QA Compliance Expert – Reg CMC Facilitator

Job ID
REQ-10013378
Juli 01, 2024
Indien

Summary

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

About the Role

QA Compliance Expert – Reg CMC Facilitator

Location - Hyderabad

About the Role:

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

Key Responsibilities:

- Maintaining close cooperation with RA CMC to discuss regulatory requirements, strategies and knowledge of global product dossiers to stay up-to-date.
- 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 products and customer products.
- Contact person for regulatory matters and intermediary between RA CMC and production unit at strategy decisions and in the product life cycle.
- Support of timely reviews of CMC documents for defined products; Support with and Identification of challenges in the course of regulatory compliance audits.
- Implementation and overview of initiatives to improve (regulatory) compliance.
- Coordination, guidance, and support in the preparation of CMC responses to health authorities for specific products.

Essential Requirements:

- Advanced University or academic degree in chemistry, biology, pharmacy, engineering or equivalent.
- Fluent English (German desired).
- More than 3 years of experience in an operational GxP area, in Manufacturing, Development or QA or

Regulatory Affairs; with a thorough knowledge of biologic drug substance manufacturing processes for recombinant proteins and/or nucleic acids.
- Ability to speak up and to take Quality decisions during challenging situations.

Desirable Requirements:

- 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

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

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

Division
Operations
Business Unit
Innovative Medicines
Standort
Indien
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work

No
Apply to Job

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

EEO Statement :

Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.

Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.

Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create

sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.

Job ID
REQ-10013378

QA Compliance Expert – Reg CMC Facilitator

Apply to Job

Source URL: *https://qa1.novartis.de/de-de/careers/career-search/job/details/req-10013378-qa-compliance-expert-reg-cmc-facilitator*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/QA-Compliance-Expert---Reg-CMC-Facilitator_REQ-10013378-1
4. mailto:diversityandincl.india@novartis.com
5. https://talentnetwork.novartis.com/network
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/QA-Compliance-Expert---Reg-CMC-Facilitator_REQ-10013378-1