U NOVARTIS

Executive-Complaint Hub

Job ID REQ-10010880 Jun 21, 2024 India

Summary

-Responsible for the managing day to day process of Complaint management activities under NCQ complaint hub responsibility. Identification, reporting and escalation of critical complaint events followed by building the strong collaboration with NCQ sites to ensure customer service, compliance, and efficiencies. -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

Executive Complaint Hub

Location - Mumbai #LI Hybrid

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

Key Responsibilities:

• Support management of document based GMP compliance inspection and Regulatory compliance with the registered dossiers of Novartis Japan. Support Quality responsible person for Novartis Pharma Japan.

• 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 with other line functions to keep the compliance of Japan approval files for the products. Effective communications with manufacturing sites.

• Change control related to GMP compliance inspection. Support projects of new launched product and product transfer. GMP compliance inspection information. Collection of required information and share with relevant stakeholders, efficient handling of information and management of critical information.

• 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. Fulfil the responsibility of the Document Management and required Education & Training.

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:

- Postgraduate in Life Sciences or Pharma
- Knowledge of the cGMP/GDP/QMS, ICH guidelines
- Knowledge of quality for pharmaceuticals, medical devices, and human cell therapy/gene therapy products
- Knowledge of HSE regulation and Novartis HSE requirements
- 1 to 3yrs of experience in quality assurance activities in pharma domain

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

Division Operations Business Unit Innovative Medicines Location India Site Mumbai (Head Office) Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited 2/3

Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Job ID
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Executive-Complaint Hub

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