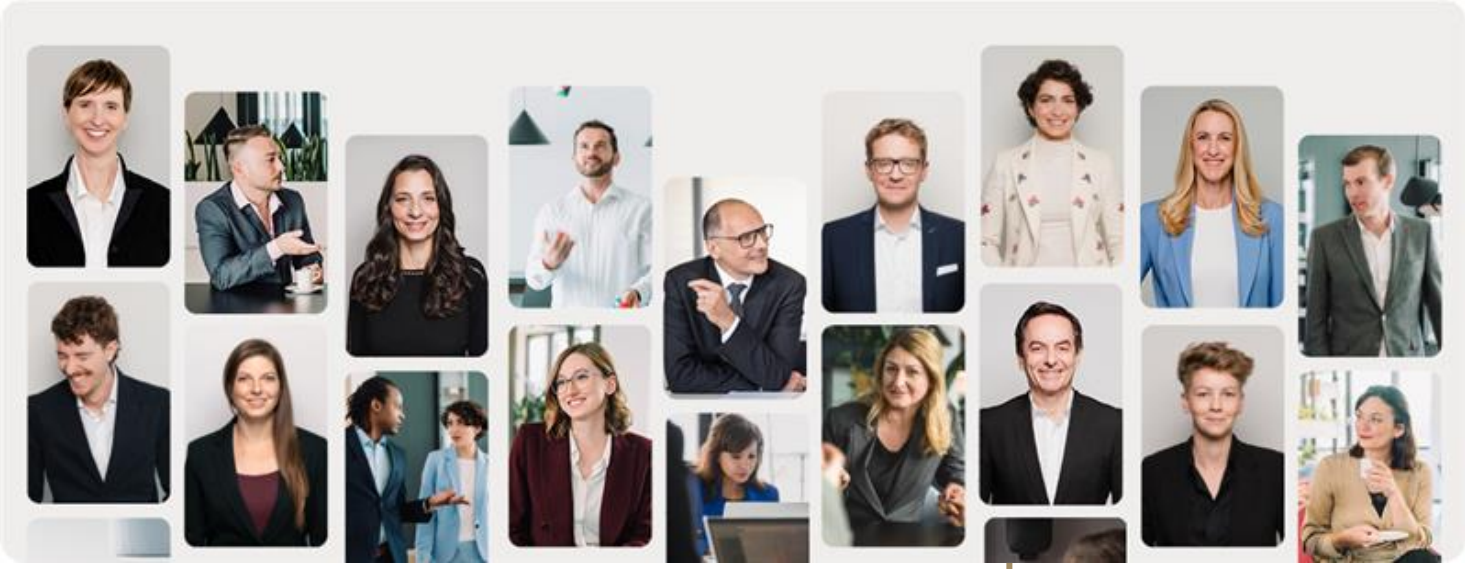
AOP Health is the European pioneer for integrated therapies for rare diseases and in critical care. To enhance our team in Italy we are looking for a:

Quality & Compliance Specialist (Italy) (f/m/d)

56122 Pisa | Full-time employee | Start: as of now |



In this role, you will ensure compliance with regulatory and corporate requirements while supporting our local Quality Management System. You will work in close collaboration with cross-functional teams to maintain the highest standards of quality and compliance.
This position is limited to a minimum of one year as maternity leave cover.

What Your Day To Day Will Look Like

- Support the Quality Management System (QMS/eQMS) in compliance with GxP and corporate procedures.
- Draft, update, and maintain quality documentation and SOPs.
- Provide training (onboarding and recurring) on quality and compliance processes.
- Manage incidents, complaints, CAPAs, deviations, and returns.
- Ensure compliance in daily operations, including documentation and archiving (paper and digital).
- Conduct supplier and customer qualification.
- Coordinate internal and external audits, including follow-up and CAPA plans.
- Monitor compliance with GDP, GVP, GDocP, Legislative Decree 219/2006, AIFA, EMA, and other regulations.
- Support corporate compliance policies (anti-bribery, transparency, HCP interactions, scientific information, drug traceability).
- Handle transparency reporting (Sunshine Act) and approval workflows for promotional materials, events, donations, and sponsorships

Main Benefits

- Bonus
- Homeoffice
- Flexible working hours
- Initial and continuing education
- Employee events

Your Contact

Kathrin Breuer, BA, MA
Senior Associate Talent Aquisition

Further information on our website:

Your Qualifications and Experience

aop-health.com

- Degree in Pharmaceutical Chemistry and Technology, Pharmacy, Biology, or related field.
- Minimum of 3 years of professional experience in Quality Assurance or Compliance in the pharmaceutical or healthcare sector.
- Solid knowledge of GxP standards (GDP, GVP, GDocP) and understanding of EU/Italian regulatory frameworks (AIFA, EMA, Legislative Decree 219/2006)
- Hands-on experience with Quality Management Systems (QMS/eQMS) and document control processes
- Proven ability to manage audits, CAPAs, deviations, and complaints
- Strong communication and organizational skills with the ability to work independently
- Fluency in English and Italian (spoken and written)

Our Offer

- An open corporate culture with the opportunity to contribute your own ideas
- Structured onboarding and training opportunities to support your professional growth.
- Being part of a successful team who drives the business forward
- Competitive bonus scheme, additional benefits and employee events.
- Opportunities for personal and professional development within an international environment
- A role with high impact and responsibility in a growing, innovative company

If you would like to work as a team player in an international environment and can identify with our values "Agile, Ambitious, Aligned, Accountable and Appreciative", then: Take this CHANCE and