QA Specialist QMS Support

Job ID
REQ-10046745

May 20, 2025

India

Summary

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems

About the Role

Key Responsibilities:

Ensure timely collection of required documents and information for document based GMP compliance inspection of manufacturing sites registered in Japan. Efficient communication with relevant stakeholders and manufacturing sites in timely manner.

Support the following regulatory compliance activity under GQP/QMS. Work together and communicate effectively with manufacturing sites and other line functions to keep the compliance of

Japan approval files for the products undergoing the following type of inspections:

Partial Change Application (PCA) inspections: for any changes post approval of drug New Drug Application (NDA) inspections: for new drug approvals Periodic inspections: conducted for manufacturing sites every five years

Proper collection of required information and share with relevant stakeholders Proper and efficient handling of information Rapid and proper management of critical information Proper cooperation with Novartis Japan NCQ members Status monitoring and trend of document collection timelines Report to Quality Assurance Supervisor in Japan Review collected documents and contents checks

Ensure that a timely, effective, continuous quality improvement in corroboration with relevant stakeholders.

Support projects of new product launch and product transfer.

Provide support for the preparation and follow-up of GMP inspections at the Country Japan

Ensure that a local Quality System and Standard Operating Procedures are in place for all GxP related activities and that compliance with cGMP is maintained through training and internal audits.

- Ensures the timely collection, monitoring, and reporting of Quality Key Performance Indicators (KPIs) for management reporting Assists in Health Authority inspections and internal audits by supplying information and documentation in a timely manner -Support and track the implementation and maintenance of the local Quality system in in accordance with the Novartis Quality Manual -Manages processes and systems for all GxP Quality Assurance e.g. Change control, Training Management, Escalation Management, Risk Management.
- Ensures that processes are conducted in full compliance with the GxP and the Novartis Quality.
- Contributes to an improvement of current processes and/or to an implementation of modified processes.
- Ensures adequate tracking and on time completion of corrective and preventive actions (CAPA), inc escalation of issue related to the closure of CAPA, as appropriate.
- Review quality deliverables to ensure compliance, with health authority requirements and SOPs, including procedural documents, records, third party work, contractors, clinical trial material, components, and gap assessments -Prepare and review GxP documentation; assists in the release of GxP documentation, filing and archiving of GxP documentation -Supports Compliance review of projects and inspection readiness and management -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Commitment to Diversity & Inclusion: :

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

Essential Requirements:

- Quality standards are understood, designed into work activity, andachieved.
- In accordance with departmental objectives such as support ofprojects with agreed quality and delivery date, passing of internal and external inspections
- Local GxP Quality systems in place and maintained.
- GxP risks proactively identified and effectively mitigated.
- Number of severity of GxP/DI issues identified during internal/external audits and timeliness of collection of required information.
- Timely completion of assigned activities.
- No critical observations from internal audits or Health Authority Inspections

Desirable Requirements:
Work Experience:

- Functional Breadth.

Skills:

- Compliance Requirements.
- Continuous Learning.
- Dealing With Ambiguity.
- Decision Making Skills.
- Gxp.
- Industry Standards.
- Project Management.
- Quality Management Systems (Qms).
- Quality Standards.
- Risk Management.
- Self Awareness.
- Technological Expertise.

Languages :

- English.

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

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

部門
Operations

部門
Universal Hierarchy Node

国
India

勤務地
Mumbai (Head Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

職種
Full time

雇用形態
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 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.

Job ID
REQ-10046745

QA Specialist QMS Support

Apply to Job.

Source URL:
https://prod1.novartis.com/jp-ja/careers/career-search/job/details/req-10046745-qa-specialist-qms-support

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/NovartisCareers/job/Mumbai-Head-Office/QA-Specialist-QMS-SupportREQ-10046745
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Mumbai-Head-Office/QA-Specialist-QMS-SupportREQ-10046745