Nitrosamines Specialist

Job ID
REQ-10053035

5月 27, 2025

T ü rkiye

摘要

We are looking for a highly motivated and skilled Nitrosamines Specialist to join our Analytical Sciences & Technology (AS&T) Hub and Nitrosamines in Istanbul. The candidate will be responsible for managing all analytical activities within the Nitrosamine laboratory in compliance with GxP, including method development, validation, and transfer studies using LC-MS/MS, GC-MSMS and HR-MS. This role requires strong technical expertise, meticulous documentation skills, and adherence to quality and data integrity standards (ALCOA+). The candidate will work collaboratively with cross-functional teams, support audit readiness, and contribute to continuous improvement initiatives while ensuring compliance with Novartis Quality Management Systems.

About the Role

Major accountabilities:

- Management of all analytical processes in the Nitrosamine laboratory in accordance with GXP

- Completion of assigned responsibilities correctly the first time, in accordance with relevant procedures (SOP, GOP, etc.) and workflows
- Execution and documentation of analytical method validation, analytical method transfer, and method development studies planned under the responsibility of Nitrosamine department
- Unexpected situations experienced during analytical studies are recorded and carried out in accordance with the relevant SOP within the scope of OOX- Deviation- TTI
- Preparation of all documents prepared after analytical studies (worksheet, FRM, analytical report, etc.)
- Preparation of documents related to the license
- Ensuring and maintaining the general order of the laboratory
- Using the devices in the laboratory in accordance with the operating instructions
- Compliance with HSE rules required in the laboratory
- Execution of laboratory operation in line with data integrity (ALCOA+) rules
- Self-sacrificing follow-up and implementation of delegated responsibilities within the team
- Updating and reviewing department procedures
- Taking responsibility for pre-audit preparations and subsequent actions
- Taking necessary actions in escalation processes

Key performance indicators:

- Quality oversight and timely execution of all analytical tasks under Nitrosamine scope
- Full compliance with GxP and Novartis Quality Management Systems
- Effective communication and collaboration with stakeholders
- Documentation and audit readiness at all times

Essential Requirements:

- University degree in Chemistry, Chemical Engineering, Pharmacy or related scientific fields
- Minimum 4 years of experience in analytical development or quality control in the pharmaceutical industry
- Proven experience in LC-MS/MS method development, validation, and feasibility testing - preferably with Nitrosamine studies
- Sound knowledge of mass spectrometry, GLP/GMP practices, and regulatory expectations
- Communication Skills
- Continuous Learning
- Dealing With Ambiguity
- Decision Making Skills
- Gxp
- Industry Standards
- Laboratory Equipment
- Laboratory Excellence
- Quality Control (Qc) Testing
- Quality Control Sampling
- Technological Expertise
- Total Quality Management
- English

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部门
Operations

Business Unit
Innovative Medicines

地点
T ü rkiye

站点
İ stanbul Kurtk ö y

Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sa ğ l ı k, G ı da ve Tar ı m Ü r ü nleri San. Ve Tic. A. Ş .

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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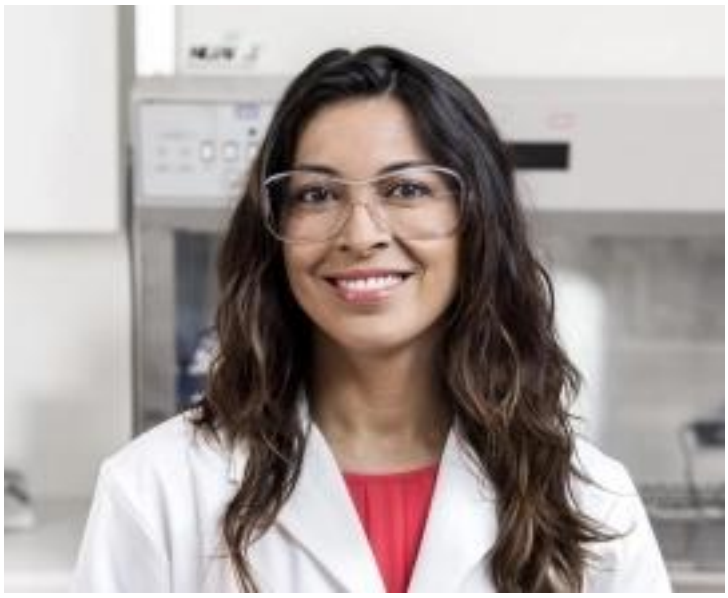

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