

Site Quality Head Changping

Job ID
REQ-10076386
апр 28, 2026
Китай

Сводка

- Provides strategic and technical leadership for the site in all quality and cGMP compliance related matters and ensures that all aspects of the operational business comply with cGMP legal and regulatory requirements and Novartis Quality Manual requirements.
- Leads the team for Quality in the site and works in strong collaboration with other members of the site leadership team.

About the Role

Major Accountabilities:

- Leadership of Site Quality organization
- Implement, comply with, and govern practices prescribed in the Novartis Manufacturing Manual
- Quality oversight of GxP site functions
- Acts as site Technical Responsible Person (Qualified Person)
- Ensure product quality
- Ensure regulatory compliance and implementation of corporate quality standards and regulation
- Ensure status of local HA registration
- Preparation of Site Master File for regulatory purposes
- Site quality risk assessment
- Quality Management Review
- Approval or rejection of raw materials, facilities, utilities, preliminary, finished product or stability samples
- Approval of PQR/APQR
- Ensure exception management
- Ensure complaint investigation
- Ensure training execution across site
- Ensure DI, eCompliance and compliance with all cGxP and all regulatory requirements for manufacturing, control and distribution operations
- Ensure adherence to HSE guidelines and requirements
- Collaboration in GxP internal audits
- Ensure fulfilment of internal/external audit and inspection plans
- Ensure any collaborations with 3rd parties are performed with adequate Quality Assurance Agreements in place
- Ensure any additional local legal requirements are fulfilled
- Ensure Business continuity management
- Ensuring personal and people development
- Lead and develop QA team and develop for successful workforce planning and future success skills
- 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:

- No critical observations during authority inspections.
- No delay with new product introductions caused by the unit.
- Timely closing of deviations/complaints.

Minimum Requirements:

Work Experience:

- Audit & Inspection Management.
- Good Manufacturing Practices (cGMP).
- Product Quality (PQ).
- Release Management.
- Contract Manufacturing.
- Supplier Relationship Management (Srm).
- Technical Operations.
- GxP Experience.
- People Management.
- Quality Assurance.
- Quality Compliance.
- Quality Management Systems.
- Quality Control.

Skills:

- Analytical thinking.
- Business Acumen.
- Business Strategy.
- Finance Acumen.

- Leadership.
- Risk Management.
- Smart Risk Taking.
- Stakeholder Management.
- Strategic Planning.
- Strategic Thinking.
- Organizational Saviness.
- Industry standards Knowledge
- Storytelling.
- Collaboration.
- Communication skills.
- Data Integrity.
- Digital saviness.
- Decision Making.

Languages :

- English.

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Дивизион
 Operations
 Business Unit
 Quality
 Место
 Китай
 Сайт
 Changping County (Beijing)
 Company / Legal Entity
 CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
 Functional Area
 Quality
 Job Type
 Full time
 Employment Type
 Regular
 Shift Work
 No

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