NOVARTIS

Qualification Expert

Job ID
REQ-10091329

十一月 17, 2026

India

摘要

Provide end-to-end technical ownership and coordination of analytical/laboratory instrument qualification projects to ensure laboratory equipment is fit for intended use and appropriately qualified before GMP/GxP release, with qualification documentation demonstrating conformance to predefined user requirements. This includes associated software-validation activities where applicable.
The Qualification Expert acts as the technical qualification specialist connecting all internal stakeholders

About the Role

Key Responsibities:

- Develop and implement qualification strategies and plans for laboratory instruments and equipment, ensuring activities are aligned with applicable GMP requirements, internal procedures, and the intended use of the equipment.

- Perform risk assessments and equipment classification to determine the appropriate qualification approach and define the required level of testing and documentation based on instrument criticality and GMP impact.
- Lead the preparation and review of User Requirements Specifications (URS), ensuring that business, technical, compliance, and data integrity requirements are clearly defined and traceable throughout the qualification lifecycle.
- Develop, review, coordinate, and execute qualification protocols, including IQ, OQ, and PQ activities, and ensure that deviations, observations, acceptance criteria, and qualification results are appropriately documented and resolved.
- Support the qualification of computerized laboratory instruments and associated software, ensuring that system functionality, interfaces, access controls, electronic records, and applicable data integrity requirements are adequately addressed.
- Maintain requirements traceability and qualification reporting, ensuring that qualification evidence demonstrates that user requirements have been successfully verified and that equipment is suitable for its intended use.
- Coordinate qualification activities with vendors, service providers, engineering, laboratory users, QA, maintenance, and calibration teams, including management of changes, requalification requirements, periodic reviews, and lifecycle activities.
- Maintain oversight of the instrument inventory and qualification status throughout the equipment lifecycle, ensuring continued qualified status through calibration and maintenance interfaces and supporting equipment retirement and decommissioning when required.

Essential Requirements

- 7+ years overall experience in pharmaceutical/biopharmaceutical laboratory equipment qualification, validation or engineering.
- 5+ years hands-on qualification experience in GMP/GxP environments.
- Demonstrated independent experience qualifying both conventional laboratory equipment and computerized analytical systems.
- Bachelor's or Master's degree in Instrumentation Engineering, Electronics/EEE, Biomedical Engineering, Mechanical Engineering, Pharmaceutical Sciences, Analytical Chemistry, Biotechnology, Chemical Engineering, or a closely related technical/scientific discipline.
- Knowledge of GAMP-based computerized-system concepts is also highly desirable because the laboratory-equipment qualification procedure explicitly addresses GAMP software categories in configuration/qualification considerations.

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

Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

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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