

QA Specialist

Job ID
REQ-10069516

1月 12, 2026

South Korea

摘要

Ensure the quality of the finished products that are imported and distributed by Country Organization is complied with both a) Korea Pharmaceutical Law and the related regulation and b) Novartis Corporate Quality Manual and Policies (Quality manual and the relevant SOP) including cGxP requirements

About the Role

Major Accountabilities:

- Accountable for product compliance to local/international regulations as well as Novartis Corporate Quality Policy.
- Ensure that all drug products are released to the market in a timely manner in accordance with the registered specifications and with local/international regulations.
- Manage the effective Change Control process.

- Manages the documentations and archiving of QA data and records to be compliant with local regulations, Novartis Corporate guideline and GMP requirements.
- Conducts the review of the accordance between the analytical testing specifications/methods and registered product license.
- Performs management of analytical method transfer and analytical testing documents transfer complied with both Novartis QM/QD and relevant SOPs under pharmaceutical law.
- Manage external inspections, complaints, deviations, recalls, counterfeits and product tampering according to the Novartis Corporate Quality Manual and local written procedures and implement each CAPA timely. Manage technical complaints including reporting to appropriate investigation sites, managing investigation processes, and ensuring that appropriate corrective actions are taken.
- Identifies and reports any quality or compliance concerns and implementation of immediate corrective action as required.
- Ensures the readiness for escalation including prompt decision and actions of recall / Market action.
- Report monthly Key Quality Indicators (KQIs) and monitor them and assure that gaps are addressed appropriately in order to mitigate risk.
- Establish a good working relationship with the Supply Chain Management (SCM) / RA departments as well as External Supply Organization (ESO) allowing to keep QA oversight on all partners (e.g. third-party activities).
- Ensures that returned and defective products are managed and disposed in accordance with GMP requirements.]
- Ensure reporting and follow up of all spontaneous adverse events (AE) and technical complaints for all Novartis Corporate products according to respective SOP

Essential Requirements:

- Minimum 1 year of experience in a pharmaceutical manufacturer or importer
- Licensed Pharmacist (mandatory for Import Manager registration and execution of batch release responsibilities)
- Demonstrated ability to proactively manage diverse operational issues, collaborating effectively with internal and external stakeholders to drive resolution
- Experience in leading and uniting teams toward shared goals, fostering an inclusive environment that respects diversity and motivates team members
- Good command in English (speaking and writing)

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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>

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部门
Operations

Business Unit
Quality

地点
South Korea

站点
Seoul

Company / Legal Entity
KR01 (FCRS = KR001) Novartis Korea Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Temporary (Fixed Term)

Shift Work

No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||  
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =  
document.getElementById("kalturaplayer6982e48d2c7b1698548720"); 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 < originalWidthValue) {  
var config = { targetId:  
"kalturaplayer6982e48d2c7b1698548720", provider: { widgetId: "10m7rm1pm", partnerId:  
"2076321", uiConfd: "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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