NOVARTIS

QA Compliance Expert – Reg CMC Facilitator

Job ID
REQ-10013378
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India

Περίληψη

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

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Location - Hyderabad

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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

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

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