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:

Senior Associate Product Quality Compliance

1190 Wien | Vollzeit | Start: as of now |



We are looking for a Senior Associate Product Quality Compliance to join our Quality Product Compliance team. You will manage PQR/APQR processes and ongoing stability studies to ensure compliance with quality and regulatory requirements. You will also support Change Control activities throughout the product lifecycle.

What Your Day To Day Will Look Like

- Product Quality Reviews (PQR): Prepare, review, and maintain annual PQRs, including reports from CMOs, and follow up on CAPAs and quality improvement actions.
- Ongoing Stability Studies (OGS): Coordinate annual stability studies with CMOs, review and trend stability data, assess potential OOT/OOX results, and support investigations and annual reporting.
- Product Change Control: Manage Change Controls throughout the full lifecycle, including impact assessments, implementation, documentation, and coordination with relevant stakeholders.
- Cross-functional Collaboration: Work closely with Regulatory Affairs, Technical Development, Supply Chain, CMOs, and other teams on product quality topics.
- Quality Support: Provide quality guidance to internal stakeholders and support quality KPI monitoring, trending, and reporting.

Your Qualifications And Experience

- Bachelor's degree / or adequate (e.g. higher technical school in natural science) in a relevant scientific discipline
- 3 years of experience in a similar role within the manufacturing/quality department/QC of pharmaceutical industry
- Experience with Product Quality Report, Ongoing Stability Studies and change control management
- Solid understanding of GMP and regulatory expectations (EU, FDA, ICH guidelines)
- Strong organizational and analytical skills with attention to detail
- Experience working with CMOs and cross-functional stakeholders

- Effective communication skills
- Fluent in German and English (written and spoken)
- professional technical writing skills

Our offer

- Open corporate culture with the opportunity to bring in your own ideas
- Great opportunities for personal and professional development
- Attractive work environment with excellent career opportunities and flat hierarchies
- Competitive salary package plus bonus and various benefits
- Gross annual salary provided for this function is a minimum of EUR 45.080,- based on full-time employment (38,5h/week). Any potential overpayment depends on professional experience and qualifications.

By submitting your application, you accept AOP's Data & Privacy Policy.

Main Benefits



Bonus



Homeoffice



Employee mobile phone



Flexible working hours



Laptop



Initial and continuing education



Canteen



Good transport connection



Employee events



Meal allowance



Company doctor



Parking spot

Healthmeasures

Employee discount

Your Contact



Kenny Trappl
Talent Acquisition Manager

Further information on our website:
aop-health.com