NOVARTIS

Qualified Person (QP)

Job ID
REQ-10083725
июл 20, 2026
Италия
Available in: English

Сводка

#LI-Onsite
Location: Colleretto Giacosa (Ivrea), Italy

This role is based in Ivrea, Italy. 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 to oversee and ensure the compliance of manufacturing and quality control activities at the site, in accordance with the applicable drug manufacturing license and local regulatory requirements.

In this role, the Qualified Person will independently supervise manufacturing processes and control testing activities, acting in full compliance with Article 52 of Legislative Decree No. 219 of April 24, 2006, derived from EU Directive 2001/83/EC, and subsequent amendments. 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 national medicines legislation, applicable 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, GMP requirements, and Marketing Authorization conditions.
- Ensure batch documentation and records are complete, accurate, properly stored, and available for inspection or upon request by Health Authorities.
- Assess and release manufactured medicinal products in accordance with national legislation and Qualified Person responsibilities.
- 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 the Italian Medicines Agency, AIFA, as required.
- 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.

Obligatory Requirements:

- Degree in **Pharmacy, Pharmaceutical Chemistry and Technology, CTF, Chemistry**, or a related scientific discipline.
- Previous experience as a **Qualified Person** within a pharmaceutical sterile manufacturing environment.
- Qualification as an **Authorized Qualified Person**, in accordance with **Legislative Decree No. 219 of April 24, 2006**.
- Strong understanding of GMP requirements, pharmaceutical quality systems, and regulatory expectations.
- 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 **Italian and English**, both written and spoken.

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: EUR 43,800-81,300.

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/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 / 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
€43,800.00 - €81,300.00
Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Италия
Сайт
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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