



Data Integrity & CSV Quality Expert

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

- Lead and maintain the Site Data Integrity and CSV programs, ensuring compliance with GxP and corporate standards (EU GMP Annex 11, 21 CFR Part 11, ALCOA+).
- Oversee the full Computer System Validation (CSV) lifecycle, including planning, testing, documentation, and periodic review.
- Define and monitor Data Integrity governance, perform risk assessments, and ensure compliant system implementation across Quality, Manufacturing, Engineering, and Laboratory systems.
- Support deviation, CAPA, and change control management related to computerized systems and data integrity.
- Act as subject matter expert during audits and inspections, providing training and promoting a strong data integrity culture.

Your profile

- Degree in Engineering, Computer Science, Chemistry, Pharmaceutical Technology, or related scientific field.
- Minimum 3–5 years of experience in Computer System Validation and Data Integrity within a pharmaceutical GMP environment.
- Deep knowledge of EU GMP Annex 11, FDA 21 CFR Part 11, ICH Q9, and Data Integrity guidelines (EMA, MHRA, FDA, WHO).
- Strong understanding of IT systems used in GxP environments (e.g., SAP, LIMS, TrackWise, SCADA, EBR, Empower).
- Excellent communication, analytical, and teamwork skills, with very good English proficiency .

Please note: Applications **must be submitted in English**. Applications in Italian or any other language will **not be considered**.

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 - Lukas Rödder / Human Resources - will be happy to help you: [+49 151 16260074](tel:+4915116260074)