NOVARTIS

# Site Quality Head Changping

Job ID
REQ-10076386
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Китай
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### Сводка

Lead the site quality organization to ensure regulatory compliance, product quality, and operational excellence across all manufacturing activities, in alignment with cGMP, ISO standards, and Novartis quality policies.

### 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

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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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