

Associate Expert Science & Technology (Qualification Expert)

Job ID
REQ-10064555

12月 03, 2025

India

摘要

The Qualification Expert for Analytical Instrumentation is responsible for ensuring the accuracy and reliability of analytical instrumentation used in various scientific processes. They will be responsible for assessing and verifying the qualifications of these instruments, as well as documenting and maintaining the records.

About the Role

MAJOR RESPONSIBILITIES:

- Perform qualification assessments on analytical instruments to ensure compliance with regulatory requirements and industry standards.
- Develop and execute qualification protocols, including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ), for analytical instruments.

- Collaborate with cross-functional teams to ensure alignment on qualification processes and requirements.
- Ensure that all qualification activities are properly documented and maintained in accordance with company policies.
- Troubleshoot any issues or discrepancies that arise during qualification and propose and implement appropriate corrective actions.
- Stay up to date with industry trends, regulations, and best practices related to analytical instrumentation qualifications, and incorporate them into the qualification processes as necessary.
- Provide technical expertise and support to internal teams relating to the qualification and maintenance of analytical instruments.
- Continuously improve the qualification processes to enhance efficiency, accuracy, and compliance.

WHAT YOU ' LL BRING TO THE ROLE:

- Solid understanding of analytical instrumentation principles and technologies.
- Proven experience in qualifying and validating analytical instruments Like HPLC, GC , UV, FTIR, KFT, Balances, etc, including the development and execution of qualification protocols.
- Sound Knowledge on Software validation, software operation of CDS like Empower, Chromeleon, etc.
- Knowledge of relevant regulatory requirements and standards, such as FDA regulations and GMP guidelines.
- Strong analytical and problem-solving skills, with the ability to troubleshoot and resolve issues related to instrumentation qualification.
- Excellent documentation and record-keeping abilities, with strict attention to detail.
- Effective communication and interpersonal skills, with the ability to collaborate and liaise with cross-functional teams.
- Ability to work independently and prioritize tasks in a fast-paced environment.
- Continuous learning mindset and willingness to stay updated with industry advancements.
- Good knowledge of current Good Manufacturing Practices (cGMP); Advanced scientific/technical writing skills Wide experience on de-formulation studies of the drug products, especially in the microscopic evaluation of drug component.

MINIMUM REQUIREMENTS:

- B.E./B.Tech/Bachelor's or Master ' s degree in Chemistry, Analytical Chemistry, or a related field with experience of 2 + years.
- Good communication skills
- Knowledge of Good Documentation Practices.
- Knowledge of Good Laboratory Practices.

SKILLS:

- Laboratory instrument qualification
- Instrument lifecycle management
- Laboratory Equipment.
- Sop (Standard Operating Procedure).

LANGUAGES:

- English.

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部门

Development

Business Unit

Development

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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