

Associate Director Science & Technology

Job ID
REQ-10053501

7月 11, 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:

- Formulating, developing and driving an overall science, quality and regulatory driven analytical project strategy including contingency plans and risk evaluations in the course of early and late clinical development responsibility for drug substance.

- Leading and overseeing analytical activities throughout drug development within a global project team such as specification setting, method development and validation, stability and release testing. Activities may cover early/late phase clinical development as well as transfer to commercial production sites and New Drug Application registration.
- Being a core member of the technical development sub-team, representing Analytical Research & Development; co-owning the technical development in partnership with Chemical and Pharmaceutical Development; contributing actively to the elaboration of the overall technical development plan and state of the art control strategy.
- Accountability to meet quality, timelines and budget for assigned projects, defining clear analytical project plans
- Managing interactions with internal and external stakeholders, including potential outsourced activities
- Proactively identifying potential scientific, technological and GMP gaps, proposing creative solutions and ensuring appropriate communication within and across units
- Providing input into CMC documents to support regulatory submissions
- Acting as the analytical project representative in peer reviews as well as internal and external audits
- Supporting the analytical project teams with quality awareness, strategic input, scientific and technical expertise in a phase dependent manner
- Strong contribution to advance science, technology and innovation within Analytical R&D

Minimum Requirements:

- Minimum MS in analytical chemistry with significant experience in pharmaceutical industry, preferably PhD in analytical chemistry or equivalent desirable
- Leadership experience in managing projects ideally in a global matrix environment
- Strong quality focus, experience in a GMP environment
- Understanding of regulatory expectations and profound scientific knowledge in analytical development
- Fluent in English (oral and in writing)
- Ability to perform in a highly dynamic environment

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部门
Development

Business Unit
Development

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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