Qualified Person

Job ID
REQ-10044134

3月 13, 2025

Italy

摘要

Responsabile della gestione degli aspetti qualitativi all'interno dell'area di responsabilit à e di garantire che l'attivit à operativa sia conforme alle cGMP (Current Good Manufacturing Practices), all'Accordo di Garanzia della Qualit à , ai requisiti normativi e al Manuale di Qualit à Novartis e sia condotta secondo le relative Procedure Operative Standard

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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