

# Associate Director - Global GxP Quality Incident Management

Job ID  
REQ-10020687  
Sep 03, 2024  
Inde

## Résumé

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>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Operations

Business Unit

Innovative Medicines

Emplacement

Inde

Site  
Hyderabad (Office)  
Company / Legal Entity  
IN10 (FCRS = IN010) Novartis Healthcare Private Limited  
Functional Area  
Qualité  
Job Type  
Full time  
Employment Type  
Regular  
Shift Work  
No  
[Apply to Job](#)

## Accessibility and accommodation

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](mailto: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.

```
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://prod1.adacap.com/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://www.novartis.com/careers/benefits-rewards>
4. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Hyderabad-Office/Associate-Director---Global-GxP-Quality-Incident-Management\\_REQ-10020687](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Associate-Director---Global-GxP-Quality-Incident-Management_REQ-10020687)
5. <mailto:diversityandincl.india@novartis.com>
6. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Hyderabad-Office/Associate-Director---Global-GxP-Quality-Incident-Management\\_REQ-10020687](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Associate-Director---Global-GxP-Quality-Incident-Management_REQ-10020687)