# **AS&T Expert - Quality Operations**

Job ID REQ-10013372
Sep 03, 2024
India
Summary
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
About the Role:

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.

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部門 Operations

部門 Innovative Medicines

国 India

Hyderabad (Office)
Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area Quality
職種 Full time
雇用形態 Regular
Shift Work No
Apply to Job.
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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 diversity and incl. india@novartis.com and let us know the nature of your request and

Novartis is committed to building an outstanding, inclusive work environment and diverse teams'

your contact information. Please include the job requisition number in your message.

representative of the patients and communities we serve.



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