

Site Quality Head Changping

Job ID
REQ-10076386

5月 06, 2026

China

摘要

- 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

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

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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部门

Operations

Business Unit

Quality

地点

China

站点

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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sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true,
showSpeedMenu: false }, css: "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css",
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(KalturaPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(KalturaPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", //
Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default:
alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled:
false, printDisabled: false, disable: true }; } if (KalturaPlayer.plugins["preventSeek"]) {
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false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; }
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(KalturaPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if
(KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents =
[]; if (KalturaPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {};
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false, playlistEvents: false, castEvents: false } }; }

```

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kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var
kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other
media. kalturaPlayer.loadMedia({entryId: "1dgvmafo"}); } catch (e) { console.error(e.message) }

```

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