Manager - MS&T

Job ID
REQ-10015229

7月 11, 2024

India

摘要

The purpose of the Investigation & Deviation Owner role is to work collaboratively with process experts and the multifunctional operations teams in Steriles/large molecules platform and take ownership of the deviation management for the site. The individual shall actively participate in investigations of Deviations/Complaints/OOXs by interacting with Cross Functional Teams (CFT) and implementation of Corrective and Preventive Actions (CAPA), Effectiveness Check (EC), Risk assessment and Quality management. The individual plays a key role in facilitating effective communication between teams and supporting problem-solving activities. The individual shall contribute to the enhancement of quality, productivity, and efficiency by supporting and driving improvements within the organization.

About the Role

Manager - MS&T

Location - Hyderabad

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Key Responsibilities:

- The individual shall have a comprehensive understanding and experience of using Quality Risk management framework and shall possess excellent investigational report writing skills.
- The individual shall have hands-on experience of using structured RCA (Root Cause Analysis) methodologies such as impact assessment, Fish bone diagram, 5 whys, Timeline & process mapping for investigation of deviations.
- Experience in handling Investigations and Deviations related to Process (Upstream / Downstream), Product & Equipment
- Understanding of core manufacturing unit operations such as sampling, monitoring, and continuous process support.
- The individual shall have broad experience working in GxP environment and handling procedural requirements for HA audits.
- The individual will also be responsible for offering technical and scientific expertise to address process-specific matters, ensuring compliance with cGMPs, SOPs (Standard Operating Procedures), and relevant guidelines and functional standards (such as HSE (Health, Safety and Environment) and NOSSCE).
- Prior experience of handling internal and health authority audits and inspections is preferred
- Ensure overall inspection readiness for area of responsibility -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable).
- Certification in investigation handling - Root cause analysis (RCA) is preferred.

Essential Requirements:

- Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biomedical engineering, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Min 8 years of experience in MS&T, Quality Assurance, Regulatory or in the manufacturing of

pharmaceutical drug substance or drug products in Sterile/Large Molecules platform/facility
- Minimum of 5 years of pharmaceutical process validation and cleaning validation.
- Should be familiar and able to perform basic statistical evaluations using Minitab or other statistical analysis tools.
- Proficient knowledge on deviation handling, incident investigations, root cause analysis, and CAPA management.
- Knowledge of risk assessment and risk management programs.
- Should be familiar with regulatory guidance on validation, product filing and post approval changes.
- Basic knowledge of statistical analysis, results interpretation, and usage of statistical tools (Example: Minitab, Statistica etc.).
- Good communication, presentation and interpersonal skills.

Desirable Requirements:

- Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biomedical engineering, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.

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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
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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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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