

QA Specialist

Job ID
REQ-10080295

6月 10, 2026

Hong Kong Special Administrative Region, China

摘要

在责任范围内管理质量方面和项目。
确保和支持全面的 GxP 符合性和符合诺华质量管理体系

About the Role

Major Accountabilities

- 根据 Novartis 的 SOP 确保变更请求从接收到实施和关闭都能得到管理。
- 对所有部门进行 GxP 监控,对不合规项进行 QA 调查,跟进纠正措施。归档相关文件。
- 协调质量体系 and 程序的实施,以实施 Novartis 质量手册和质量协议。
- 确保在国内处理和销售药品的所有方面都符合 Novartis 质量手册和政策的要求,并满足所有相关的 cGMP 法规和立法要求。
- 确保所有与 cGMP/GDP 相关的活动都有当地的“质量体系”和“标准操作程序”,并通过培训和内部审计保持 cGMP/GDP

法规合规性。

-保有对当地和国际法规及立法要求和趋势的最新知识,以确保向国家/地区提供所有质量相关事宜的技术支持。

-与“供应链管理”(SCM)、DRA 和医疗部门建立良好的工作关系。

-确保与监管机构、本地合作伙伴、供应商、第三方、授权商和分销商和“全球质量保证”保持协调的联系。

-确保所有进口药品在投放市场前都要按照现行的程序、注册的规范和当地/国际法规进行检验。

-确保有一个有效的“变更控制”流程。

-根据“Novartis 质量手册”和当地书面程序管理投诉、召回、仿冒品和产品篡改。根据需要支持/参与 NEM 案例。

-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

•在责任范围内管理质量方面和项目。

确保和支持全面的 GxP 符合性和符合诺华质量管理体系

Work Experience

运营管理和执行

参与志愿者/社区项目

职能广度

跨界协作

Skills

QA(质量保证)

质量管理

调节

指引

卡帕知识

良好的文档实践

处理歧义

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

Operations

Business Unit

Development

地点

Hong Kong Special Administrative Region, China

站点

Hong Kong

Company / Legal Entity

HK02 (FCRS = HK002) Novartis Pharma

Functional Area

Quality

Job Type

Full time

Employment Type

正式

Shift Work

No

```
var config = { targetId: "kalturaplayer6a2b76f0e2c2b860802979", provider: { widgetId:
"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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1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartis.com/files/novartis-life-handbook.pdf>
3. <https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/Hong-Kong/QA-SpecialistREQ-10080295>
4. <https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/Hong-Kong/QA-SpecialistREQ-10080295>