

Quality Operations Partner, AS&T Specialist

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Available in: English

Сводка

The Quality Operations Partner, AS&T Specialist performs analytical tasks in responsibility of AS&T group to support AS&T Experts in overall management of their projects. Ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements & the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures. Support analytical Life Cycle Management for commercial products and support timely analytical implementation for new projects.

About the Role

Major accountabilities:

- Support management of all analytical activities related to projects within in responsibility of AS&T group
- Support Life-cycle management of analytical methods, including control of method performance, analytical method improvements, pharmacopoeia and health authority compliance (support subject matter expert in health authority inspections)
- Single point of contact for internal and external clients and contract laboratories, if applicable.
- Support timely analytical implementation (Method Transfer and Method Validation) for (new) projects in the course of product transfers
- Setup and monitoring of stability studies
- Support overarching product investigations cross functional, e.g. QC, QA, Production, MS&T
- Support implementation of GMP requirements. Support compilation and review of documents (analytical protocols and reports, annual performance quality reports, ongoing process verification reports, registration documents)

Minimum Requirements:

- Education: M.Pharm/ Engineering/MSc/M.Tech/equivalent from a reputed institute.
- Experience: Minimum 5 years' experience in Quality Assurance, Quality Control, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ medical device/ expertise in Learning management system
- Problem Solving skills and stakeholder management.
- Basic awareness of GxP compliance requirements.
- Languages: English fluent, written and spoken.

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>

Commitment to Diversity and Inclusion:

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

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

Дивизион
Operations
Business Unit
Other
Место
Индия
Сайт
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

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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