

# Senior Expert Science & Technology - I

Job ID REQ-10053500 Jun 17, 2025 China

# **Summary**

Being late phase center of excellence, Novartis Technical & Research Development (TRD) Changshu (Jiangsu province, China) site is responsible for around 70% of global Novartis New Chemical Entity (NCE) project portfolio. This role is critical for drug substance synthesis and process R&D analytical quality control strategy defining and execution by applying state of the art analytical technology, pharmaceutical industry regulations, as well as Novartis group systematic quality and compliance policies.

#### About the Role

## Major accountabilities:

- Defining the analytical strategy for development projects, including analytical method development and specification setting according to ICH or Novartis guidelines; contributing to regulatory Chemistry,
  Manufacturing & Controls relevant dossiers; effectively communicating and aligning the strategy with local and global project team stakeholders.
- Writing, checking, and/or approving analytical-related documentation, including testing monographs, method validation reports, transfer reports, instrument qualification reports, and SOPs.
- Leading investigations of Out of Specification/Out of Expectation results and Deviations, writing investigation reports, and defining corrective actions and preventive actions.
- Following cGMP regulations and Health Safety & Environment standards, and supporting Novartis internal and/or Health Authority inspections.
- Bringing Data & Digital ideas and solutions to the team and contributing to innovations.
- Enriching the organization culture by providing and implementing ideas and suggestions and coaching/mentoring junior colleagues.

#### **Minimum Requirements:**

#### Work Experience:

- Education background of analytical chemistry, pharmaceutical chemistry, medical chemistry;
- Masters with minimal 8 years or PhD with minimal 3 years related working experience.
- Fluent & effective spoken, and written communication in English.
- Strong inter-personal stakeholder management skills.
- Good understanding of small molecular analytical technologies, e.g. HPLC, GC, titration, IR, NMR, LC-MS;
- Pharmaceutical, nutrition, or food industry working experience, familiar with FAD, EMA etc. guidelines.

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Division

Development

**Business Unit** 

Innovative Medicines

Location

China

Site

Changshu (Jiangsu Province)

Company / Legal Entity

CN23 (FCRS = CN023) Suzhou Novartis Technical Development Co., Ltd.

Functional Area

Research & Development

Job Type

Full time

**Employment Type** 

Regular

Shift Work

No

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