Global QMS Operations Team Lead

Job ID
REQ-10047330
Jun 11, 2025
India

Summary

The Global QMS Operations Team Lead ensures maintenance and continuous improvement of designated Quality processes and respective tools to drive standardisation and harmonization further and meet compliance requirements. Leads the QMS GMP/GDP QMS Network for Novartis Operations areas and drives interactions with all relevant Novartis Functions and Entities for all QMS topics. Leads/participates in key QMS projects or initiatives and maintains knowledge with current industry trends, Health Authority expectations.

About the Role

Key Responsibilities:

- Lead and continuously coach, guide and develop the QMS Operations Team.
- Establish and run the QMS network for GMP (Good Manufacturing Practices and GDP (Good Distribution Practices) areas and drive interactions with all functions within the commercial Operations through the defined governance model. Ensure the management of the Global Procedure Governance Board is in place and the document change management process is effective.
- Manage the QMS documentation activities to ensure the documentation in use is in compliance with processes and procedures agreed with Global QMS, including document review to ensure a high standard of documentation is in place.
- Manage and perform the required QMS Communications to the organisation
- Act as BSO (including Deputy) for ESOPS D2/ CONDOR/ CIRF/ GxP NESS; ensure the management of the backlog maintenance and system release activities. Act as the End user support for IT systems.
- Ensure that the Periodic Review management is in place and effective to reduce the number of overdue documents within the QMS.
- Provide Audit & inspection support for QMS Operations topics.
- Act as a subject matter expert for selected Quality processes and collaborate with the respective QSO/Process owner to ensure GxP compliance of the processes and tools within own remit.
- Author/review respective QMS documentation.
- Lead and/or participate in key QMS projects or initiatives ensuring that:
  - defined quality elements and compliance requirements are addressed,
  - all required activities for successful and timely execution are completed,
  - the roll-out to impacted local entities across Novartis is achieved
- Establish and maintain community/network of Subject Matter Experts or Single Points of Contact and drive interactions with corresponding Functions. Establish strong partnership with key stakeholders.
- Create synergies and opportunities by leveraging lessons learned and communicating them to the SMEs and stakeholders as applicable.
- Participate in benchmarking activities as applicable and keep up to date with industry standards.

- Maintain knowledge of current industry trends and Health Authority expectations.

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:

- Education: University degree in Pharmacy, Chemistry, Engineering or equivalent related discipline preferably in Quality Systems.
- Min. 8-10 years' experience in the pharmaceutical industry in a relevant field, such as quality assurance, quality control, registration, clinical development or manufacturing or a directly related area.
- Broad experience in QA processes and underlying regulatory requirements and industry standards/best practices.
- Fluent English, other languages are a plus.

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

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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
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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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