NOVARTIS

Instrument Qualification Expert

Job ID
REQ-10085008
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Индия
Available in: English

Сводка

Performs, supports or supervises instrument related qualification activities and change control including issuing, review and LU approval of corresponding documentation. Serves
as the point of contact between local QA and local ARD for inquiries regarding instrument related processes and represents Analytical research & development in related networks, committees, and initiatives, if necessary, and collaborates with Qualification Experts and similar roles across line functions.
Responsible for instrument lifecycle activities like calibration and requalification. Serves on site level as the point of contact between QA, ARD laboratories, other Qualification Experts (QE),
and service provider (if applicable).

About the Role

Major Accountabilities

- Oversee GMP analytical instrument lifecycle activities within ARD, including instrument qualification, maintenance, calibration, testing, and coordination with vendors, QA, and IT functions.
- Maintain the GMP instrument management system and analytical instrument database, ensuring compliance with applicable regulations, validation requirements, and data integrity standards.
- Develop, review, and update instrument-related procedures, guidelines, validation documentation, and validation master plans as required.
- Support regulatory inspections, audits, and laboratory walkthroughs by coordinating preparation activities, addressing observations, and ensuring timely follow-up actions.
- Provide technical expertise and troubleshooting support for analytical instrument-related deviations, issues, investigations, and continuous improvement initiatives.
- Act as a liaison between local QA and ARD teams, ensuring alignment on GMP instrument management practices, technical agreements, qualifications, and compliance requirements.
- Coordinate training programs for employees and contractors, ensuring appropriate qualification and training on analytical instruments, GMP procedures, and related systems.
- Represent ARD in global instrument-related initiatives and ensure the availability of certified reference measuring instruments, including review and assessment of external calibration results against instrument requirements.

Minimum Experience

- Bachelor's or master's degree in chemistry, Pharmaceutical Sciences, Analytical Sciences, Engineering, or a related scientific discipline.
- Minimum 2 years of hands-on experience in analytical instrument qualification, calibration, validation, and lifecycle management within a GMP-regulated environment.
- Strong understanding of GMP principles, data integrity requirements, and analytical instrument lifecycle management, including qualification, maintenance, and compliance processes.
- Excellent scientific, communication, and presentation skills, with the ability to effectively collaborate across Quality, IT, laboratory, and external vendor teams.
- Strong organizational skills, quality mindset, and teamwork capabilities, with a proven ability to manage multiple priorities while maintaining a high level of compliance and operational excellence.

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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Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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