QC Micro Expert

Job ID
REQ-10035835

1月 20, 2025

Italy

摘要

As a Micro QC Expert, you will be in charge of the execution and documentation of biological and microbiological testing in conformity to GMP standards and SOPs.
Maintenance of the Micro laboratory compliance status and resolution of compliance-related issue. Competency in core activities of the microbiology laboratory such as hygiene, plating, aseptic technique, documentation and Environmental investigation. Perform investigation assessing the impact of microbiologically linked events to the safety of the product. Perform periodic training and qualification of analyst.

About the Role

Key responsibilities:

- Perform Micro / EM analysis of batches according to internal SOPs;

- Execute process validation protocols, method validation protocols and every study tied to drug products involved in technology transfer for the field of expertise.
- Promptly report to Quality Control Head and Qualified Person any deviation and/or out of specification detected during the analysis activities; cooperate with all the departments at the resolution of extra-laboratory investigations and put in place corrective and preventive actions and guarantee the correct flow and timely closure.
- Perform instrument performance qualification tests, routine maintenance and cleaning for QC equipment and support external specialized personnel in carrying out extraordinary maintenance/qualification activities; collaborate in the maintenance of good conditions of laboratories, instruments and work environment.
- Register the analysis correctly and in compliance with ALCOA+ principles other than the relevant applicable SOPs and collaborate in keeping quality control SOPs updated.
- Microbiological related training of new personnel; support the Aseptic operations in production and Quality; support for EM sampling plan definition and risk assessment and supervise the EM sampling and planning in collaboration with Production; media fill follow up and supervision.
- Assure that all the relevant internal changes are managed with Change Controls.
- Guarantee the correctness and the update of the QC SOPs and verify the compliance of them with Pharmacopoeias and regulatory requirements.
- Collaborate with QC Head for the periodical self-inspections and external audits (Health Authorities, Certified Bodies, Supplier).

Essential requirements:

- Biology or biotech degree;
- Previous experience in a similar role within the pharmaceutical industry;
- Fluent in Italian. Good knowledge of English.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

部门
Operations

Business Unit
Innovative Medicines

地点
Italy

站点
Ivrea

Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10035835

QC Micro Expert

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10035835-qc-micro-expert

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network
6. https://www.novartis.com/careers/benefits-rewards
7. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ivrea/QC-Micro-ExpertREQ-10035835
8. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ivrea/QC-Micro-ExpertREQ-10035835