

Associate Director, Quality Evaluations, Integrations, and External Services

Job ID
REQ-10075831

4月 13, 2026

China

摘要

为开发和研究职能提供质量保证和合规监督。推动全球、区域和国家组织内的质量管理体系和举措的监督,确保符合适用的卫生当局监管要求例如, GCP、GLP、GMP、PV、IP以及诺华的程序和质量标准。在促进质量文化例如,第一次等的同时,以良好的质量行为为榜样,对非质量利益相关者例如 NIBR、GDD产生积极影响。制定、推动和/或支持质量计划计划举措,以实现组织战略、使命和愿景。

About the Role

Major Accountabilities

提供质量保证专业知识和指导,以确保符合质量体系的要求,包括实施质量风险向导流程和GxP相关流程。

- 领导和质量管理保证组织和/或质量项目团队，并与业务合作伙伴及其他质量小组合作，以确保完全满足卫生当局和监管要求
- 将职能质量保证策略转化为适用的运营/合规活动，并支持风险向导的流程实施和执行。
- 确保质量和合规性差距得到解决和执行，以实现可持续性，并执行战略流程的改进，包括审查程序更新、培训、流程改进、有效性检查等。
- 监督质量计划的实施，支持检查准备活动，包括参与监管检查的准备、管理和跟进。
- 对支持研发活动的外部服务提供商和IT系统提供质量监督/管理支持，推动促进审计检查及其后续跟进，并确保针对发现的问题制定、实施和完成适当的纠正和预防措施
- 确保对偏差/事件及时升级，并对偏差/事件提供质量监督，包括稳健的调查、根本原因分析和纠正措施的实施。
- 根据审计、检查、事件、监管情报、流程实施有效性检查和衡量指标，总结经验教训，支持积极的风险向导行为文化
- 收到后 24 小时内报告与诺华产品相关的技术投诉/不良事件/特殊情况
- 营销样本的分发适用)

Key Performance Indicators

- 战略项目文件和陈述的质量及时间线: 及时提供高质量文档
- 可靠、及时、准确的信息/沟通 与关键利益相关者就项目具体问题。
- 按部门成本/预算交付
- 制定继任计划
- 树立Novartis文化、价值观和行为榜样

Work Experience

- 行业/业务接触
- 跨界协作
- 领导力
- 职能广度
- 关键谈判
- 项目管理
- 运营管理和执行

Skills

- 员工绩效评估
- 人员管理
- 质量管理
- 卫生当局
- 审计管理
- 影响技能
- 风险管理
- 供应商管理
- 审计
- 药物开发
- 国际标准化组织 9001
- QA(质量保证)
- 质量管理
- 质量管理体系(Qms)
- 风险管理

根本原因分析 (RCA)

领导

敏捷

业务合作

利害关系人管理

自我意识

持续学习

精明的组织能力

技术专长

Language

英语

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

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
正式

Shift Work
No

```
var config = { targetId: "kalturaplayer69fb72943ff0a676699651", provider: { widgetId:
"1Qm7rm1pm", 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) }
```

无障碍及便利设施

诺华承诺与残障人士共事并为他们提供合理的便利设施。如果您由于健康状况或残障在招聘过程的任何环节需要合理便利设施或者为了履行职位的基本职能请发送电子邮件至 diversityandincl.china@novartis.com 告知您的需求和联系方式,并在邮件中附上您的职位申请编号。

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1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
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