NOVARTIS

QC and AS&T Lead

Job ID
REQ-10092044

十一月 09, 2026

China

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摘要

-Primary responsibilities for this position include performing tasks associated with release testing and reviewing laboratory data, coordinating the team/lab under its responsibility. Communicating with internal and external partners for the Quality Control organization. Supports site as technical expert in related field

About the Role

Major Accountabilities:

- For QC/A S and T, AS required, based upon size of site / span of Control.
- Coordination of departmental Operational activities (listed in QC Head role).

- Initiate and drive local hiring process.
- Line responsibility and daily walkthrough.
- Lead OpEx Projects.
- Investigation of Deviation, OOx, Complaints.
- Define and implement CAPAs.
- Support transfer Projects and validation studies.
- Track team metrics and ensure KQI /KPI meet requirements.
- Review and approve text and design.
- HSE incidents reporting and action follow up.
- New equipment commissioning Support (OQ, PQ).
- Define improvement areas in process and products.
- Resource and capacity (people and equipment) planning and workload management.
- Performance and leadership Support to specialist team.
- Ensure availability of equipment, chemicals and consumables, AS appropriate.
- SOP review and revision.
- Perform local training and monitor training status for Microbiological QC as above, plus: management of Microbiological activities in Line with site objectives.
- Ensure training according to cGxP requirements.
- Management of documentation and Methods according to cGxP.
- Exception management.
- Complaint Investigation Support.
- Ensure DI and compliance with cGxP and all regulatory requirements.
- Collaboration in GxP internal audits and ensure fulfillment of internal/external audit and inspection plans.
- Equipment qualification review /release.
- Ensure activities executed according to cGxP standars planning, Collaboration in GxP audits/inspections.
- Ensure Methods and Procedures are up to date.
- Management of documentation and Methods according to cGxP.
- Ensure qualification /calibration status of analytical equipment.
- Ensure compliance of products and other materials with specifications and with corporate, health authorities, and E5 requirements.
- Microbiological testing review and approval.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)

Key Performance Indicators:

- QC of products & monitoring of processes and facilities; timely handling & settlement of deviations
- Timely update of SOPs.
- Timely delivery of documents
- Timely delivery of registration documents
- Coaching tasks; compliant archiving
- No avoidable safety incidents
- Cost control and delivering key figures for QC with agreed timelines
- Yearly training schedule

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

Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部门
Operations

Business Unit
Quality

地点
China

站点
Haiyan (Zhejiang Province)

Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work

No

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