Specialist - Quality Operations

Job ID
REQ-10019211

9月 03, 2024

India

摘要

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Position Title : Special - Quality Operations

Location - Hyderabad, India

About the Role:

This position is responsible for quality oversight of contract manufacturers for drug product/drug

substance/intermediate product/raw material of ADACAP.

Key Responsibilities:

- Develops and maintains a Quality Assurance Agreement in cooperation with the external partners.
- Responsible for the initial qualification and onboarding of contract manufacturers as well as for performing regular quality risk assessments.
- Ensures that all aspects of manufacturing, testing, release and distribution of drug substance/drug product/ intermediate product/material are in compliance with applicable ADACAP and Novartis standards, the effective Quality Assurance Agreement, relevant guidelines and the Quality Management System of the external partners.
- Manages and oversees contract manufacturer ' s activities related to quality processes such as deviations, complaints, recalls, counterfeits, product tampering, stability failures, etc. according to the Quality Assurance Agreement and the Novartis Quality Manual. Ensures investigations are appropriately executed within agreed timelines, including documentation and effective measures to prevent recurrence. Support the Novartis audit of contract manufacturers and act as QARP and or FURP as required.
- Ensures that change requests, either from contract manufacturer or from ADACAP, are managed according to the Quality Agreement and ADACAP change control procedures from receipt, through to the implementation and closure.
- Reviews third party documents from a quality point of view (i.e. product test methods, specifications, and protocols/reports for activities such as stability, analytical method transfer, manufacturing process transfer, product comparability, process characterization, process validation, etc.).
- Performs, coordinates or archives GMP documentation as defined by the Quality Agreement and ADACAP SOPs. Responsible for compiling product quality reviews in cooperation with external partners. Initiates and drives quality improvement projects as required.
- Supports the quality function on general topics as assigned. Writes and maintains general concept descriptions of the assigned topics and presents the assigned topic in audit situations. Develops related procedures or provides input as needed.
- Escalates significant quality incidents and supply risks as per ADACAP and Novartis escalation policies to management. Responsible for reporting and trending of defined key performance indicators per assigned contract manufacturers. Implement and maintain a local Quality System and Standard Operating Procedures defining all the processes for managing of External suppliers.

Commitment to Diversity & Inclusion: :
We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

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Role Requirements :

Essential Requirements:

- At least 6 years of experience in pharmaceutical quality assurance, quality control or manufacturing

- At least 3 years of experience in a Quality Assurance function
- Thorough knowledge of cGMP requirements and their practical application in routine biological manufacturing
- Proven track record of maintaining quality oversight on external partners
- Experience with biological manufacturing would be an additional asset
- Good communication skills
- Team and consensus builder, with definitive and authoritative decision making ability.

Desirable Requirements:

- Higher university degree (Masters, PhD or equivalent) in Pharmaceutical, Chemistry, Biochemistry, or another related science
- Languages: Fluent in speaking and writing in English

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部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
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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Accessibility and accommodation

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