

RA Manager GDD - Oman (Omani National)

Job ID
REQ-10073066

3月 02, 2026

Oman

摘要

We are hiring for a RA Manager role in Oman. This role will provide effective regulatory support to Oman for new product registration, regulatory maintenance , and regulatory intelligence activities.

This role is only for Omani Nationals who are based in Oman currently.

#LI-Onsite

About the Role

Ø NEW PRODUCT REGISTRATION

- Implementing the registration of priority / new products in Oman as per the agreed yearly objectives. With minimum supervision, evaluate, prepare and submit drug registration applications in

a timely manner and follow through the application during the evaluation phase to achieve a favourable outcome for registration and pricing.

- Coordinate with Regional Brand Regulatory Managers (RBRMs) in Basel and Hyderabad team to ensure having the registration requirements on time, hence fast submission / approval of new products.
- Coordinate with 3rd party suppliers for reference / related substance requests from the MOH.

Ø REGULATORY MAINTENANCE:

CMC, PT and Update - responsibilities:

- Receive and archive all ' CMC, PT & Update ' that are dispatched by Regulatory team in Hyderabad
- Prepare and submit the ' CMC, PT & Update ' that are relevant to assigned countries
- Ensure speedy approvals from Health Authorities in assigned countries
- Update local registration files with new ' CMC, PT & Update ' approvals
- Update the approval to Regulatory team in Hyderabad and logistics for assigned countries, by sending notification.
- Coordinate with maintenance group - Team Leader to ensure correct and speedy implementation / correct consignments

New / Renewal of registration of Manufacturing site/s - responsibilities:

- Ensure new/renewal of registration of manufacturing site as per new and mature products registration plan in the assigned countries
- Request all required documentation concerning manufacturing site registration from Basel and support team in India
- Ensure speedy submissions and approvals of manufacturing site registration in the assigned countries in order to shorten time of product registration
- Update local archives for manufacturing site new/renewal of registrations
- Coordinate with maintenance group Team Leader to ensure correct and speedy implementation / consignments
- Develop and maintain good working relationship with DRA Team in Middle East Cluster and Indian DRA support team

- Develop and maintain strong relationship with the Health Authorities and Agents in the assigned countries

De-registration of pruned products - responsibilities:

- Initiate de-registration of pruned products without affecting the existing stock, coordinating with the respective countries and keeping informed the country managers
- Update local registration files with submission and/or confirmation from HA for the de-registration
- Update the de-registration to Regulatory team in Hyderabad and logistics for assigned countries

Divestment projects - responsibilities:

- Provide necessary supports to the responsible parties of the acquired companies for the Novartis products divested to them.
- Provide necessary maintenances (CMC/PT/Renewals) to the divested products until the divestment process is completed
- Necessary follow-ups until the Marketing Authorization of the divested product is transferred to the new company

Renewal:

- Co-ordinate with Renewal coordinator ME in Regional office to ensure the registration renewal is submitted and approved in assigned countries as per the local regulations and the renewal plan.

LABELING:

- Coordinate with logistics to ensure availability of correct pack in assigned countries.
- Sign PPMS (material and shipment approval).
- Answer manufacturing site queries concerning shipment approval/authorisations /pre license sale
- Coordinate with Logistics/ chain supply/ Artwork teams and manufacturing site to obtain valid artworks and implementation dates.
- Coordinate with Logistics/ chain supply/ Artwork teams and manufacturing site to ensure that the registered product specifications are compliant and being imported to each country.

QUALITY ASSURANCE RESPONSIBILITIES:

- Assist Quality Assurance Manager for QA issues in assigned countries.

Regulatory intelligence Responsibilities:

- Developing and maintaining Healthy professional relationships with MOHs in assigned countries.
- Monitor competitor activities.
- Establish and maintain the Health Authority stakeholder mapping.
- Establish and maintain regulatory country fact book.
- Design and implement Health Authority management plan.
- Effective identification and communication of regulatory changes and emerging opportunities in assigned countries.
- Ensure transparency in Health Authority communication and interaction.
- Ensure participation at relevant local trade association.

OTHERS:

- Ensure full support to Global regulatory compliance initiatives in BOQ including:
 - DRAGON updates and verification.
 - Registration and implementation of labelling changes.
 - Submission of Risk Management plans (RMP) and Periodic Safety Update Reports (PSURs).
 - Ensure submission of new Safety updates received from DRA Regional office
- Update logistics with the DRA related information for the completion of Notification of Introduction (NOI).
- Communicate pricing of new products / Re-pricing to local logistics department and global - operations department.
- Monthly update of the registration data sheet (RDS) for Oman based on “Global project list”, in order to have a plan for registration and/ or launch for new products. The same being a very important tool which provides a registration update to various departments (Marketing, Medical, logistics etc.), at any time.
- Monthly reporting regulatory activities to Head Regulatory affairs Department - ME cluster.

- Provide regulatory advice to country managers in Oman.
- Develop and maintain healthy working relationship with colleagues in DRA department and with other Novartis department both locally in the ME , Hyderabad DRA support team and with Head office.
- Develop and maintain strong relationship with the Health Authorities and Agents in the assigned countries

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

Oman

站点

Oman

Company / Legal Entity

OMP0 (FCRS = CH024) Oman (AEP0)

Functional Area

Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer69a588556a48b903015929"); 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 < deviceWidth) { var config = { targetId:
"kalturaplayer69a588556a48b903015929", 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: "1_dgfvmafo"}); setTimeout(() => {
```

```
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {  
  players.forEach((currentPlayer) => { currentPlayer.addListener('play', () => {  
    players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===  
    'function') { otherPlayer.pause(); } }); }); }); } catch (e) { console.error(e.message) }
```



VIDEO

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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