Manager - MS&T

Job ID
REQ-10015229
Juli 11, 2024
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Summary

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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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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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.

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