QA expert, ESO Large molecules

Job ID
REQ-10020228
Sep 03, 2024
India

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

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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 negations skills. Advanced decision-making skills.
- Basic leadership skills.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Division
Operations
Business Unit
Innovative Medicines
Location
India

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
Apply to Job

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Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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