Global QMS Manager

Job ID
REQ-10017805
Aug 05, 2024
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Summary

-Ensure compliance and further development, support, maintenance and constant review of the Quality Systems and support for projects as well as the reporting of the necessary performance indicators (KPIs) & quality indicators (KQIs). Support implementation of effective & efficient processes that fulfill regulatory requirements & expectations in a sustainable way for the global Novartis portfolio of products.

About the Role

Global QMS Manager

Location – Hyderabad #LI Hybrid

About the Role:

Responsible for the development, implementation, and continuous improvement of owned processes within Third-Party Management Global Quality System and its Global procedures and standards in compliance with cGMP/ICH, Regulatory Authority, and Novartis Group Quality Manual requirements and Policies. Maintain knowledge with current industry trends, Health Authority expectations and incorporate them into Novartis QMS

Key Responsibilities:

- PO (Process Owner) for Supplier Lifecycle Management (Third Party Approval, Exit) and Quality Agreements. Performs PO responsibilities in a timely manner in collaboration with QSO and the network of Functional Representatives.
- Support execution of the Quality System strategy as per defined timelines and updates it where needed Develop and maintain a compliant, effective, and efficient process. Support the execution of Annual Quality System Review. Drive simplification and optimization to the processes and document landscape related to the processes under responsibility. Review and update definitions for terms belonging to the Quality System under the scope. Review the list of documents under Process and define applicability using the dimensions set up and document landscape architecture. Assess the emerging technology specific needs together with the respective experts and adapt Quality System processes and procedures as applicable.
- Support QSO with ensuring compliance to regulations through timely assessment of newly issued GxP requirements and incorporation into Novartis QMS as needed. Support QSO with QMS integration of acquired companies as needed. o Participate in benchmarking activities as applicable and keep up to date with industry standards through external engagement. Author – as required – of QMS documentation related to owned process. Act as SME for Event Risk Control and Third-Party Master data.

- Act as a SME or Business System Owner for respective IT system including maintenance and continuous enhancement (i.e. 1QEM related to third party tasks, TPRM - Third Party Risk Management and MDGS – Master Data Governance System) for Quality/GMP. Interact with main stakeholders/ other functions / platforms/sites / entities to improve the quality and compliance of owned processes. Establishes or support the maintenance and use of the communication channels (community calls, participation, when needed, on the Event triggered meetings, committees, etc.).

- Support or drive quality related initiatives in Global QMS or provide SME inputs, support the roll out to Novartis functions where suppliers are managed. Drive improvement projects across functions as needed. To be externally engaged by maintaining current knowledge of local and international regulatory and legislative requirements and trends. Support as advisor or SME any assigned specific Global QMS activities or projects as required.

Essential Requirements:

- Fluent spoken and written English; second language desirable
- Thorough knowledge of cGMP requirements – At least 10 years' experience in pharmaceutical industrial Quality and Compliance related activities or strong proved background and knowledge in GMP operations (e.g. Manufacturing and Science).
- Desirable supplier management oversight background. Strong analytical skills and understanding of risk management fundamentals / tools. Good interpersonal skills, organizational, analytical, intercultural communication, and negotiation.
- Team and consensus builder, with definitive and authoritative decision-making ability and experience in an matrix organization Experience working in a global matrix organization preferred
- Experience in supplier approval process, quality agreement management, design process and systems, stakeholder management at different site level

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

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Innovative Medicines
Standort
Indien
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Hyderabad (Office)
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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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Job Type
Full time
Employment Type
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Shift Work
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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.

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