

Specialist-Quality Operations

Job ID
REQ-10024783

10月 08, 2024

India

摘要

-The role is responsible for coordination and management of analytical equipment related activities as well as to provide scientific analytical Support. This includes the evaluation, development and validation of methods required for raw materials and finished products. -Performs qualitative and quantitative analyses of organic and inorganic compounds to determine the identity, purity and homogeneity of drug substances and products related to each project. -Organizes and interprets all data obtained using a wide variety of instrumental technologies

About the Role

Major accountabilities:

- Statistical analysis -Support transfer projects -Product and process validation support
-Validation and qualification analytics -Method transfer -Implementation of new techniques/technologies -Method optimization -Equipment qualification -Equipment calibration

-Equipment breakdown management -Implementation of new technologies -Preparation of equipment qualification plan -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:

- No delay in registration and APR/PQR due to faulty stability study design -No critical delays in study start - approved protocol available on time, prompt storage of stability samples
- Stability Study reports and evaluation documents available on time; proper support for method transfer activities and other transfer projects
- Timely evaluation and communication of transport temperature excursions
- Additional KPIs as defined within the management team
- Samples and associated documents are delivered to the laboratories on time.

Minimum Requirements:

Work Experience:

- Sound technical & scientific knowledge of pharmaceutical/ chemical.
- analytics/QC/ equivalent.

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部门

Operations

Business Unit

Innovative Medicines

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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