NOVARTIS

Qualified Person (QP/Sachkundige Person) (m/w/d)

Job ID
REQ-10090599

十月 27, 2026

Germany

摘要

#LI-Onsite

Location: Halle, Germany

This role is based in Halle, Germany. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

We are seeking a highly qualified and independent Qualified Person / Sachkundige Person to oversee and ensure the compliance of manufacturing and quality control activities at the site, in accordance with the applicable manufacturing authorization, EU GMP requirements, and German regulatory requirements.

In this role, the Qualified Person will independently supervise manufacturing processes and control testing activities, acting in compliance with the applicable provisions of Directive 2001/83/EC, EU GMP, the German Medicinal Products Act – Arzneimittelgesetz, AMG, and the German Ordinance on the Manufacture of Medicinal Products and Active Substances – Arzneimittel- und Wirkstoffherstellungsverordnung, AMWHV, as amended. The role is critical in ensuring that medicinal

products meet the required standards of quality, safety, and regulatory compliance.

Working closely with the Site Quality Head and Site Manager, the successful candidate will support the effective implementation, monitoring, and continuous maintenance of a GMP-compliant Quality Management System. This includes ensuring adherence to German medicines legislation, applicable EU and national regulations, internal ADACAP quality standards, approved product quality requirements, and site SOPs.

As part of the Quality Assurance function, the role will provide both operational and strategic support for GMP-related activities, helping to identify, manage, and resolve quality issues while promoting a culture of compliance, accountability, and continuous improvement across the site.

About the Role

Major Accountabilities:

- Certify and release medicinal product batches, ensuring manufacturing and testing are performed in compliance with applicable laws, EU GMP requirements, the manufacturing authorization, and Marketing Authorization conditions.
- Ensure batch documentation and records are complete, accurate, properly stored, and available for inspection or upon request by the relevant German competent authorities.
- Assess and release manufactured medicinal products in accordance with German national legislation, EU GMP requirements, and the responsibilities of the Qualified Person / Sachkundige Person.
- Collaborate with Quality Control and Production teams to support batch-related activities and ensure smooth, compliant production operations.
- Review, support, and approve quality processes including deviations, complaints, change controls, CAPAs, and related investigations.
- Immediately escalate any significant quality irregularities identified in marketed products to site management and, where required, to the relevant German competent authority in accordance with applicable reporting obligations.
- Partner with functional leaders to maintain, monitor, and continuously improve an effective GMP-compliant Quality Management System.
- Identify and propose technological, procedural, and organizational improvements to enhance quality, productivity, cost efficiency, and resource optimization.

Essential Requirements:

- Degree in Pharmacy, Chemistry, Pharmaceutical Chemistry, Biology, Human or Veterinary Medicine, or another relevant scientific discipline meeting the requirements for a Qualified Person / Sachkundige Person under applicable German legislation.
- **Eligibility to act as a Qualified Person / Sachkundige Person in Germany**, including compliance with the qualification and practical experience requirements under the **German Medicinal Products Act – AMG** , in particular the applicable requirements for sachkundige Personen.
- Previous experience as a Qualified Person / Sachkundige Person within a pharmaceutical manufacturing environment; sterile manufacturing experience is strongly preferred.

- **Strong understanding of EU GMP requirements**, pharmaceutical quality systems, German regulatory expectations, and batch certification responsibilities.
- High level of quality awareness, with a proactive approach to identifying and resolving compliance-related issues.
- Excellent **collaboration and communication skills**, with the ability to work effectively across Quality Control, Production, and site leadership teams.
- Ability to support daily production operations while ensuring compliance, safety, and product quality.
- Fluency in **German and English**, both written and spoken.

Benefits & Rewards

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

Expected Annual Base Salary Range for role: € 79,800 to € 119,800

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.

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

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)

Primary location salary range
$0.00 - $0.00

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: "kalturaplayer6ae3b85736c61966217670", 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 } }; }

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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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