

Novartis Business Services
HR University Relations



Regulatory Affairs

Postgraduate Training Program





Regulatory Affairs Postgraduate Training Program

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

“The Regulatory Affairs (RA) Postgraduate Training Program is an opportunity to discover the global functions of Regulatory Affairs (RA) and RA Chemistry, Manufacturing and Controls (RA CMC).”



Mission of Regulatory Affairs (RA) and Regulatory Chemistry, Manufacturing and Controls (RA CMC)

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 product life-cycle management.

The RA organisation is structured around **Global Franchises** representing different therapeutic areas such as Oncology or Established Medicines, **Regional and Global Strategy and Excellence Groups** are representing the backbone of all Business Franchise activities.

RA CMC aims to provide regulatory strategic input to enhance the quality of technical activities and produce high quality regulatory CMC dossiers for both pre- and post-approval submissions. RA CMC also supports the regulatory requirements for formulation, scale-up, product launch and site transfer activities throughout the product lifecycle from concept to commercialization and divestment. RA CMC operates in collaboration with RA across all therapeutic areas.

Regulatory Affairs 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 regulatory input to development, plan submission strategy, communicate submission documentation needed as well as timelines and strategic risks
- 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.)
- Prepare high quality dossiers according to specific requirements in the different countries and regions
- Lead submission and response activities (planning, preparation, review, coordination, submission) as key Health Authority (HA) contact
- Ensure regulatory compliance by creating awareness of requirements and guidelines, facilitating timely variations submissions and participation in the change control operations
- Develop and globally maintain consistent product information
- Lead Intelligence Networks and comment on draft regulatory guidelines and legal framework
- Monitor, search for and evaluate legislation as well as guidelines from different sources. Prepare adequate training documentation.

Program concept

Regulatory Affairs Postgraduate Program



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.



Comments from current and successful Graduates and Postgraduates and current interns

By stepping into this program in Novartis, I've gained a comprehensive overview of drug development, benefited from a first-rate training in key aspects of RA, and built on my aptitude to work in a distinctly multinational matrix environment. Moving through a variety of roles within RegCMC, the Oncology Business Unit and Global Labeling, I managed clinical trial applications, tailored the original MAA dossiers and even coordinated the creation of core labeling for exciting game-changing cancer immunotherapies. Not only did I join a network of industry recognized experts shaping the regulatory future, but I also discovered a stimulating work culture which embraces your creativity, and inspires you to dream big about what you can achieve.

Sonja Nektarijevic, Postgraduate in RA Global Labeling (joined Novartis as RA intern in April 2014)

Thanks to this Regulatory Affairs Graduate and Post-Graduate Program, I could rotate in different groups (Business Franchises, Global Regulatory CMC and DRA Global Labelling). In those groups I could work on a variety of regulatory activities covering the whole drug lifecycle and including Reg CMC tasks. The knowledge and the network acquired help me a lot now in my current GPRM role.

Fiona Dillschneider, Global Program Regulatory Manager in Oncology (joined Novartis as RA intern in 2011)

I started in Novartis in March 2014 as an intern in the Global Labeling department, and then joined the Postgraduate program, where I rotated in the Respiratory Franchise and in the RegCMC group. Being part of this program gave me the opportunity to get hands-on experience on a variety of regulatory topics and led me to interact with many different stakeholders. It allowed me to increase my regulatory knowledge, develop my communication skills and grow a network of colleagues that I often reach out to for advice or simply for sharing lunch.

Gaëlle Le Provost, Regulatory Affairs Manager in PIE (joined Novartis as RA intern in 2013)

I joined Novartis as a graduate in Regulatory Affairs CMC department followed by two rotations within the post-graduate program in RA Global Labeling and RA Cardio-Metabolic Franchise. The postgraduate program was a great opportunity for me to expand my knowledge and gain experience in Regulatory Affairs. Furthermore, working on various regulatory activities through all lifecycle of a drug product such as development and post-marketing phases settled the basis of my career in RA. Following the post-graduate, I achieved my project to get a position as a Global Program Regulatory Manager in RA Cardio-Metabolic Franchise.

Cécile Hauschka, Global Program Regulatory Manager in Cardio-Metabolic (joined Novartis as RA intern in 2013)

The Regulatory Affairs Graduate and Postgraduate Program gave me the opportunity to apply and strengthen the knowledge acquired during my studies. I worked in different groups within the Regulatory Affairs department (Global Labeling and Business Franchises) where I could expand my regulatory expertise and acquire a practical experience on development and post-marketing activities, such as clinical trials, type II variations for the registration of a new indication, core data sheet updates and divestments; practical experience that I can now apply in my day to day work as GPRM. These programs are thus a very good opportunity to build and start a promising career within the challenging and dynamic environment of the pharmaceutical industry.

Gaëlle Enderlin, Global Program Regulatory Manager in Immunology and Dermatology (joined Novartis as RA intern in 2011)

The Graduate and Postgraduate Program in Regulatory Affairs is one of the best platforms to start your career in the pharmaceutical industry as it combines high-level training and hands-on experience in the heart of drug development. Coming from an engineering background, when I first joined the Neuroscience Business Franchise as a Graduate, I was completely new to the field of RA and by supporting the global team in charge of all post-approval regulatory activities of a blockbuster marketed drug, I got to grow a lot as a professional, get expertise in regulatory affairs and discover the extensive impact we have in the business. Later, by joining the team of RegCMC Biologics for my first rotation as a Postgraduate, I got to discover a new field within RA where I could better combine my technical background and my regulatory knowledge, which was at the end the perfect career fit for me.

Andres Ricardo Lopez, RegCMC Manager in BTDM (joined Novartis as RA intern in 2015)

Qualification and requirements

You are recognized for your skills in your field and you have just completed your Master studies in Sciences (e. g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology, Veterinary Medicine) or equivalent and Regulatory Affairs.

Candidates who recently completed a PhD or a postdoc are welcome to apply to the Postgraduate Training Program.

RA Postgraduate Training Program

- Strong interest in Regulatory Affairs and Drug Development
- Master studies in Life Sciences or equivalent and in Regulatory Affairs (desirable)
- Fluency in English; additional languages, e. g. German or French are welcome
- Ready to expand your knowledge and are open minded with an international outlook
- Strong interpersonal skills, i.e. can demonstrate your ability to communicate well with people from a variety of backgrounds / cultures and at different hierarchy levels inside & outside the company

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 respective Job ID of the program and submit your application online for the respective Job ID.



