NOVARTIS

Site Quality Head

Job ID
REQ-10045720
Απρ 17, 2025
Germany

Περίληψη

In this role you will provide quality assurance oversight and be accountable for supporting Quality operations and provide technical and strategic leadership for all quality-related matters. Accountable to ensure compliance to GxP standards including product manufacturing and testing. You will also ensure Compliance with cGMP requirements and with the Novartis Quality Manual and policies.

About the Role

Possible locations: **Halle, Dresden, Leipzig.**

Major accountabilities:

- Provide leadership for strategic site initiatives, and represent site SLT quality in local cross-functional and global projects teams as team member or team leader that represent site quality.
- Provide leadership, direction and support to the people within the Quality Assurance department and ensure that they are qualified, achieve a high level of competence, are motivated and carry out their duties in a safe manner.
- Work with internal and external personnel to create user requirements and specifications to be used for projects in compliance with company standards for equipment, process and facilities.
- Liaise with the various stakeholders on projects to ensure coordination and clear communication between all parties.
- Ensure all facilities, utilities and equipment are designed and installed to be operated in a safe and effective manner and are compliant with applicable standards
- Ensure that during project phase planning, construction, commissioning, qualification (IQ, OQ and PQ) including any other validation activity complies with cGMP
- Create and maintain updated project plans to track progress, and support in informing senior management
- Timely escalation of risks in meeting timelines and / or budget incorporating site master planning and the long-term strategic plan.
- Ensure adequate management of product critical quality issues (deviations, out of specifications). Ensure investigations are correctly executed and adequate CAPAs are defined, and proper follow up of CAPAs effectiveness. Review, provide guidance for, escalate where appropriate, and approve HA notifications (compliance related such as Exception requests, other).
- Define, implement, monitor, consolidate and analyse Site Quality KPIs. Ensure Site Quality Committee is established, ensure relevant corrective and preventive actions are endorsed and implemented.
- Drive for Site management team accountability. Coordinate the generation and monitor the execution of the Site Quality Plans, DI Plan, Site Quality Risk Assessments and other relevant gap assessments.
- Ensures proper preparation and consolidation of the budget for the Quality Unit, ensures health & safety

procedures are followed

Minimum Requirements:

- Education: BS/MSc in Life Sciences and/or related experience.
- 10 years of experience in GMP Pharmaceutical Manufacturing (including laboratory operations and Aseptic experience), at least 3 years combined of relevant experience in Quality Control and/or Quality Assurance covering quality areas.
- Proven track record and practical experience in supporting a Quality Control operations unit and operating in full compliance with global cGMP requirements. Successfully managed inspections from major Health Authorities (e.g. US FDA, EMA)
- In-depth knowledge of cGMP, FDA regulations (21 CFR Parts 211, 212), local regulations and ICH regulations.
- Proven ability to manage multiple projects with moderate resource requirements, risk and/or complexity.
- Highly developed management and communication skills, with experience in working in a matrix organization.
- Strong organizational and time management skills.
- Experience in process improvement approaches (Lean Six Sigma, Total Quality Management, 5S, etc.)

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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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

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Τομέας
Operations
Business Unit
Universal Hierarchy Node
Τοποθεσία

Germany
Τοποθεσία
Nuremberg (Novartis Business Services GmbH)
Company / Legal Entity
DE61 (FCRS = DE061) Novartis Business Services GmbH
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve. Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability. The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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