QC Specialist II

Job ID
REQ-10046770

4月 17, 2025

Romania

摘要

Highly skilled and experienced laboratory professional who contributes by:
-Ensuring the quality system for quality control in accordance with current regulations;
-Ensuring the compliance of quality specifications and analytical procedures with current regulations and registration dossiers;
-Archiving documents from the control department for the internal laboratory;
-Active involvement in the supplier approval process.

About the Role

Key Responsibilities:

- OOX/Deviation handling. Prepares analytical procedures specific to raw materials, primary packaging, and finished products; Prepares standard operating procedures specific to the Physico-Chemical laboratory; Participates in the approval and evaluation process of

suppliers of raw materials, primary and secondary packaging; Collaborates with the AS&T, QSC, and MS&T departments for the preparation of procedures, data evaluation, and document drafting;
- Implements actions established within the change control process; Responds to requests from the QSC department regarding raw materials and primary packaging; Periodically verifies the validity of procedures in the Physico-Chemical laboratory; Updates standard operating procedures and analytical procedures in accordance with changes in USP, EP, JP, and BP;
- Prepares inspection plans for raw materials, packaging, and finished products in the Shape system; Prepares bulletins for working standards; Prepares necessary documents for registrations; Participates in GMP, job-specific, HSE, and HR training; Participates in the performance management process (EVOLVE);
- Maintains basic data in the system (inspection methods, testing parameters, inspection plans, etc.); Performs activities in the SHAPE/SLIM system according to allocated roles; Archives and disposes of archived documents according to current procedures; Involvement in initiatives to increase efficiency in the quality control laboratory, within the department; Ensures timely and accurate reporting of detected quality issues; Ensures the correct application of current quality control standards;
- Stimulates process optimization, continuous improvement, operational excellence, and innovation within the team; Responsible for reporting to management any activities that have the potential to compromise the quality system or product quality, in accordance with the Quality Escalation Directive from the Novartis Quality Manual; Responsible for the accuracy and completeness of completed documentation;
- Manages quality events in the 1QEM system, mainly deviations related to planning;
- Complies with GMP, SSM, SU, and environmental protection standards, as well as job-specific procedures in force.

Key performance indicators:

- The relevant KPIs that are defined in the Quality Control areas apply: e.g. analytical lead times -Timely and GMP-compliant analysis & documentation of the results.
- Error rate: Number of OOS (analysis errors) related to the number of analyzes -No complaints about official inspections.
- Individual performance is assessed using the PMP performance dialog together with the manager

Essential Requirements:
Work Experience:

- Functional Breadth.
- 2-5 years' experience in Pharma/Manufacturing sector in analytical lab in.
- Collaborating across boundaries and a GMP environment/equivalent.

Skills:

- Continuous Learning. Dealing With Ambiguity. Decision Making Skills.
- GxP
- Industry Standards.
- Laboratory Equipment. Laboratory Excellence.
- Quality Control (Qc) Testing. Quality Control Sampling.

- Self-Awareness. Technological Expertise. Total Quality Management.

Languages :

- English: Advanced Level

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部门
Operations

Business Unit
Universal Hierarchy Node

地点
Romania

站点
Targu Mures

Company / Legal Entity
RO03 (FCRS = RO003) SC Sandoz S.R.L

Functional Area
Quality

Job Type
Full time

Employment Type
Temporary (Fixed Term)

Shift Work
No

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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