

Associate Director, Quality Evaluations, Integrations, and External Services

Job ID
REQ-10075831

4月 13, 2026

China

摘要

The BR Quality Operations role is primarily responsible for managing and executing quality related operational activities, continuous improvement initiatives and for leading/supporting execution of Quality Due Diligence (DD) activities, related integration, and Third-Party oversight. The role is responsible for assuring compliance to regulatory and internal standards/guidance of operational and BD&L / M&A activities within respective/assigned areas.

The role leads/supports the focused (where applicable) and confirmatory due diligence to identify potential quality gaps, risks, and issues in a proactive manner, proposes mitigation, and ensures transparency throughout the DD through integration process. Escalates where applicable and briefs BR Quality and DD management.

About the Role

Major Activities

- Executes Quality Operational & continuous improvement activities.
- Responsible for all relevant Due Diligence, Integration, and Third-Party management activities as outlined in the applicable procedures.
- Conduct focused (where applicable) and confirmatory due diligence to detect quality assurance risks, trends and to identify potential quality and performance issues with in-licensed medicinal products and/or inclusive product portfolio in cases of acquisition.
- Collaborate with BD&L / M&A DD teams to ensure timely communication of risks to the business and follow-up on required actions for respective QA areas of expertise/focus.
- Owner of inputs to the overall DD report for assigned QA focus area and input to finalize QA due diligence report in collaboration with BD&L QA Partners per defined timelines.
- On assignment of applicable integration activities, partner with respective integration teams to execute/ oversee QA remediation activities and action plans for assigned QA focus area.
- Provides support for internal and external audits and inspections.
- Lead/Participate relevant Third Party (vendor oversight) quality activities including CRO selection, governance, and performance monitoring) as outlined in applicable procedures.
- Collaborates with internal business partners, R&D Procurement and other Novartis functions to participate in vendor selection and strategic planning, review quality requirements, perform risk evaluation and follow-up on required actions.
- Drive quality initiatives and continuous improvement for internal & out-sourced activities to assure compliance with regulations & Quality procedures and implement operational quality efficiencies.
- Fulfill Functional Representative (FR) responsibilities for designated projects and activities.

Ideal Background

- Ph.D. or Masters in Life Sciences, Pharmacy or Medicines.
- Demonstrated quality/scientific operations experience with a minimum of 8 years (AD) 4 years (Manager) working in a pharmaceutical industry with knowledge of R&D programs (research, preclinical safety, bioanalytics and clinical)
- Broad understanding and interpretation of regulatory requirements understanding of Industry Quality Standards and International Regulations (OECD, FDA, GLP, GCP)
- Expertise in managing third parties and in conducting internal / external scientific & quality assessments
- Familiarity with chemical / bio analytical methods, Cell & Gene /Radio Ligand / xRNA platforms, Cell and Molecular Biology, Animal Welfare is a plus.
- Strong leadership experience including excellent communication, collaboration/consensus building, considerable organizational awareness, influencing and negotiation skills.
- Demonstrated ability to lead and partake interdisciplinary-nary projects with scientific, finance, and/or commercial business functions and successfully work in a global cross-functional matrix.
- A clear sense of personal accountability, an ability to empower people, ability to drive quality culture with partners and a high degree of mutual respect and integrity are essential factors to succeed.
- Strong risk management skills, ability to balance with strategic benefits, and to translate appropriately.
- Strong customer focus and quality driven

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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部门

Biomedical Research

Business Unit

Research

地点

China

站点

Shanghai (Shanghai)

Company / Legal Entity

CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
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"10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause:
false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: {},
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"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) {
config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible:
false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; }
if (KalturaPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if
(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 = {};
config.plugins.googleTagManager.customEventsTracking = {};
config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
false, playlistEvents: false, castEvents: false } }; }
```

```
try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof
kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var
kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other
media. kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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