U NOVARTIS

QA Compliance Expert - Reg CMC Facilitator

Job ID REQ-10013378

9月 03, 2024

India

摘要

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

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 preevaluation 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.

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部门 Operations

Business Unit Universal Hierarchy Node

地点 India

站点

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

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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 <u>diversityandincl.india@novartis.com</u> and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Page 6 of 6