

## QC Specialist Microbiology

Job ID  
REQ-10061288

9月 02, 2025

China

### 摘要

Responsibility for microbial testing relate work (contain sterile testing, bioburden testing and EM)

### About the Role

#### Major accountabilities:

Operational

- OOX/deviation handling
- CAPA definition
- KPI trending
- Ensure all activities in compliance with cGxP, incl. data integrity
- Review and approval of analytical data / tests (analytical release)
- Perform microbiological testing of materials and utilities, environmental and personnel

monitoring

- Provide expert support for site qualification and validation activities
- Maintain and calibrate equipment incl. plan preparation
- Support in supplier qualification
- Trending and analysis of KPI/KQI of environmental monitor data.
- Support sample planning and sampling execution

## HSE

- Comply with all HSE guidelines
- Detect and report potential accident, risks and propose solutions
- Participate in HSE risk assessments
- Preparation and participation to internal HSE audits
- Responsible for participating in initial training and retraining

## Key Performance Indicators

- Analytical lead times
- Timely and GMP-compliant analysis and documentation of the results
- Error rate: Number of OOS (analysis errors) related to the number of analyzes
- No complaints about official inspections

## Ideal Background

### Relevant Experience

- Professional experience (3-5 years) in the pharmaceutical sector or in the manufacture of active substances in analytical laboratories in a GMP environment or equivalent; Collaborating across boundaries; Functional Breadth; efficient inter and intra-departmental communications.

### Education & Qualification

- Technical education & 3-5 years relevant experience or
- University degree in Microbiology, Biochemistry or equivalent + 0-4 years working experience

### Languages

Good (oral and written) in English; fluent in local language (oral and written)

### Competencies

- Collaboration; result-oriented
- Breakthrough Analysis; Being Resilient; Operational Excellence; Continuous Learning; Digital

& Tech Savvy

- MS Office applications and other standard IT applications supporting Quality activities
- Laboratory equipment; Quality Control (QC) Testing; Quality Control Sampling; Knowledge of TQM and related industry GxP standards and processes; Laboratory Excellence; Quality decision making

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部门  
Operations

Business Unit  
Innovative Medicines

地点  
China

站点  
Haiyan (Zhejiang Province)

Company / Legal Entity  
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area

Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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