QA Manager ESO

Job ID
REQ-10043200
März 07, 2025
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Summary

Approve and maintain quality oversight with respect to supply of materials to Novartis, from global external suppliers of chemicals (strategic raw materials, Intermediates and Drug Substances) by working in Supply Relationship Teams. These materials are being supplied to multiple Novartis Technical Operation sites.
To ensure appropriate quality oversight, assessment and mitigation of quality risks that may potentially negatively impact the supply of purchased strategic ESO chemicals (regulatory starting materials, intermediates and API's), and to ensure that all aspects of the relationship and management thereof, are in compliance with cGMP's, legal and regulatory requirements, the Novartis Quality Manual and Policies.

About the Role

Key Responsibilities:

- Responsible for ensuring quality oversight for purchased API's and strategically important regulatory starting materials and chemical intermediates supplied into Novartis NTO sites worldwide.
- Participates in and approves changes of supplier qualification and certification status for all external Suppliers, and maintain all associated quality systems e.g. maintain and update documents related to the supplier qualification and monitoring.
- Participate in escalation of all potential quality issues as per the Novartis escalation policy to higher level management.
- Manage major and critical quality issues (Complaints, deviations, recalls, stability failures and any regulatory non-compliance identified, as applicable) according to the Quality Agreement and the Novartis Quality Manual. Ensure investigations are correctly executed.
- Perform risk assessments in case of specific quality events at supplier, including collecting relevant data from NTO sites and other stakeholders, and approval of site specific risk assessments where required. Evaluates risks for product quality and patient safety and proposes market actions
- Provide direction and support to third parties and ensure that they are qualified, achieve a high level of competence and are motivated to carry out their duties to ensure that the materials produced meet the Novartis quality, efficacy and safety requirements.
- Travel to external suppliers manufacturing sites during audits, continuous improvement activities or to resolve any issues.
- Responsible for preparing Quality Agreements and Quality Risk assessments for all External Suppliers within the responsibility of the team, and for maintaining of documentation in relevant IT systems.
- Support remediation of any gaps identified in Quality Systems and ensure any issues are addressed.
- Provide the quality presence and in-put to Technical Meetings with the external suppliers and establish good working relationships with clear communication and defined actions and goals.
- Request, review and process GMP documentation as defined by the Quality Agreement and Novartis

SOPs. Manage the Quality Aspects of the relationship in accordance with the effective Quality Agreement. Perform the required periodic review and make recommendations for amendments to the agreement based on identified needs and issues.

Essential Requirements:

- 15 years' experience in the pharmaceutical industry, with direct experience with API's. Experience in QA Operations, production, QC and/or other relevant operational areas, but must include minimally 5 years in QA, and 3 years of management and or project management experience.
- Thorough knowledge of cGMP requirements. Strong understanding of regulatory requirements for commercial products.
- Proven track record with FDA, EMEA and other Health Authorities. Strong understanding of risk assessment and risk management fundamentals/tools.
- Strong Technical understanding of pharmaceutical processes. Team and consensus builder, with definitive and authoritative decision-making ability

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