U NOVARTIS

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.

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <u>https://www.novartis.com/careers/benefits-rewards</u>

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 Apply to Job

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 <u>diversityandincl.china@novartis.com</u> and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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