Senior QC Specialist

Job ID
REQ-10054047

6月 24, 2025

Romania

摘要

Coordinate and execute all activities to ensure the timely testing and release of all samples, collaborate with team in the design and execution of validation and other major projects. Provide employees with training and resources to meet or exceed customer requirements. Monitor processes and products to identify opportunities for continuous improvement. Serve as the subject matter expert on specific areas and techniques and proactively provides education technical knowledge and skills to less experienced scientists.

About the Role

Major accountabilities:

- Implementing corrective and preventive actions within the established timeframe as a result of deviations, complaints, internal and external audits, as well as inspections by authorities; Conducting appropriate risk assessments for compliance within the Site risk

assessment process and implementing actions to improve quality;
- Implementing actions established within the change control process Initiatives in the quality control laboratory regarding operational excellence; Reporting the number of batches and products analyzed for clients on a monthly basis; Participating in the creation and establishment of quality contracts for external products; Providing support for projects related to the transfer or validation of new products;
- Contributing to the current maintenance of the RCCP plan; Being responsible for the accuracy and completeness of the completed documentation;
- Preparing documentation containing raw data obtained in the laboratory for the registration department; Ensuring cost control and maintaining performance indicators;
- Participating in the selection and recruitment process of laboratory personnel; Providing support to laboratory personnel throughout the recruitment process, training to meet all operational requirements, and offering support in creating and implementing a career plan for laboratory personnel; Providing support to the team of quality specialists;
- Conducting periodic training sessions for subordinate personnel.
- Supervises the preparation of procedures and specifications necessary for conducting analyses, procedures for equipment, and standard operating procedures specific to the laboratory; verifies their correct preparation. Approving Monitoring documents. Preparation of retain sample lists (annual, for lab if needed and for APQR purposes)
- Mentor and coach staff members for ongoing growth and leadershi. Performs other job duties as assigned

Minimum Requirements:
Work Experience:

- Minimum of 5 years experience in the pharmaceutical/Biotechnology industries conducting QC testing, release testing and coordinating the activities of a QC laboratory.
- Thorough knowledge of cGxP expectations. Knowledge of ICH, Eur. Ph., USP and FDA and JP guidelines. Experience using LIMS systems. Experienced in writing OOS/OOE/OOT and/or deviation investigations
- Experience in supporting internal and/or external laboratory audits
- Advanced written and verbal communication skills. Advanced experience in the use of computer-based systems and applications associated with bioanalytical testing
- English - Advanced level
- Continuous Learning. Dealing With Ambiguity. Decision Making Skills.
- Gxp. Industry Standards. Laboratory Equipment. Laboratory Excellence. Managing Resources. Organizational Skills
- Quality Control Testing. Quality Control Sampling. Self Awareness. Smart Risk Taking. Total Quality Management.

Why consider Novartis?

766 million lives were touched by Novartis medicines in 2021, and while we ' re proud of this, we know there is so much more we could do to help improve and extend people ' s lives.
We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.
We believe our potential can thrive and grow in an unbossed culture underpinned by integrity,

curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world ' s toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

Imagine what you could do at Novartis!

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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) Novartis Pharmaceuticals S.R.L

Functional Area

Quality

Job Type
Full time

Employment Type
Regular

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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