

Senior QA expert, ESO Large molecules

Job ID
REQ-10020228
Sep 03, 2024
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Summary

Ensure that for all Novartis products - manufactured by external supplier in scope of personal portfolio - all aspects of manufacturing, testing, release and distribution/import comply with international standards of GMP, regulatory requirements, the Novartis Group Quality Manual, and the applicable Quality Agreements.

About the Role

Senior QA expert, ESO Large molecules

Location – Hyderabad

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Key Responsibilities:

- Acts according to Novartis values and behaviors.
- Provides direction and formulates strategies to maintain and improve the external supplier quality oversight. Establishes and maintains quality relationship with suppliers in scope.
- Acts as Single Point of Contact (SPOC) for all quality related activities at assigned external suppliers. Provides the quality presence and input to technical meetings with the external suppliers and establishes good working relationships. External supplier quality related activities are further described in the subsequent paragraphs. Conducts all necessary trainings in due course to be suitably qualified to perform the assigned duties.
- Supplier qualification: Ensures a valid Quality Agreement in line with the requirements of the Novartis global template is in place and continuously amended to the business needs. Ensures current external supplier quality risk assessments are in place and appropriate actions are taken to mitigate potential risks.
- Ensures site readiness for regulatory inspections and quality audits and supports during such events.
- Routine monitoring: Assesses quality trends and drives continuous improvement including stability reports and annual product quality reviews. Critically assesses the performance of the product and process performed at the external supplier. Escalate any issues or instances of instability as necessary. Implements and monitors Key Performance Indicators (KPI) and ensures that all parts of ESO are working in a consistent manner against harmonized expectations. Initiates corrective actions when necessary and performs follow-up on resulting measures.

- Maintains relevant data bases in a timely manner with accurate information.
- Incident management: Manages all quality issues (complaints, deviations, OOX). Ensures investigations are correctly executed and all required actions are taken appropriately and in a timely fashion. Escalates and represents cases within the Novartis quality escalation process.
- Change controls: Ensures that change requests, either from the external supplier or from Novartis, are managed appropriately from receipt, through to the implementation and closure.
- Manufacturing process and analytical methods transfers: Ensures QA Oversight during commercial product transfers. Ensures knowledge transfer for stable commercial manufacturing operations. Supports the establishment of continuous process verification programs.

Essential Requirements:

- Min 8 years of experience in in the pharmaceutical industry. Min 5 years of experience in the manufacturing of sterile pharmaceuticals. Expert knowledge in aseptic/sterile pharmaceutical processes and manufacturing of biologics.
- Min 5 years of experience in operational quality assurance. Expert knowledge of cGMP requirements for major regulated markets (EU, US). Advanced experience with FDA, EMEA and other Health Authorities. Expert in risk management. Advanced understanding of project management.
- Expert in communication and advanced negotiations skills. Advanced decision-making skills.
- Basic leadership skills.

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TEst Hello

Division

Operations

Business Unit

Innovative Medicines

Standort

Indien

Site

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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