

Associate, Country QA Operations, Products, ATMP

Job ID
REQ-10070071

1月 29, 2026

Japan

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
Quality

地点
Japan

站点
Toranomom (NPKK Head Office)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Quality

Job Type
Full time

Employment Type
正式

Shift Work
No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||  
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =  
document.getElementById("kalturaplayer697b554c517ed936864595"); var mediaContainer =  
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";  
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
```

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parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth > 0) var config = { targetId:
"kalturaplayer697b554c517ed936864595", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "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 } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false },
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward:
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };
config.ui.uiComponents = []; 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"}); setTimeout(() => {
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {
players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => {
players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===
'function') { otherPlayer.pause(); } }); }); }); } catch (e) { console.error(e.message) }

```



VIDEO

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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>
3. <https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/Toranomon-NPKK-Head-Office/Associate--Country-QA-Operations--Products--ATMPREQ-10070071-5>
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