

Patient Safety Group Manager

Job ID
REQ-10076426

4月 22, 2026

China

摘要

监督和审核公司的药品、生物制品或医疗器械监督计划，包括不良报告的摄入量、评估、处理和跟进。参与解决任何法律责任并遵守政府法规。确保根据产品标签准确接收、维护和评估。按照监管机构的要求报告事件或反应，包括临床试验的不良事件数据、自发或征集来源、定期和经验报告。提供趋势和安全信号检测和评估。支持所有临床试验活动和上市后服务。

About the Role

Major Accountabilities

- Novartis各部门指定药物警戒流程的端到端管理
- 负责确保最高限度遵守全球监管要求
- 领导指定的跨职能患者安全项目
- 为指定流程编写和维护程序文档，并通过全球和本地相关利益相关方的协调推动持续改进
- 为Novartis集团和第三方员工开发和维护培训材料和沟通

- 支持评估新出台法规的影响,并确保持续符合全球监管要求
- 领导指定流程改进计划,包括IT项目/系统主导强化和管理实施)
- 分析其他流程和组织变革的影响
- 与其他职能部门合作,编制合规报告,完成质量检查,以监控监管合规性和对内部要求的遵守情况。如出现任何延误,调查根本原因,制定并实施纠正和预防措施。评估所采取行动的有效性
- 在审核和检查期间担任主题专家(例如,FDA和EMA),领导响应调查结果的准备工作以及制定和实施纠正和预防措施。
- 解决来自其他职能部门和国家组织(QO)关于指定流程的问询,并担任监管要求事宜的顾问。
- 指导和培训新手
- 营销样本的分发(如适用)

Key Performance Indicators

- 遵守Novartis的政策和准则
- 项目和利益相关方的反馈
- 降低操作风险和审核/检查结果
- 优质及时的KPI报告和安全报告/更新
- 审核/检查结果

Work Experience

运营管理和执行

- 项目管理
- 跨界协作
- 职能广度
- 人员挑战
- 管理危机

Skills

- 药物警戒
- 安全科学
- 数据库
- 员工培训
- 报告
- 项目管理

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

Development

Business Unit

Development

地点

China

站点

Shanghai (Shanghai)

Company / Legal Entity

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

Functional Area

Research & Development

Job Type

Full time

Employment Type

正式

Shift Work

No

```
var config = { targetId: "kalturaplayer69ea1f1ec990e960615654", 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) }
```

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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2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <mailto:diversityandincl.china@novartis.com>
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