NOVARTIS

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

Job ID
REQ-10090599
Nov 11, 2026
LOC_DE

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.
- Qualification as a Qualified Person for radiopharmaceuticals according to AMG §15 (3a) 5.
- 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.
- 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.

Desirable Requirements:

- Previous experience as a Qualified Person / Sachkundige Person within a pharmaceutical manufacturing environment; sterile manufacturing experience is strongly preferred.

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/novartis_com/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.

Role Requirements

Primary location salary range
$0.00 - $0.00

Division
DIV_TO
Business Unit
Production / Manufacturing
Location
LOC_DE
Site
Halle (Saale)
Company / Legal Entity
D122 (FCRS = DE122) Novartis Radiopharmaceuticals GmbH
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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