U NOVARTIS

QC Supervisor

Job ID REQ-10042641 Feb 28, 2025 Italy

Summary

The QC Supervisor supports the QC Head to ensure that Quality Control processes for materials acceptance, batches quality control and QC equipment validation/qualification are executed and fully compliant to cGMPs regulation, corporate and national guidelines.

About the Role

Major accountabilities:

- Be the Deputy of QC Head in managing, coordinating and approving the execution of the analytical activities for the batch release and in raw materials and packaging materials acceptance according to specifications;
- Ensure that the stock of materials, reagents, standards is properly available and ordered; ensure that all QC materials are properly and safely stored, identified, labelled recorded and monitored according to SOPs and specifications; ensure the correct storage of Reference and Retention Samples of the raw materials and products;
- In case of analytical results out of specification (OOS), out of trend (OOT), out of expectation (OOE) or System Suitability Test failures, and in case of deviations, in collaboration with QC Head, perform the investigation and verity the implementation of the related CAPAs; ensure that all methods used in QC analysis are validated according to SOPs, MA and cGMPs; support the QC Head to assure the adequacy of the SOPs of Quality Control department; redaction and review of SOPs, Protocols and Reports;
- Collaborate with QC Head for the redaction of the stability programs and the annual product review; ensure that the stability analysis are performed on time;
- Collaborate with QC Head to ensure the initial and periodic training of QC analysts; manage the presence, shifts and performances of the QC Technicians when QC Head is not on site;
- Maintain, review and approve the records of the QC activities (i.e. logbook, form, analytical batch record);
- Collaborate with QC Head for the periodical self-inspections and external audits (Health Authorities, Certified Bodies, Supplier); contribute in maintaining the local quality system as per GMPs and corporate guidelines and in assuring the respect of the GMPs and Health Authorities requirements at local level;
- Guarantee the cleanliness and tidiness and application of Good Laboratory Practice;
- Ensures high level of attention for handling of radioactive materials within the area of responsibility. Running operations in full compliance with HSE guidelines (internal/external);
- Support the development and implementation of projects related to new or existing products.

Essential requirements:

- Scientific Degree (CTF, Pharmacy or Chemistry preferred);
- Previous experience in a similar role within a GMP/gab environment;

- Available to work in shifts, including night shifts.
- Fluent in Italian. Good knowledge of English.

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Division Operations **Business Unit Innovative Medicines** Location Italy Site lvrea Company / Legal Entity IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl **Functional Area** Quality Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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representative of the patients and communities we serve.

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