NOVARTIS

Site Quality Head Changping

Job ID
REQ-10076386
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Китай

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

Accessibility and accommodation

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