



## Quality System & Compliance Manager

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

- Ensure the maintenance and effectiveness of the site's GMP quality system.
- Guarantee the management and oversight of Change Control, CAPA, GMP documentation, training, and GMP supplier management processes.
- Ensure planning and execution of the internal audit program and manage regulatory and customer inspections.
- Coordinate overall Risk Management process according to ICH Q9 guidelines.
- Monitor and communicate quality system and compliance KPIs, supporting the Quality System Review.
- Support alignment with global functions and implementation of company best practices.
- Guarantee the maintenance of quality culture and support continuous improvement initiatives.
- Analyze quality system data to identify trends, risks, and improvement opportunities.
- Collaborate with HR for GMP training definition and monitoring, and personnel training compliance.
- Manage the preparation, execution, and follow-up of regulatory inspections and customer audits.

### Your profile

- Degree in scientific disciplines (Pharmacy, Chemistry, Biology, or equivalent).
- At least 5 years of experience in Quality Assurance / Quality Systems in pharmaceutical GMP environments.
- People management experience.
- Strong knowledge of EU and FDA GMP regulations.
- Data analysis and management skills.
- Fluent in English and Italian.
- Continuous improvement mindset.
- Critical thinking and quality orientation.
- Proactivity and decision-making ability.
- Effective communication and cross-functional collaboration.

### 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](mailto:Chiara.Fanasca@aenova-group.com)

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