Qualified Person

Job ID
REQ-10059263

7月 31, 2025

Italy

摘要

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 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 od deviations, complaints, change control and CAPA.

Essential requirements:

- Degree in Pharmacy, CTF or Chemistry.
- Previous experience in the role within a pharmaceutical 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.

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部门
Operations

Business Unit
Innovative Medicines

地点
Italy

站点
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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