

Regulatory Affairs Portfolio Manager

Job ID
REQ-10089433

十月 06, 2026

South Africa

摘要

The Regulatory Affairs Portfolio Manager is responsible for managing a portfolio of pharmaceutical products throughout their regulatory lifecycle, enabling timely patient access, maintenance of marketing authorizations, and compliance with local regulatory requirements and Novartis standards. The role leads the planning, preparation, submission, implementation, and tracking of regulatory activities, while serving as the strategic regulatory partner to internal and external stakeholders.

About the Role

Major accountabilities:

- Achieve the best product registration with commercially attractive labelling in accordance with registration plan
- Maintain and secure product license in terms of CMC/CDS/safety update according to local regulations/law/guidelines, company strategy and global compliance -

- Ensure compliance with DBE/MCA, relevant local regulations and laws for related CPO activities (RIM updates, RMP, product packaging material, promotional materials/activities, g etc.)
- Foster and maintain good relations with internal and external stakeholders -
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt.

Key performance indicators:

- Manage assigned product portfolios across multiple therapeutic areas.
- Develop and execute regulatory plans for new registrations, variations, renewals, safety updates, and dossier maintenance activities.
- Support accelerated approvals, line extensions, new indications, and product launches.
- Maintain current product licenses and ensure alignment with global regulatory strategy.

Minimum Requirements:

Work Experience:

- Manage complex product portfolios and regulatory work plans.
- Prioritize submissions, coordinate resources, and track milestones.
- Lead follow-up activities for approvals, health authority feedback, and implementation actions.
- Support business continuity through handovers, portfolio planning, and workload management.
- Partner with Medical, Quality, Supply Chain, Pharmacovigilance, Commercial, Global Regulatory Affairs, manufacturing sites, and external service providers (Cross Cultural Experience).
- Build and maintain effective relationships with health authorities and industry stakeholders.
- Provide regulatory guidance and influence cross-functional decision making.

Skills:

- Strong regulatory knowledge of South African pharmaceutical legislation and SAHPRA processes.
- Effective project management and prioritization skills.
- Attention to detail and dossier quality.
- Strong stakeholder management and communication capabilities.
- Ability to manage multiple submissions and products simultaneously.
- Regulatory systems knowledge (e.g., Regulatory Information Management systems, eCTD processes, regulatory databases).
- Cross-functional collaboration and compliance mindset.

Languages:

- English.

Education & Qualification

- B.Pharm. Registration with SAPC.
- Regulatory Experience: 3-5 years.

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
Development

Business Unit
Development

地点
South Africa

站点
Midrand

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6ac74158946e6896270456", 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_data_layer.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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