

Quality Project Lead- FTC

Job ID
REQ-10087796

9月 11, 2026

South Africa

摘要

Project lead for Analytical Method transfers and post-importation testing exemption application management

About the Role

Major Accountabilities:

- Establish and maintain a prioritised tracker for all post importation exemption applications. Coordinate supporting documents from manufacturing sites and relevant functions. Compile and quality-check submission packages. Coordinate submission applications, proof of payment and respond to Health Authority queries. Escalate overdue inputs through established governance channels.
- Analytical Method transfer: 1) Lead end-to-end method transfer schedules between sites and the

local laboratory, 2) Draft, review, and approve method transfer plans, protocols, comparative testing strategies, acceptance criteria, and final reports. 3) Act as the Subject Matter Expert (SME) to resolve out-of-specification (OOS) results, deviations, and analytical challenges, 4) Ensure equipment and reference standards are available

- Complete an orderly handover at the end of the project.

Key Performance Indicators:

- Adherence to cGMP and SOPs
- Project targets are met
- Quality related processes carried out in a timely way
- GxP risks proactively identified and effectively mitigated
- Timely close out of deviations, out of specifications and corrective and preventative actions
- Compliance with all aspects of the Code of Conduct/ Novartis Policies and Procedures

Minimum Requirements:

Work Experience:

- Managed health authority submissions and applied guidelines to ensure compliance.
- Engaged with SAHPRA on regulatory, quality, and compliance-related matters.
- Post-importation testing exemption and analytical method transfer.
- Collaborated with Quality Control (QC) laboratories to support testing, investigations, and compliance requirements.

Skills:

- Knowledge and understanding of GMP, quality systems and quality and regulatory practices
- Understanding and interpretation of regulations & guidelines
- Document management
- Analytical thinking and problem solving
- Project management
- Planning & organizing
- Good time management

- High compliance
- Communication and interpersonal skills.
- Self Awareness

Languages :

- English.

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部门
Operations

Business Unit
Quality

地点
South Africa

站点
Midrand

Company / Legal Entity
ZA01 (FCRS = ZA001) Novartis SA (Pty) Ltd.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6aa42f4fb91ef211480400", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop:
false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options:
{}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu:
false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets:
['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(kPlayer.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 (kPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation =
{ position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if
(kPlayer.plugins["hotspots"]) { config.plugins["playkit-js-hotspots"] = { disable: true }; } if
(kPlayer.plugins["moderation"]) { config.plugins["playkit-js-moderation"] = { disable: true }; } if
(kPlayer.plugins["info"]) { config.plugins["playkit-js-info"] = { disable: true }; } if
(kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if
(kPlayer.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 } };
```

```
// Ensure the global player registry array always exists, regardless of embed type.  
window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise =  
_thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // _thumbnailEmbed() returns a  
Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to  
capture the player directly. thumbEmbedPromise .then(function(player) {  
window.kalturaPlayerVideos.push(player); // Notify kaltura_dataLayer.js that a new player is ready so  
it can // attach custom event listeners immediately, regardless of when // the user clicked the  
thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', {  
detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) {  
console.error(e.message) }
```

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