months;

- Fluency in English;

- Ready to expand your knowledge and are open minded with an international outlook

- Strong interpersonal skills i.e. can demonstrate the ability to communicate well with people from a variety of backgrounds/cultures in a matrix environment

Novartis is an equal opportunity employer committed to embracing and leveraging diverse backgrounds.

How to apply

To apply please access the Novartis Career website at www.novartis.com /careers search for the program and submit your application online.
Qualification and minimum requirements