NOVARTIS

Country Quality Specialist

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India

Resumen

Monitor quality governance and compliance in the Country organization in all GxP related areas (Supply chain, C&F Ware house, Market Compliant, etc) to ensure that all aspects of the operational business comply with cGxP, legal and regulatory requirements and the Novartis Pharma Corporate Quality Manual and Policies. Prevent significant quality issues or regulatory non-compliance which could lead to product stock-out or withdrawal, product approval delays or which would negatively impact the financial performance of the company as well as the reputation.

About the Role

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Location - Hyderabad

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Key Responsibilities:

- Ensure implementation, maintenance and upgrading of the local Quality System and Standard Operating Procedures in order to drive compliance of all cGXP and Pharmacovigilance related processes and tasks with local/International regulatory requirements and the Novartis Quality Manual.
- Actively involved in ensuring quality governance and quality planning in the Country organization through the establishment and implementation of the annual Quality Plan, appropriate Key Quality Indicators, and Quality Risk Assessments.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all GxP related activities and that compliance with cGMP is maintained through training and internal audits.
- Ensure that all drug products are released in accordance with the registered specifications and are released to the market in accordance with local regulations and ensure that a respective Change Control procedure is in place. (Batch Release).
- Ensure that all aspects of the handling and distribution of pharmaceutical products at Novartis India Limited through Central Warehouse & C & F's comply with the requirements of the Novartis Pharma

Quality Manual and Policies and meet all relevant cGMP, regulatory and legislative requirements.

- Visit, supervise and co-ordinate CPO Vendors(C&Fs, Stickering site etc) activities and ensure that vendor perform the respective activities are in compliance with Novartis Standards.
- Participate in resolving all Critical Quality Issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc) according to the Quality Assurance Agreement and the Novartis Pharma Quality Manual. Ensure investigations are correctly executed. Ensure they are updated in AQWA (Adaptable Quality Workflow Application)
- Ensure that Change requests, either from the External Supplier/Vendor or from Novartis CPO, are managed according to the Quality Assurance Agreement and/or Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for preparing Quality trends and driving Continuous improvement for processes and product quality performance.
- Provide the quality presence and in-put to Compliance / Technical meetings with the CPO Vendors and establish good working relationships with clear communication and defined actions and goals. In addition, provide support to internal functions (BD&L, CRO and other functions) by evaluation and decision of new products as per Novartis Pharma Quality Manual and standards. Perform the required periodic review and make recommendations for amendments to the evaluation based on identified needs and issues.

Essential Requirements:

- 2-3 years in QA / QC.
- Knowledge of cGMP and regulatory compliance of all relevant operations like C and F cold chain etc.
- Proficient in communicating with vendors and internal customers. Good in presentation skills
- Interacting with people from interface functions in the local organisation. Support for resolving GMP and GxP related issues.

Desirable Requirements:

- B.Sc., B.Pharm Post graduate Diploma added advantage
- Fluent in English and proficient in local language.

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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Employment Type
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