NOVARTIS

QC Supervisor

Job ID
REQ-10031253
Nov 25, 2024
Italy

About the Role

Major accountabilities:

- OOx/Deviation handling .
- CAPA definition -KPI trending -Ensure all activities in compliance with cGxP, incl. data integrity review and approval of analytical data / tests (analytical release) Stability -Stability testing (Projects) – protocol preparation, evaluation, report preparation .
- Reporting (Stability plan preparation, trend analysis, evaluation) -Performance of Stability studies, protocols and comparative reports for supplier qualification -Review and approval of analytical tests (analytical release) -Microbiological QC -Perform Microbiological testing of materials and utilities, environmental and personnel monitoring -Provide expert Support for site qualification and validation activities -Maintain and calibrate equipment incl. plan preparation -Support in supplier qualification -Trending and analysis of KPI/KQI -Support sample planning and sampling execution -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

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

Minimum Requirements:
Work Experience:

- Functional Breadth.
- 3-5years experience in Pharma/Manufacturing sector in analytical lab in.
- Collaborating across boundaries.
- 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.

Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Division
Operations
Business Unit
Innovative Medicines
Location
Italy
Site
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) AAA Italy Srl.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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