NVS Compliance Quality RLT support (fixed term)

Job ID
REQ-10016965
Ago 05, 2024
Italia

Resumen

-Assurance that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements. Ensure that relevant documentation is up-to-date and archived correctly. Ensure “state of the art” GxP know-how and future trends in the field of GxP

About the Role

Major accountabilities:

- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.
- Prepare, review and check the batch documentation for correctness, completeness and safely archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections.
- Monitor actions and corrections accordingly.
- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, follow up the corrective actions.
- Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual.
- Ensure investigations are correctly executed.
- Ensure all required actions are taken appropriately and in a timely fashion.
- Escalate any issues or instances of instability per the Novartis escalation policy, and initiate any market action that is required.
- Decide escalation to Senior Management Level and lead Global Quality Assessments and manage filing accordingly as well as ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintain access to regulatory and Pharmaceutical authorities in respect to up-dated GxP ovide latest know how in the field of GxP and other quality related fields.
- Identify repetitive activities and regulatory areas for which SOPs are required.
- Initiate the introduction of SOPs.
- Plan, initiate and monitor basic GxP-training for all employees in regular intervals.
- Be responsible for annually training program and implementation.
- Establish and maintain cross-functional contacts with peer organization and authorities and, follow-up

quality related developments in the field of Pharmaceutical products -Support launches of product in close collaboration with BDand L partner and/ or development organization.
- Ensure that all drug products are released to the market in accordance with the registered specifications and with local/international regulations.
- Ensure that coordinated contact is maintained with all parties (the Regulatory Authorities, the local partners and stakeholders and Global QA.
-) -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Local GMP/GDP Quality System in place and continuously updated, asrequired -GMP/GDP risks proactively identified and effectively mitigated.
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Minimum Requirements:
Work Experience:

- Participating in volunteer / community projects.
- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Change Control.
- Continuous Learning.
- Dealing With Ambiguity.
- Guideline.
- Product Release.
- Qa (Quality Assurance).
- Quality Management.
- Regulation.
- Risk Management.
- Self Awareness.
- Technological Expertise.

Languages :

- English.

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

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Milano
Company / Legal Entity
IT08 (FCRS = IT008) Novartis Farma S.p.A.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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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