U NOVARTIS

Expert Science & Technology (Qualification expert)

Job ID REQ-10053798

7月 06, 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 accountabilities:

- 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.

Key performance indicators:

- Successful execution of assigned tasks within given timelines at expected quality; right first time and right in time -Adherence to appropriate standards as defined in Quality Manual, SOPs, ethical, health, safety, environment (HSE), and information security (ISEC) guidelines -Adherence to costs, quality, quantity, and timelines for all assigned tasks.
- Feedback from other team members/leaders.
- Refer to annual individual and team objective setting.
- Measurable contributions to increasing efficiency and productivity in the work related to assigned projects.

Minimum Requirements:

- B.E./B.Tech/Bachelor's or master 's degree in chemistry, Analytical Chemistry, or a related field with experience of 10 + years.
- 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.

Skills:

- Laboratory Equipment.
- Laboratory equipment qualification
- GMP.

- Sop (Standard Operating Procedure).
- Technical Writing.

Languages :

• English.

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部门 Development

Business Unit Innovative Medicines

地点 India

站点 Telangana

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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