# QA Compliance Expert – Reg CMC Facilitator

Job ID
REQ-10023720
Ott 03, 2024
Austria

## Sommario

Supporting product registration and maintenance throughout the product life cycle by aligning regulatory strategies and reviewing documents related to CMC (Chemistry, Manufacturing & Control). This applies to site specific (global and local) products and is intended to ensure timely market supply in compliance with regulatory requirements. Supporting change control and inspection management within the QA Compliance Team.

Relocation for this role will not be supported from the company. Please think about it when applying to this role.

## About the Role

**Key Responsibilities:**

- Contact person for regulatory matters and intermediary between RA CMC and Production Unit for strategy decisions and in the product life cycle.
- Maintaining close cooperation with RA CMC to discuss regulatory requirements, strategies and knowledge of global product dossiers to stay up-to-date.
- Support of timely reviews of CMC documents for defined products, as well as support with and identification of challenges in the course of regulatory compliance audits.
- Coordination, guidance, and support in the preparation of CMC responses to health authorities for specific products.
- Conducting training to ensure appropriate knowledge and regulatory compliance.
- Supporting the area in effective change control. Examination of reg. relevance and pre-evaluation amendments to Novartis and customer products.
- Implementation and overview of initiatives to improve (regulatory) compliance.

**Essential Requirements:**

- Bachelor or academic degree in Chemistry, Biology, Pharmacy, Biotechnology or equivalent.
- Fluent English (German desired).
- More than 3 years of experience in an operational GxP area, in Manufacturing, Development, QA or Regulatory Affairs; with a thorough knowledge of biologic drug product manufacturing processes.
- Ability to speak up and to take Quality decisions during challenging situations.

**Desirable Requirements:**

- Regulatory CMC experience preferred.

- Expertise in organization dynamics and culture, ability to gain trust and confidence at all levels in the organization, leadership, and project management experience.
- Ability to work independently and effectively in international, complex, and multifaceted environments.

**Why Novartis?**

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

**You'll receive:**

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group. In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is € 64.023,54/year (on a full-time basis). In most cases, the actual salary will be higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

**Commitment to Diversity & Inclusion:**

Novartis is committed to building an outstanding, inclusive working environment and diverse teams, representative of the patients and communities we serve.

**Adjustments for Applicants with Disabilities:**

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

**Join our Novartis Network:**

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

https://talentnetwork.novartis.com/network

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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Operations
Business Unit
Innovative Medicines
Posizione
Austria
Sito
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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