

# Site Quality Head Changping

Job ID

REQ-10076386

May 07, 2026

LOC\_CN

## About the Role

## Core Responsibilities

### Quality Leadership & Governance

- Lead and structure the site Quality organization to support all manufacturing operations
- Establish and maintain an effective Quality Management System (QMS)
- Drive quality governance, including Management Review and performance monitoring
- Own Manufacturing Quality Systems within the SM platform

### Regulatory Compliance & Inspection Readiness

- Ensure full compliance across all products with regulatory and corporate quality standards
- Maintain continuous inspection readiness and audit compliance
- Manage regulatory registrations and authority interactions
- Lead internal/external audits and GxP inspection activities

### Product Quality & Release

- Ensure quality across all manufacturing streams (solid, ophthalmic, aseptic)
- Approve batch release ensuring compliance with filings and specifications
- Approve Product Quality Reviews (PQR/APQR)
- Act as Qualified Person / Technical Responsible Person

### Quality Systems & Risk Management

- Lead risk-based quality management and continuous improvement
- Ensure effective management of deviations, OOS/OOX, complaints, and recalls
- Act as escalation point for critical quality issues
- Monitor Key Quality Indicators (KQIs)

### GxP Oversight & Change Management

- Provide oversight across all GxP processes
- Ensure compliant and timely handling of change controls
- Ensure data integrity, eCompliance, and regulatory adherence

### Qualification, Validation & Equipment

- Ensure facilities, utilities, and equipment are qualified and maintained
- Ensure all products undergo appropriate process validation

### Leadership & Culture

- Build and develop high-performing Quality teams

- Drive talent management, succession planning, and capability building
- Foster a culture aligned with Novartis values: Inspired, Curious, Unbossed
- Ensure workforce training and GMP qualification compliance

## **HSE & Business Continuity**

- Promote strong Safety & Quality culture
- Ensure business continuity and crisis management readiness
- Participate in site emergency management as required
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## **Key Accountabilities (China GMP Focus)**

- Ensure effective operation of Quality Assurance & Quality Control systems
- Guarantee data integrity, traceability, and regulatory compliance
- Approve and oversee:
  - Batch records and release
  - Deviations, change controls, and investigations
  - Validation, qualification, and technical documentation
- Ensure effective:
  - Supplier qualification
  - Stability programs
  - Complaints and recall handling
- Lead periodic quality risk reviews and continuous improvement

## **Ideal Candidate Profile**

### **Experience**

- 12–15+ years in pharmaceutical QA/QC and/or manufacturing
- Strong experience in GMP, aseptic and solid dosage environments
- Proven leadership in operations, quality systems, and cross-functional collaboration

### **Education**

- Degree in Pharmacy, Chemistry, Engineering, Biotechnology or equivalent

### **Languages**

- Fluent English; local language preferred

### **Key Competencies**

- Strategic leadership & change management
- Deep expertise in GxP quality systems
- Strong stakeholder engagement and regulatory interface
- Risk management & decision-making capability
- Communication and influencing skills

### **Role Requirements**

**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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Division

DIV\_TO

Business Unit

Quality

Location

LOC\_CN

Site

Changping County (Beijing)

Company / Legal Entity

CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area

FCT\_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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