NOVARTIS

Qualified Person

Job ID
REQ-10073536
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Италия

Сводка

Independently supervise, without any interference of third persons, manufacturing processes and control testing of the site, related to the drug manufacturing license, operating as Qualified Person according to the local law (Article 52 of the Legislative Decree n. 219 of April 24th 2006 from EU directive 2001/83/CE and following modifications). With respect to the quality of the medicinal products, assurance of compliance to the National Medicines Law and other applicable regulations and together with the Site Quality Head and Site Manager maintaining an effective implementation, monitoring and maintenance of a GMP-compliant quality system.

As Quality Assurance, it is required to support all GMP relevant tasks/issues (operational and strategic) by ensuring compliance according to the ADACAP internal quality standards, relevant regulatory requirements, filed product quality standards and SOPs in place

About the Role

Major accountabilities:

- Guarantee and certify that each batch of medicines is produced and checked in compliance with the law and the conditions imposed in the marketing authorization.
- Assessment and release of manufactured medicinal products, in accordance with national legislation.
- Guarantee that the documentation attesting the suitability of each product lot is available and can be shown at the request of the health authority.
- Collaborate in the approval of deviation investigations.
- Make sure that the batch record of the released batch is stored correctly and can be exhibited at the request of the health authority.
- Communicate immediately to the national Health Authority (AIFA) and to the Management any substantial irregularity detected in the product that has already been placed on the market.
- Work in collaboration with Quality Control and Production departments in the activities related to the manufactured batches.
- Identify and propose technological and organizational interventions aimed at improving manufacturing processes in terms of quality, productivity and costs and the optimization of resources.
- Collaborate with the Function Managers in order to guarantee the correctness of the Quality Management System.
- Management of deviations, complaints, change control and CAPA.

Essential requirements:

- Degree in Pharmacy, CTF or Chemistry.
- Previous experience in the role within a pharmaceutical sterile manufacturing environment (Authorized Qualified Person certificate according to Legislative Decree n. 219 of April 24th, 2006).
- Strong affinity with quality and awareness of quality issues.
- Open and clear collaboration and communication to make sure the daily production operation runs smoothly and safely.
- Fluent in Italian and English.

This role is 100% site based in Ivrea.

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)

Дивизион
Operations
Business Unit
Quality
Место
Италия
Сайт
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area
Quality
Job Type
Full time
Employment Type
Regolare
Shift Work
No

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