

## Patient Safety Specialist (12 months fixed term)

Job ID  
REQ-10076022

4月 27, 2026

Mexico

### 摘要

监控和审核公司的药物, 生物制剂或医疗器械监测计划, 包括不良报告的摄入, 评估, 处理和随访。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。根据监管机构的要求报告事件或反应, 包括来自临床试验的不良事件数据, 自发或征来的来源, 定期和经验报告。可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。

### About the Role

#### Major Accountabilities

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支持运营流程管理, 确保符合诺华全球/本地程序、国家和国际法规/标准/诺华营销和调查产品药监指南  
-管理所有诺华产品从临床试验、营销后研究 RMS、患者导向计划  
ROP、注册和所有自发报告 SR 的收集、处理、文档、报告和后续行动报告。  
-转录、翻译必要时并输入所有严重不良事件临床试验和所有不良事件从持久性持久性文件

## PMS, 注册和所有

SR的数据,从源文档准确且始终如一地将数据输入到安全系统,强调及时性和质量。

-与其他部门合作记录和跟踪 SES、SR、调查员通知等文档的收据、提交和分发情况

-与其他部门合作,管理向当地卫生当局和/或临床业务报告/提交/分发安全报告/更新/信息。

-与其他本地/全球光伏同事合作,确保对安全数据进行准确评估。

-如适用,可与 LHA、光伏同事、其他功能组和第三方承包商互动并交换相关安全信息。

-调查和监测全球/区域/国家如适用的药监法规,并提供全球 PVO 组织的更新。

-制定、更新和实施当地程序,以确保遵守 PVO 全球程序和国家要求。

-如果适用,管理和维护所有相关的分配 PVO 数据库。

-开发和更新药监培训材料

-确保支持和关闭审计、纠正行动计划活动和卫生局检查。

-向审判协调员、CLA 和其他诺华员工提供及时的相关信息

-营销样本的分发(如适用)

## Key Performance Indicators

监控和审核公司的药物,生物制剂或医疗器械监测计划,包括不良报告的摄入,评估,处理和随访。

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。根据监管机构的要求报告事件或反应,包括来自临床试验的不良事件数据,自发或征求的来源,定期和经验报告。

可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。

## Work Experience

运营管理和执行

跨界协作

职能广度

## Skills

备案文件)

药物警戒

安全科学

数据库

员工培训

报告

## 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

Mexico

站点

INSURGENTES

Company / Legal Entity

MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area

Research & Development

Job Type

Full time

Employment Type

正式

Shift Work

No

```
var config = { targetId: "kalturaplayer69f07935b7307820749259", 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) }
```

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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/INSURGENTES/Patient-Safety-Specialist--12-months-fixed-term-REQ-10076022>
4. <https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/INSURGENTES/Patient-Safety-Specialist--12-months-fixed-term-REQ-10076022>