

Associate Director - Global GxP Quality Incident Management

Job ID
REQ-10020687
Sep 03, 2024
India

Summary

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

About the Role:

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.

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/life science field such as but not limited to a pharmacist, biochemist, microbiologist or other specialized biologist or chemist

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>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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](#)

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

```
iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
```

Job ID
REQ-10020687

Associate Director - Global GxP Quality Incident Management

[Apply to Job](#)

Source URL: <https://qa1.novartis.us/us-en/careers/career-search/job/details/req-10020687-associate-director-global-gxp-quality-incident-management>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Associate-Director---Global-GxP-Quality-Incident-Management_REQ-10020687
4. <https://talentnetwork.novartis.com/network>
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Associate-Director---Global-GxP-Quality-Incident-Management_REQ-10020687