Qualification / 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

We're currently looking to expand our Quality and Engineering teams with experts in Qualification, as Qualification Specialist, Requalification Specialist and QA Equipment Validation Specialist.
As we are recruiting for several roles, feel free to apply even if your profile does not match with all the requirements below.

PURPOSE AND RESPONSIBILITIES
The purpose of these roles is to ensure the qualification status of the production equipment, QC instrument & equipment and Warehouse through the definition of procedures/protocols and the execution of requalification activities, in compliance with applicable regulations (laws, GMP, FDA, etc.), the guidelines contained in the dossier, and company quality standards.

- Review master and complete qualification and validation protocols, summary reports and associated data for conformance to regulations, SOPs, specifications and other applicable acceptance criteria.
- Troubleshoot / investigate validation-related deviations and non-conformances.
- Maintain organization and archival of completed validation and qualification document packages.
- 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.
- Interface and coordinate qualification activities with Engineering, Production, Quality Assurance, Maintenance, MSAT, and HSE functions within a CDMO environment.
- Provide support during internal audits, client audits, and regulatory inspections (EMA, FDA), including periodic review of qualified systems.
- Ensure the analysis and evaluation of raw technical data and documentation related to equipment and instruments subject to requalification, in order to acquire the information necessary for defining procedures/protocols and carrying out re-qualification activities, in compliance with company procedures.
- 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).
- 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).
- Technical/engineering knowledge of sterile lyophilized pharmaceutical production systems.
- 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, and ERP platforms.

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 - Luca Cenciarini / Human Resources - will be happy to help you: luca.cenciarini@aenova-group.com

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Haupt Pharma Latina S.r.l. • Member of the Aenova Group • Strada Statale 156 dei Monti Lepini • 04100 Borgo San Michele LT, Italy