AS&T Expert - Quality Operations

Job ID
REQ-10013372

9月 03, 2024

India

摘要

The Analytical Science and Technology (AS&T) Expert is responsible for coordination and management of analytical activities of commercialized products as well as to provide scientific analytical support.

About the Role

AS&T Expert - Quality Operations

Location - Hyderabad

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The Analytical Science and Technology (AS&T) Expert is responsible for coordination and management of analytical activities of commercialized products as well as to provide scientific analytical support.

Key Responsibilities:

- Coordination and management of analytical method transfers and stability studies. Compilation of data reports.
- Compilation of Quality control monographs describing test procedure and specification setup.
- Scientific analytical support for quality control, production, registration, marketing.
- Presentation and discussion of analytical data in local and international project teams.
- Life-cycle management of analytical methods, including control of method performance, pharmacopoeia
- and health authority compliance and definition of method improvements. Handling of deviations,
- investigation, OOS/OOE/OOT cases as well as changes and complaints.
- Cross-functional interface with Manufacturing Science & Technology team, analytical development, production and regulatory department.
- Management and coordination of analytical activities at external laboratories (CROs). Support for trouble shooting activities and continuous improvement initiatives.
- Implementation of GMP requirements. Compilation and Review of documents (analytical protocols and reports, annual performance quality reports, ongoing process verification reports, registration documents (Common Technical Document modules)).
- Budgeting and cost control of external analytical activities.
- Contribution to QC/AS&T network teams.
- Management of reference substances and control samples.

Essential Requirements:

- Minimum 10 years in pharmaceutical industry and/or analytical laboratory in GMP environment. MS Office- and other standard IT applications.
- External orientation: proactive communication, collaboration and exchange with PUs and SUs within local organisation and Novartis organisation.
- Innovation: continuously thrives for improvements and questions processes and procedures for improvements.
- Reacts in a flexible and fast way on changes and challenges.
- Ability to analyse complex processes.

Desirable Requirements:

- Degree in Chemistry, Pharmacy, Biology, Engineering or another related science.
- Language proficiency: English, German optionally.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

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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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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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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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