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Regulatory Affairs

Postgraduate Training Program

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Regulatory Affairs Postgraduate Training Program

The RA Postgraduate training program will enable you to develop extensive regulatory knowledge and hands-on experience, by contributing to diverse activities across the entire life cycle of pharmaceutical products and within a dynamic cross-functional environment. The diversity of the Novartis research and development portfolio provides a great opportunity for gaining broad experience of RA activities.

“The Postgraduate program is a training program aimed to provide a broad regulatory knowledge and gain first hand experience, by contributing to a number of cross functional areas in the dynamic RA Novartis network. This training program encourages the individuals to be curious, pro-active and engaged and also provides a solid foundation for a career in Regulatory Affairs.”

Janina Dzambazosk
Head RA, Region Europe

“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 in RA at Novartis.”

Diane Zezza
Global Head Regulatory RA CMC

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

“The history of the Novartis Postgraduate Regulatory Affairs training program is something that I am very proud of. For many years, the program has provided unparalleled experiential training in the area of regulatory science, across all of the functional disciplines in Regulatory Affairs, to many bright young professionals that have gone on to have very successful careers in medicinal product development. It also has been an essential source of talent for our Regulatory Affairs function at Novartis and I look forward to seeing its continued success.”

Kevin Carl
Global Head RA

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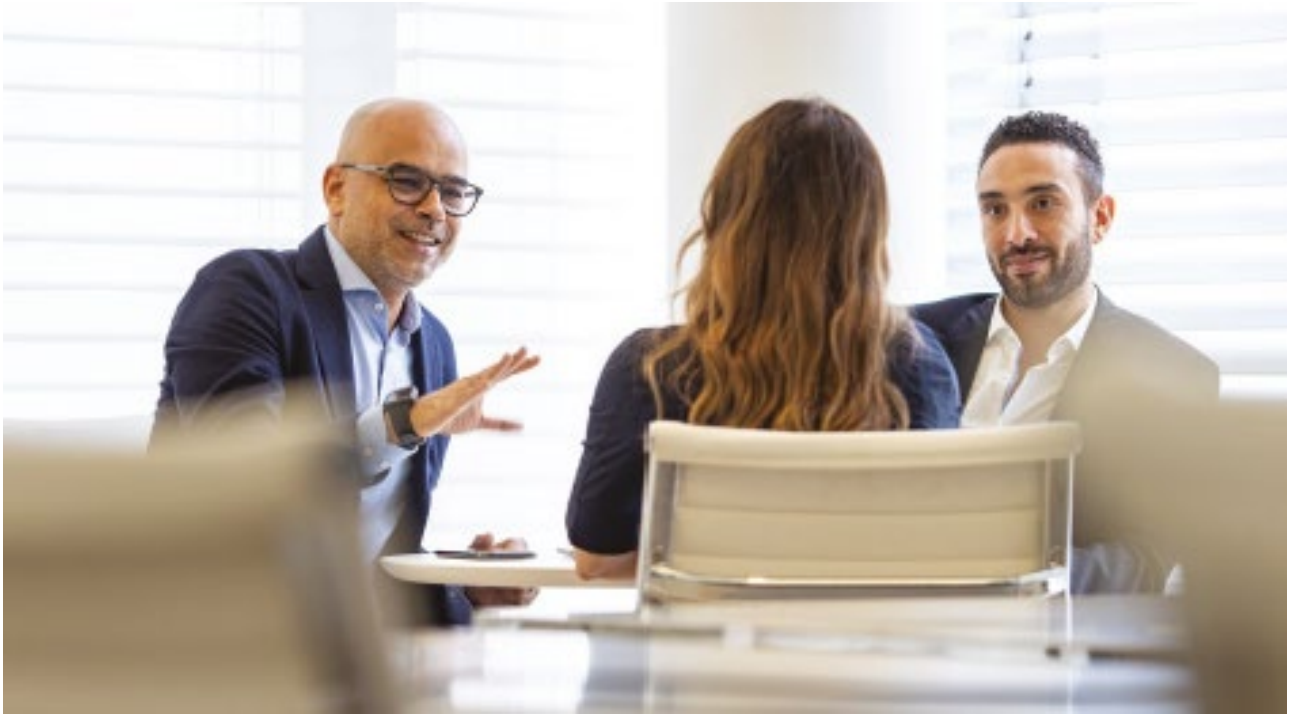
Mission of Regulatory Affairs (RA)

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.

RA Organisation

The RA organisation is structured around Development Units representing a number of therapeutic areas such as for example 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.



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Activities covered by RA and/or RA CMC (non-exhaustive list)

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.).

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 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 internal training documentation.

Program concept

First rotation (from Jan to Dec)	Second rotation (from Jan to Dec)
Development Unit, CMC or Line Function	Development Unit, CMC or **Line Function**
Objective Setting, Training & Appraisal	Objective Setting, Training & Appraisal

2 year rotational program

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

Find more information at
novartis.com/careers/career-programs

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Qualification and minimum requirements

- Strong interest in Regulatory Affairs and Drug Development
- Completion of a PharmD, MSc, PhD or Post-doctoral qualification in Pharmaceutical Sciences/Pharmacy/Life Science or equivalent and in Regulatory Affairs (desirable) within the last 24 month
- Fluency in English
- CV and Cover letter in English, articulating clearly your motivation(s) to join the program and regulatory affairs
- 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 and at different hierarchical levels inside and outside the company

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

To apply, please follow the link
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For more information, please follow the link
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