



Sterility Assurance Specialist

for the site Borgo San Michele LT, Italy

Would you like to make a valuable contribution to the health of patients? And do something really meaningful on your own responsibility? Then we look forward to hearing from you! Excellence beyond manufacturing - that's what we stand for as Aenova, one of the world's leading contract manufacturers and developers for the pharmaceutical industry with 4,000 employees at 15 sites. Latina is a leading centre of excellence in sterile liquid production, with a strategic investment plan to become one of Europe's foremost hubs.

Your key responsibilities

- Support and oversee Sterility Assurance and aseptic processing activities within sterile manufacturing areas, including APS.
- Collaborate with Production, Engineering & Maintenance, MS&T, Validation and Quality Assurance to identify, assess and mitigate microbiological contamination risks.
- Support the definition and implementation of contamination control requirements for sterile operations, qualification and validation activities.
- Support deviation investigations, root cause analysis and CAPA definition related to sterility assurance and microbiological events.
- Support the implementation, maintenance and periodic review of the Contamination Control Strategy (CCS).
- Provide Sterility Assurance expertise during regulatory inspections, customer audits and corporate assessments.
- Support technology transfer, qualification/validation and continuous improvement projects within sterile manufacturing.

Your profile

- University degree in a scientific discipline (Biology, Biotechnology, Pharmaceutical Chemistry and Technology, Pharmacy, Chemistry or related fields); Master's degree preferred.
- At least 3 years of relevant experience in Sterility Assurance, Microbiology, Quality or Manufacturing within a sterile pharmaceutical environment.
- Good knowledge of GMP and EU GMP Annex 1; knowledge of FDA requirements is considered an advantage.
- Experience or solid knowledge of aseptic processing, APS and contamination control principles.
- Knowledge of Contamination Control Strategy principles.
- Good written and spoken English.
- Strong analytical, communication and cross-functional collaboration skills.
- Experience with cleanroom qualification, technology transfer, environmental monitoring and electronic quality systems is considered a plus.

Annual salary range: EUR 30.000 - 40.000

Your motivation

Are you looking for new challenges in a highly competitive environment? And you want to tackle them creatively and on your own responsibility? Do you prefer a "get-it-done" culture and think in terms of solutions rather than problems? What are you waiting for? We would be happy to explain our corporate benefits in a personal conversation!

Apply now

If you have any questions, I - Chiara Fanasca / Human Resources - will be happy to help you: Chiara.Fanasca@aenova-group.com

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