

Senior Regulatory Affairs Manager

Job ID
REQ-10072808

3月 19, 2026

China

摘要

指导提交产品注册、进度报告、补充、修订和/或定期经验报告的进度。
为团队进行交互沟通提供战略性产品指导，并与监管机构协商证据。
与监管机构人员进行沟通和协商，以加快批准未决注册并回答任何问题。
在整个产品生命周期中担任项目团队的监管联络员。确保快速及时批准新药、生物制品/生物技术和/或医疗器械，并确保上市药品或医疗器械的持续批准状态。
担任市场营销或研究项目团队和政府监管机构的监管代表。
向开发和/或营销团队提供有关制造变更、生产线扩展、技术标签、适当法规和解释的建议。
协调、审查，或编制要提交的报告。

About the Role

Major Accountabilities

-负责实施监管策略，并管理指定中型区域的运营活动。

- 负责推动在DRA GPT代表和/或GTAL的指导下,及时向卫生局提交和批准档案。
- 可独立领导或与DRA GPT代表和/或GTAL共同领导关于区域批准的谈判。
- 审查并提交风险管理计划。
- 审查、批准并提交临床试验申请(CTAs和试验性新药INDs。)
- 制定并实施计划,以避免/尽量减少出现提交审查停摆。
- 审查全球档案摘要文件。
- 错误的决策会导致项目或运营的重大延误和修改,造成大量时间、人力资源和资金的额外损失;并危及未来的业务活动
- 推动全球指定区域的协调、规划和档案提交。
- 制定并实施计划,以便及时响应卫生局的请求并协调响应。
- 促进简报簿的编制和定稿,并协助编制摘要文件。
- 确定卫生局HQA与DRA GPT代表和/或GTAL互动的要求并设立目标。
- 跨指定区域实施监管职能计划。
- 与各区域合作,统一监管策略,以实现业务目标
- 为全球监管战略提供输入,并为监管职能计划RFP和种子文件或其等效文件贡献内容,包括识别指定区域全球战略计划中的差距或风险。
- 可视乎地点(例如:美国食品药品监督管理局FDA或欧洲药品管理局EMA)),充当当地卫生局的联络人。
- 促成并经常领导制定部门目标和宗旨。
- 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
- 营销样本的分发如适用)

Key Performance Indicators

- 成功实施全球监管战略,以基于可用数据的最佳标签及时提交和批准。
- 识别卫生局主要问题
- 参与相关的监管委员会,从这些委员会中获取宝贵意见。
- 成功参与卫生局交互,以实现业务目标。
- 遵守Novartis的政策和准则
- 项目和利益相关方的反馈

Work Experience

运营管理和执行

项目管理
职能广度
跨文化经历

Skills

注重细节
药物开发
法规遵从性
生命科学
谈判技巧
临床试验

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

Beijing (Beijing)

Company / Legal Entity

CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area

Research & Development

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("kalturaplayer69bf1bc7ca118174270282"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
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  var config = { targetId:
"kalturaplayer69bf1bc7ca118174270282", 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

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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