QA Compliance Expert – Reg CMC Facilitator

Job ID
REQ-10013378
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India

Sommario

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.

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