

Site Quality Head (m/w/d)

Job ID
REQ-10072287

3月 23, 2026

Germany

摘要

#LI-Onsite

In this role you will provide quality assurance oversight and be accountable for supporting Quality operations and provide technical and strategic leadership for all quality-related matters. Accountable to ensure compliance to GxP standards including product manufacturing and testing. You will also ensure Compliance with cGMP requirements and with the Novartis Quality Manual and policies.

About the Role

Major Accountabilities:

- Provide leadership for strategic site initiatives, and represent site SLT quality in local cross-functional and global projects teams as team member or team leader that represent site quality.
- Ensure all facilities, utilities and equipment are designed and installed to be operated in a safe

and effective manner and are compliant with applicable standards

- Ensure that during project phase planning, construction, commissioning, qualification (IQ, OQ and PQ) including any other validation activity complies with cGMP.
- Timely escalation of risks in meeting timelines and / or budget incorporating site master planning and the long-term strategic plan.
- Ensure adequate management of product critical quality issues (deviations, out of specifications). Ensure investigations are correctly executed and adequate CAPAs are defined, and proper follow up of CAPAs effectiveness. Review, provide guidance for, escalate where appropriate, and approve HA notifications (compliance related such as Exception requests, other).
- Define, implement, monitor, consolidate and analyse Site Quality KPIs. Ensure Site Quality Committee is established, ensure relevant corrective and preventive actions are endorsed and implemented.
- Drive for Site management team accountability. Coordinate the generation and monitor the execution of the Site Quality Plans, DI Plan, Site Quality Risk Assessments and other relevant gap assessments.
- Hiring people, team building, people development and talent retention.

Obligatory Requirements:

- Education: BS/MSc in Life Sciences and/or related experience.
- 10+ years of experience in GMP Pharmaceutical Manufacturing (including laboratory operations and Aseptic experience), at least 3 years combined of relevant experience in Quality Control and/or Quality Assurance covering quality areas.
- Proven track record and practical experience in supporting a Quality Control operations unit and operating in full compliance with global cGMP requirements.
- In-depth knowledge of cGMP regulations. Successfully managed inspections from major Health Authorities
- Proven ability to manage multiple projects with moderate resource requirements, risk and/or complexity.
- Fluent German and English, written and spoken.

Desirable requirements:

- Experience with Health Authorities and inspections is highly desirable.

You ' ll receive:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical, mental and social well-being (Wellbeing), employment at Top SI Employer, Unlimited learning and development opportunities.

Commitment to Diversity and Inclusion:

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: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

部门

Operations

Business Unit

Production / Manufacturing

地点

Germany

站点

Halle (Saale)

Company / Legal Entity

D122 (FCRS = DE122) Novartis Radiopharmaceuticals GmbH

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6a353852395bf134374735", 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 kalturaPlayer =
kPlayer.setup(config); // Add the player to the global array.
window.kalturaPlayerVideos.push(kalturaPlayer); // Load the Player for other media.
kalturaPlayer.loadMedia({entryId: "1dgvfmafo"}); } catch (e) { console.error(e.message) }
```

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve. Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability. The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Halle-Saale/Site-Quality-Head--m-w-d-REQ-10072287-1>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Halle-Saale/Site-Quality-Head--m-w-d-REQ-10072287-1>