

## **Regional Head, Pharmacovigilance Quality (PVQA)**

Job ID  
REQ-10089823

十月 13, 2026

United Kingdom

### **摘要**

#LI-Hybrid  
Location: London, UK

This role is based in London, UK. Novartis is unable to offer relocation support for this role. Please only apply if this location is accessible for you.

The Regional PV QA Head provides end to end quality assurance vigilance expertise and support to global and local operational Pharmacovigilance (PV) and Device Vigilance activities within Novartis with a focus on the country organizations, as well as quality expertise in regional and local vigilance regulation, in order to ensure compliance with applicable regulatory requirements and Novartis procedures.

### **About the Role**

## Major Accountabilities:

- Drive independently the regional and country quality oversight for implementation and maintenance of Novartis vigilance Quality Systems performed by the local teams, namely Quality Issue, proactive risk assessment and action management systems.
- Ensure, together with PS and PV in Countries and Regions team, that regional and country quality performance of the Novartis Vigilance System tasks and responsibilities is performed as required under global, regional and country PV regulations, to monitor that safety of the Novartis authorized products are met, and changes to their risk-benefit balance are identified.
- Support the regional and country Global Research and Development Quality management cycle through development, execution and accountability for deliverables of the global vigilance Quality Plan (QP). Coordinate execution of the QP with relevance to applicable regional and country patient safety activities and report the status to applicable Global PV QA team.
- Monitor indicators that relate to the performance, compliance and quality of regional and country vigilance systems, in line with indicators defined by Global PV QA team. Act as a quality champion by communicating risks to PS and PV and providing recommendations on potential mitigations Promptly communicate regional and country compliance issues to Global PS&PV, PV QA management and QPPV.
- Proactively propose potential quality improvement measures and develop strategies aimed at simplifying processes and improving quality of outputs while ensuring compliance with regulatory requirements; share best practice within and across regions. Lead regional initiatives focused on quality improvement and compliance, provide ongoing project support and governance, as assigned.
- Provide expertise and support Global PV QA team in the execution of vigilance Quality Risk Assessments (QRA) to identify and mitigate regional and country PV risks. Support maintenance of the Novartis global Pharmacovigilance System Master File (PSMF), where applicable.
- Ensure a constant state of regional and country vigilance inspection readiness. In line with Global PV QA and PS&PV teams, prepare for, facilitate, provide expertise and lead logistics for Health Authority (HA) vigilance inspections, assess results of pre-inspection activities and HA inspection findings in terms of associated risks and communicate to management. Perform Quality check of vigilance inspection deliverables. Align with PS and PV team and review the inspection corrective and preventive (CAPA) plan, to ensure quality, consistency and appropriateness of commitments. Act as the functional QA approver of inspection CAPA plans from the PV inspections in country organizations in the QMS Monitor the status of implementation of the CAPAs and approve the related evidence in the QMS, to ensure they are completed, appropriately documented and sustainable.
- Expertly guide the development of robust and sustainable CAPAs to address PV audit findings related to country organizations and act as functional QA approver of the CAPA plan in the QMS. Monitor the status of implementation of CAPAs to ensure they are completed, appropriately documented and sustainable and approve applicable related evidence in the QMS
- Provide expertise and support country PS and PV and other business partners with identification and compliance of-Quality Issue investigations, act as functional QA in the QMS and ensure timely escalation of applicable Quality Issues to management; provide assistance in the remediation of PV system issues; ensure follow-up and monitoring of completeness of CAPAs in alignment with PV QA team.
- Oversee definition of PV self-assessment plans from Regional PS & PV team to regional and country pharmacovigilance processes as well as their execution. Review vigilance self-

assessment reports and approve related action plans in the QMS

- Identify regional and local training needs (for example via Quality Issues) and deliver knowledge sharing sessions that meet the needs of business and QA partners and improve overall quality and compliance of the Vigilance system.
- Provide guidance and recommendations on Merger & Acquisition as well as divestment relevant activities for integration or disintegration of the vigilance system, where applicable.
- Lead and/or support due diligence (DD) activities for potential product and/or company acquisitions, when applicable.

### **Minimum Requirements:**

- Degree in Life Sciences or related scientific discipline. Higher degree desirable.
- Excellent written and verbal English communication skills; fluency in a second language a plus.
- Quality/ PV/ clinical/ regulatory affairs/ pharmaceutical industry/ health authority experience; GCP/PV/GMP auditing or inspection experience and Health Authority interactions a plus
- Experience in PV in a country organization and global quality support to stakeholders in country organizations a plus
- Ability to travel up to 20%
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision; Excellent problem solving, decision making and prioritization skills
- Quality mindset and excellent quality and compliance leadership and facilitation skills
- Extensive knowledge of PV regulations, guidelines and policies; Awareness of GCP and Part 11 requirements
- Ability to lead teams and operate successfully in various team capacities and diverse cultural environments
- Ability to deputize for the Global Head PV QA Regions and Countries as needed.

### **Benefits & Rewards**

At Novartis, we 're committed to reimagining medicine together - and rewarding the people that make it happen!

**Expected Annual Base Salary Range for role:** 63,917.00 - 118,703.00 GBP

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

Read our brochure to learn more about our global total rewards offering:

<https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>

*Note: Benefits and compensation may vary by country and are subject to local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process.*

**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 \(PDF 30 MB\)](#)

Primary location salary range  
£ 63,917.00 - £ 118,703.00

部門  
Development

Business Unit  
Quality

地点  
United Kingdom

站点  
London (The Westworks)

Company / Legal Entity  
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area  
Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6acf08a6da880209881621", 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 }; } }
```

```
(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 =
thumbEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbEmbed() 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 kalturadatalayer.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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