

TRD RLT Pilot Plant Microbiology Senior Expert

Job ID
REQ-10051634

5月 15, 2025

Italy

摘要

As a member of TRD RLT Pilot Plant organization, you will be responsible for providing sterile manufacturing expertise and supporting the team to ensure sterility assurance of plant design, build-up and manufacturing execution.

As part of our global Microbiology Expert Team you will have the opportunity to support a diverse project portfolio within Technical R&D, from the classical chemical molecules to biotech products and up to the new modality products such as oligonucleotides and radioligand therapy products, with strong focus on sterile manufacturing / sterility assurance related topics

About the Role

Key Responsibilities:

- Act as an expert in all sterile manufacturing and sterility assurance related topics, supporting both TRD RLT Pilot Plant operations and the global network.
- Participate in the build-up of the TRD RLT Pilot Plant, offering sterile/aseptic manufacturing expertise and developing the plant contamination control strategy.
- Promote and share best practices, bringing robust scientific and technical expertise.
- Present scientific/technical results internally and externally, contributing to publications.
- Contribute as an author or reviewer to the creation of standard operating procedures (SOPs).
- Lead or partake in investigations, corrective actions, and project risk assessments, offering microbiology-related solutions.
- Perform EM trend analysis and support related preventive and corrective actions.
- Communicate critical topics promptly to the Analytical Project Leader and other relevant team members.
- Support internal and external audits, ensuring no critical findings, and uphold collaboration with testing laboratories while respecting industry standards and internal guidelines.

Essential Requirements:

- Holding a PhD, diploma, bachelor, or master's degree in microbiology/biotechnology or a related field.
- Prior experience in Sterility assurance related topics within the pharmaceutical industry/GMP.
- Fluency in English (oral and written) and proficiency in Italian.
- Solid understanding of quality principles such as GMP and quality expectations.
- Excellent communication skills, including presentation and scientific/biotechnical writing.
- Ability to work effectively and proactively in a multidisciplinary team.
- Experience in Bacterial endotoxin, Sterility, and Bioburden testing is desirable.
- Knowledge and experience in the field of Radiopharmaceuticals and radioprotection practices would be a plus.

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部门
Development

Business Unit
Innovative Medicines

地点
Italy

站点
Ivrea

Company / Legal Entity

IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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