Associate Director - Global GxP Quality Incident Management

Job ID
REQ-10020687
Sep 03, 2024
India

Resumen

We are seeking for a GxP and Quality expert with strong management skills to direct cross-functional teams and with strong communication skills to interact with internal stakeholders and external parties on global level, including Health Authorities.
In this role you will support the strong Novartis Quality Organization in managing GxP and Quality Incidents in a cross-functional end to end process on a global level.

About the Role

Associate Director, Global GxP / Quality Incident Management

Location - Hyderabad

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Key Responsibilities:

- Manage GxP/Quality Incidents in an end to end process that require cross-functional guidance and coordination as well as alignment on global level to achieve consistent cross-functional decisions across multiple sites, entities, functions and countries
- Arrange and support the initiation of Health Authority communication on a global level
- Support the definition and drive the implementation of corrective and preventive measures related to GxP/Quality incidents on global level, this includes also market actions, if required.
- Facilitate creation of knowledge repositories and roll out of lessons learned; facilitate the maintenance of global incident management processes and procedures
- Collaborate across functions in resolving GxP/Quality Incidents and preventing recurrence. Support related GxP/Quality incident prevention activities across the entire organization.

Essential Requirements:

- Multiple years (approximately min. 6 years) of relevant thought experience in the pharmaceutical industry

(Quality, Manufacturing or Development), with strong experience in the Quality area (GxP-Compliance, Quality Assurance and/or Control).
- Experience in conducting end-to-end management of quality incidents
- Experience related to classical pharmaceuticals (various dosage forms, including steriles), biologics and cell and gene therapy products; thought understanding of pharmaceutical manufacturing processes, analytical procedures as well as Quality Management systems; knowledge of radio-ligand products and technology is favourable.
- Knowledge in and experience with major international pharmaceutical regulations (e.g US FDA, EMA, Anvisa, ICH, WHO) and with the related Health Authorities (e.g. US FDA, EMA, PMDA, TGA, Anvisa).
- Knowledge of and experience with ISO is favourable
- Good understanding of international pharmaceutical regulatory processes
- Strong analytical thinking
- Business fluent in English (verbal and in writing).
- Strong skills in applying IT tools and software programs like MS Excel, Powerpoint, Word, etc.
- Profound knowledge of pharmaceutical business in general

Desirable Requirements:

- University degree in the pharmaceutical/live science field such as but not limited to a pharmacist, biochemist, microbiologist or other specialized biologist or chemist

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