

Senior Expert Science & Technology - I

Job ID
REQ-10053500

6月 17, 2025

China

摘要

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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部门

Development

Business Unit
Innovative Medicines

地点
China

站点
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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