

Manager, Quality Assurance

Job ID
REQ-10087654

九月 29, 2026

India

摘要

About the role:

Responsible for managing quality aspects at external suppliers for pharmaceutical products and to ensure that the operational business is in compliance with cGMP, the Quality Assurance Agreement, regulatory requirements, and the Novartis Pharma Quality Manual and is conducted according to the relevant SOPs

About the Role

Key Requirements:

- Lead External Suppliers Qualification process. Acts as Single Point of Contact / SPOC for all quality related activities at the External Supplier. Ensure that all aspects of the handling, manufacturing and distribution of pharmaceutical products are in compliance with the Novartis

Pharma Quality Manual, the effective Quality Agreement that they meet relevant cGMP regulatory requirements and are conducted according to local SOPs

- Provide quality leadership and oversight for technology transfer activities involving external suppliers, ensuring successful transfer of products, processes, analytical methods, specifications, and relevant documentation in compliance with Novartis Quality Standards, Quality Agreements, and regulatory expectations.
- Review and approve technology transfer protocols, risk assessments, validation strategies, comparability evaluations, and transfer reports, ensuring readiness for commercial manufacturing and supply. Responsible for driving / initiating External Supplier Quality Risk assessments for all External Suppliers. Gaps in Quality Systems to be identified with an evaluation of the associated risks. Remediation plans are to be defined and execution is to be monitored to ensure that issues are suitably addressed.
- Provide the quality presence and in-put to technical meetings with the External suppliers and establish good working relationships with clear communication and defined actions and goals. Responsible for coordinating and ensuring that Quality auditing of External suppliers is carried out according to the Novartis Quality Manual - maintain an annual auditing program, participate in audits, manage action plans and follow up on CAPAs.
- Manage critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual. Ensure investigations are correctly executed.
- Escalate any issues or instances of instability per the Novartis escalation policy and initiate any market action that is required. Support / participate in Novartis Emergency Management cases as required.
- Ensure that Change requests, either from the External Supplier or from Novartis, are managed according to the Quality Agreement and Novartis SOPs from receipt, through to the implementation and closure. Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance.
- **Within the organization:** Implement and maintain a local Quality System and Standard Operating Procedures defining all the processes for managing of External suppliers. Ensure that the QA Lead and the Supplier Relationship Manager is kept informed of all critical and major issues which may have an adverse effect on the quality of the product at an External Supplier.
- Together with the Supplier Relationship Manager provide direction, formulate strategies and make decisions which ensure the efficient operation of the External Supplier business as a whole - Participation in the Business review of External suppliers.
- Participate in the Reporting on QA External Supplier activities - this is to include Risk Assessment, reporting and managing of defined KPI 's. Ensure that coordinated contact is maintained with other functions within Novartis also dealing with External suppliers namely Purchasing, Legal, Supply Chain, Regulatory CMC, Drug Regulatory Affairs, Quality Operations (QOP), etc.
- Participate in the ESO Quality Plan - ensure that all quality issues at External suppliers are included in this plan. Participate in projects as defined and ensure that all aspects are implemented and followed up.

Essential Requirements:

- University degree in science (chemistry, pharmacy) and/or business administration advantageous.

- Minimum 10 years, in the pharmaceutical industry, with direct experience with pharmaceutical products. Experience in QC, QA Operations and Auditing. Thorough knowledge of cGMP requirements

Desirable Requirements:

- Strong understanding of regulatory requirements for commercial products
- Proven track record with FDA, EMA and other Health Authorities.
- Understanding of risk assessment and risk management fundamentals/tools. Technical understanding of pharmaceutical processes.

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部门
Operations

Business Unit
Production / Manufacturing

地点
India

站点
Mumbai (Head Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6abd5884beb23836979189", 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
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(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 = {};
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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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