

Manager, BR Clinical Quality Assurance

Job ID
REQ-10075829

4月 13, 2026

China

摘要

为开发和研究组织的运营活动提供质量保证专业知识、指导和支持,以确保符合适用的监管要求以及诺华程序和质量标准。

管理项目,包括质量计划计划,以及支持质量目标的流程,以确保其符合 GxP 法规。

About the Role

Major Accountabilities

- 支持维护卫生当局检查所需的法规要求文件,并协助卫生当局检查管理
- 支持为临床项目制定质量计划并审查质量/安全方面的其他计划)
- 支持维持或提高运营活动的质量绩效和合规性的计划,包括风险管理,卫生当局报告,IT系统
- 支持专注于质量、流程和合规性改进的举措,包括识别机会和制定旨在提高质量的策略,同时确保符合法规要求
- 确保评估在质量和合规性计划期间获得的信息以及审计和评估结果,以确定任何法规,合规性和QA

培训需求

- 协助识别质量问题并协助根本原因调查,并支持制定纠正和预防措施(QAPA)包括监控状态以确保问题得到解决,完成和记录。
- 在纠正偏差方面提供帮助,确保跟进和监控相关的纠正和预防措施。
- 管理和支持项目和活动的质量方面,包括与第三方,分析仪器,制造设备,质量计划,培训,IT验证等相关的项目和活动。
- 审查和批准质量可交付成果以确保合规性包括程序,记录,第三方工作,承包商,临床试验材料,组件,差距评估)
- 在收到诺华产品后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
- 分发营销样本(如适用)

Key Performance Indicators

- 集群质量体系到位并根据需要不断更新
- 主动识别并有效缓解风险
- 内部和外部审核期间发现的问题数量和严重性。
- 特定GxP的示范/认可领导者;早期外部/行业参与
- 足够的财务知识如成本管理,预算预测等)
- 诺华文化,价值观和行为的榜样

Work Experience

- 跨界协作
- 职能广度
- 项目管理
- 关键谈判

Skills

- 风险管理
- 质量管理
- 卫生当局
- 审计管理
- 卡帕知识
- 影响技能
- 分析开发
- 审计
- 变更控制
- QA(质量保证)
- 质量管理
- 根本原因分析(RCA)
- 六西格玛
- SOP(标准操作程序)
- 敏捷
- 业务合作
- 自我意识
- 持续学习
- 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: "kalturaplayer69df2a3236928700197355", 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: "1dgfvmafo"}); } 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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