



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

## Application Owner (GxP / Validated Systems)

1190 Vienna | Full-time employee | Start: as of now |



***We are looking for an Application Owner with hands-on Computer System Validation (CSV) experience in a GxP-regulated environment to ensure compliant operation and lifecycle management of validated systems. You will serve as the key interface between IT, Quality Assurance, business stakeholders, and external vendors to ensure stable, secure, and inspection-ready systems.***

### What Your Day To Day Will Look Like

- Own the full application lifecycle, ensuring reliable performance, availability, and compliant upgrades/releases.
- Manage vendor relationships, SLAs, and support contracts.
- Coordinate incident, problem, and change management processes.
- Ensure validated systems remain compliant throughout their lifecycle, overseeing risk-based (GAMP 5) validation activities, change impact assessments, and required documentation.
- Support audits and inspections, conduct periodic system reviews, and ensure alignment with EU GMP Annex 11, 21 CFR Part 11, and ALCOA+ data integrity principles.
- Perform and document risk assessments, ensure proper access management and segregation of duties, and maintain full traceability across requirements, testing, and validation documentation.
- Collaborate closely with QA on compliance expectations and support continuous improvement of validation and governance processes.

### Your Qualifications And Experience

- Degree in IT, Life Sciences, Engineering, or a related field, plus several years of IT application management experience in a
- GxP-regulated environment with hands-on CSV expertise.
- Strong knowledge of EU GMP Annex 11, 21 CFR Part 11, GAMP 5, and risk-based validation and change control approaches; experience supporting audits and inspections.
- Proven experience collaborating with external software vendors.

- ISPE certification (e.g., CPGP) or GAMP 5 training is an advantage
- ASQ certifications such as CQA or CQE are a plus
- ITIL Foundation certification beneficial
- Experience with ERP, QMS, LIMS, or document management systems in regulated environments, including SaaS/cloud validation
- Background in pharmaceutical, biotech, or medical device industries  
Strong understanding of data integrity and security principles
- Experience working in complex, fast-paced environments and driving organizational change
- Familiarity with ITIL and service management principles
- Experience with Agile and/or DevOps methodologies

## Our offer

- An open corporate culture with the opportunity to contribute your own ideas
- Working independently in a collegial and committed team
- Modern working environment with good public transport connections (U4 - Heiligenstadt)
- Flexible working hours (flexitime/time-out days), bonus scheme, additional benefits and employee events
- Structured onboarding and support through a buddy system
- Due to legal requirements, we are obliged to disclose the collective agreement minimum salary, which is EUR 45.080,- gross per year, based on full-time employment. However, our actual remuneration packages are market-oriented and aligned with your qualifications and professional experience.

*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*

## Main Benefits



Bonus



Homeoffice



Employee mobile phone



Flexible working hours



Laptop



Initial and continuing education



Canteen



Good transport connection



Employee events

Employee events



Meal allowance



Company doctor



Parking spot



Healthmeasures



Employee discount

## Your Contact



**Kenny Trappi**

Talent Acquisition Manager

*Further information on our website:*

[aop-health.com](http://aop-health.com)