Globalni GMP revizor ekspert za kakovost / Senior Global GMP Quality Auditor

Job ID
REQ-10088228

十一月 11, 2026

Slovenia

摘要

#LI-Remote
Location: Ljubljana, Slovenia

Odgovornost za vodenje, podporo in poro č anje neodvisnih GMP revizij v skladu z Novartisovim sistemom kakovosti in veljavnimi GMP predpisi, z namenom, da se oceni skladnost z veljavnimi predpisi, standardi in dokumenti.
Odgovornost za pregled in odobritev na č rtov korektivnih ukrepov na podlagi revizijskih ugotovitev.
Izvedene revizije vklju č ujejo notranje in zunanje cilje proizvodnih lokacij, razvojnih centrov, sistemov kakovosti, pogodbenih proizvajalcev, laboratorijev, skladi š č , dr ž avnih organizacij in dobaviteljev.

In this role you will be required to travel up to 60% of time. You can be based either in Spain (Madrid or Barcelona) or Slovenia (Ljubljiana).

Novartis can offer relocation support for this role!

In this role you will lead, support and report independent GMP audits according to the Novartis Quality System and the current GMP regulations to assess compliance with applicable regulations, standards, and guidance documents. Review and approve corrective action plans in support of the audit observations. The audits performed include internal and external targets of manufacturing sites, development centers, quality systems, contract manufacturers, laboratories, warehouses, country organizations, and suppliers.

The Global GMP Senior Quality Auditor also ensures alignment with strategic direction of the company and assist in driving implementation of the applicable actions and provides consultation to Novartis business units through risk based assessments.

About the Role

Major accountabilities:

- Support the strategic development of an effective global risk-based audit strategy and program. Collect, collate, and incorporate input into the audit strategy and plan.
- Plan, lead, conduct, document, and follow-up of GMP audit according to the requirements specified in the respective Novartis Quality procedures as well as applicable regulations, standards, quality agreements, and guidance documents.
- For this role, auditors will be given more complex and higher-risk audits, such as sterile API, aseptic DP, and combination products. The ability to assess risk of these operations is critical to success. Provide technical guidance, mentoring, and training on audit activities.
- Provide regulatory guidance for timely remediation and recommendations regarding acceptability of the proposed filing.
- Prepare audit reports according to NVS requirements and timelines. Identify and report best practices and lessons learned to support development/training of GMP auditors. Mentor junior GMP staff as required .Act as GMP compliance consultant for GMP trainings, task forces, continuous improvement projects as needed.
- Ensure appropriate escalation to responsible management in case of critical findings and support immediate follow-up measures according to NVS requirements on Management Escalations and other relevant procedures. Ensure adequate definition and recording of mitigation plans when applicable.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with the stakeholder QA representative and Auditee.
- Review and advise on relevant policies and procedures. Maintain current knowledge of regulations, standards, and guidance documents.

Essential requirements:

- 12+ years broad experience in Pharmaceutical or Medical Device Industry. 3 years auditing experience preferred, and excellent knowledge of regulatory requirements.
- **Strong knowledge of GMP regulations**, sound and practical judgement in the interpretation and application of regulations and standards.
- **Solid operational experience,** that should include QA/QC management and manufacturing, development or other relevant experience e.g. working at a regulatory health authority.
- **Strong experience in Sterile** and/or expertise in at least one of the following areas: DP

Manufacturing, Laboratories activities, Medical Devices, API, Biologics, Microbiology, Computer System Validation, Quality Systems, Cell&Gene therapy, Radioligand therapy.
- Strong interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis colleagues, vendors and customers.
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Fluent English, written and spoken. Other languages are a plus.

Desirable requirements:

- Experience and/or interaction with local Health Authority and sporadically with other Health Authorities is a plus.

Rewards

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

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 a minimum of 14 weeks paid parental leave.

Expected Annual Base Salary Range for role:

- Slovenia: EUR 46.900,00 - 87.100,00

The 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. Further details will be provided during the application process.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics.

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.

Commitment to Diversity and Inclusion / EEO paragraph:

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

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: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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Primary location salary range
€ 46,900.00 - € 87,100.00

部门
Operations

Business Unit
Quality

地点
Slovenia

站点
Ljubljana

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6af648db75315017869391", 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 adatalayer.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) }

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversity.inclusionslo@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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