

Validation Specialist

for the site Carugate MI, 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. Our site in Carugate is a competence center for semisolids, these include creams and gels.

Your key responsibilities

The Validation Specialist ensures that all facilities, equipment, utilities, computerized systems, and manufacturing processes operate in a continuous state of compliance with Good Manufacturing Practices (GMP) and international regulatory requirements (AIFA, EMA, FDA).

- Ensure the preparation, periodic review, and monitoring of the site's Validation Master Plan (VMP).
- Provide methodological guidance and compliance oversight for process validation, holding time validation, and cleaning validation activities.
- Support the execution of Factory Acceptance Tests (FAT) and Site Acceptance Tests (SAT) for newly introduced equipment.
- Lead qualification activities (IQ, OQ, PQ) for laboratory instruments, manufacturing equipment, facility systems, critical utilities (Purified Water, HVAC, Compressed Air), and Computerized Systems, in accordance with GAMP 5 and EU GMP Annex 11 requirements.
- Coordinate and oversee the site-wide calibration and metrology program, ensuring timely execution, technical support to involved departments, and review of documentation and certificates issued by external service providers.
- Monitor environmental monitoring activities, identify deviations or trends, and ensure the implementation of appropriate corrective actions.
- Act as Subject Matter Expert (SME) in support of Change Control, Deviation Management, and Complaint investigations.

Your profile

- Scientific Degree (Chemistry, Biology, Biotechnology, Pharmaceutical Sciences, or related fields).
- 3–5 years of experience in Quality Assurance within the pharmaceutical industry, with a strong focus on validation activities.
- In-depth knowledge of GMP regulations and international regulatory standards.
- Familiarity with plant management software and SCADA systems.
- Good command of English, both written and spoken.
- Strong analytical mindset and high level of accuracy in technical documentation.
- Problem-solving skills.
- Excellent interpersonal and communication skills, with the ability to collaborate across cross-functional teams.

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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