

Regulatory Affairs CMC Manager

Job ID

REQ-10075420

4月 12, 2026

China

摘要

负责与化学, 制造和控制(CMC)特别相关的监管活动。活动, 如准备和出版REG CMC文件, 以提交给卫生当局。此外, 还就REG CMC问题与HA进行互动, 以支持新产品或上市后发布。

About the Role

Major Accountabilities

- 制定并引领全球 CMC 监管战略, 注重创新, 最大限度地提高业务收益与法规遵从性
- 为分配的项目/产品领导并实施所有全球 CMC 提交活动规划、创作、审查、协调、提交。))
- 确定全球提交所需的文档以及任何内容、质量和/或时间表问题, 并根据项目时间表协商交付已批准的技术源文件。
- 编写和/或审查用于 HA 提交的高质量 CMC 文档, 应用商定的 CMC 全球监管策略、当前监管趋势和准则。确保技术一致性和合规性, 满足商定的时间表和电子发布要求。

-准备和传达 CMC 风险管理评估、应急计划和从主要提交中吸取的经验教训，并酌情向管理层上报。
-酌情启动和领导卫生局的互动和谈判；设定目标，准备简报书，协调和规划排练和风险缓解计划。
-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

负责与化学、制造和控制CMC特别相关的监管活动。活动，如准备和出版REG CMC文件，以提交给卫生当局。此外，还就REG CMC问题与HA进行互动，以支持新产品或上市后发布。

Work Experience

运营管理和执行

项目管理

跨界协作

跨文化经历

Skills

谈判技巧

跨职能团队

项目管理

法规遵从性

风险管理

文档管理

变更控制

风险评估

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
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: "kalturaplayer69fb99b5e2401876058289", 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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