

## 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

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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部门  
Operations

Business Unit  
Universal Hierarchy Node

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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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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