

## Expert Science & Technology II- Analytical Research & Development

Job ID  
REQ-10021771

12月 03, 2024

China

### 摘要

Novartis Technical & Research Development (TRD) Changshu (Jiangsu province, China) site is responsible for around 80% of global Novartis New Chemical Entity (NCE) project portfolio. This role is critical for pre-clinic and clinic drug substance 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

Key Responsibilities :

- Defines the analytical strategy of development project, including analytical method development, specification setting according to ICH or Novartis guidelines; contributes to

- regulatory Chemistry, Manufacturing & Controls relevant dossier; effectively communicate and align the strategy with local and global project team stakeholders;
- Writes, checks and/or approves analytical related documentation, including testing monograph, method validation report, transfer report, instrument qualification report and SOPs etc.;
  - Leads investigation of Out of Specification/Out of Expectation and Deviation, writes investigation report, defines corrective actions and preventive actions;
  - Follows cGMP regulations and Health Safety & Environment standards, support Novartis internal and/or Health Authority inspections;
  - Enriches the organization culture by proactively providing and implementing ideas and suggestions, coaching/mentoring of junior colleagues.

#### Essential Requirements:

- Master with minimal 6 years or PhD with minimal 3 years related working experience;
- Fluent & effective spoken, and written communication English;
- Strong inter-personal skills.

#### Desirable Requirements:

- Education background of analytical chemistry, pharmaceutical chemistry, medical chemistry;
- 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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