

Engineering Validation 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

The Engineering Validation Specialist is responsible for planning, executing, documenting, and maintaining qualification activities for GMP equipment and utilities used in pharmaceutical manufacturing environments in compliance with applicable regulations (laws, GMP, FDA, etc.), the guidelines contained in the dossier, and company quality standards.

- Prepare, review, and maintain GMP documentation, including URS, DQ, IQ, OQ, PQ, qualification protocols, and final reports, in accordance with internal procedures and regulatory expectations.
- Ensure the analysis and evaluation of raw technical data and documentation related to equipment and instruments subject to qualification, in order to acquire the information necessary for defining procedures/protocols
- Coordinate qualification activities for manufacturing equipment, process systems, utilities, and laboratory instruments.
- Support Factory Acceptance Tests (FAT) and Site Acceptance Tests (SAT).
- Assess qualification impact of deviations, change controls, CAPAs, and maintenance activities.
- Ensure qualification documentation is generated, reviewed, and archived in accordance with GMP requirements and data integrity principles.
- Collaborate with Engineering, Production, Quality Assurance, Validation, Maintenance, and external suppliers to ensure timely project completion
- Participate in regulatory inspections and customer audits, providing technical support and qualification documentation as required.
- Contribute to the development and continuous improvement of qualification procedures, templates, and validation strategies.
- In collaboration with the Purchasing Department, prepare requests for quotation to suppliers and support the Manager in preparing a technical and economic evaluation of the offers received.

Your profile

- Bachelor’s or Master’s degree in a scientific or engineering discipline (e.g. Chemistry, Biotechnology, Engineering, Pharmacy).
- Minimum 2–3 years of experience in qualification and/or validation roles within pharmaceutical or biotechnology manufacturing environments, preferably in CDMO organizations.
- Solid knowledge of GMP and relevant international regulatory standards (EMA, FDA).
- Proven experience in the preparation and management of GMP documentation in regulated environments.
- Hands-on experience gained in pharmaceutical production areas utilizing isolator technology, particularly in aseptic and sterile Fill & Finish operations for biologics preferred.
- Knowledge of regulations related to Equipment and Utilities validation, with particular reference to sterile departments (for examples isolator, autoclave, tunnel, VHP).
- Strong attention to detail, accuracy, and ability to manage qualification activities independently.

- Excellent communication skills and ability to work effectively in cross-functional and client-facing environments.
- Good command of the English language (minimum B2 level).
- Proficiency in standard IT tools, including MS Office, document management systems.

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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