



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:

Manager Product Quality Compliance

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



We are looking for an experienced Change Control Manager to ensure compliant management of product-related quality activities across the product lifecycle. In this role, you will oversee the Change Control process, ensuring changes to products, processes, systems, and documentation are properly assessed, approved, implemented, and documented in line with quality and regulatory requirements. You will also support the preparation, review, and follow-up of annual Product Quality Reviews (PQRs).

What Your Day To Day Will Look Like

Product Change Control Management

- Manage the end-to-end Change Control process within the established Quality Management System (QMS)
- Drive the development, harmonization, and implementation of standardized Change Control processes, workflows, and best practices to enhance efficiency, compliance, and consistency
- Review, assess, and coordinate proposed changes to ensure adequate impact assessments are completed
- Monitor change implementation activities and ensure the timely completion of required actions.
- Collaborate with Technical Development, Regulatory Affairs, Supply Chain, and other stakeholders.
- Act as Change Owner, Stakeholder and supporting Quality function throughout the whole change control lifecycle

Product Quality Review (PQR)

- Contribute to the preparation, review, and maintenance of annual Product Quality Review (PQR), including PQRs provided by Contract Manufacturing Organizations (CMOs)
- Monitor and drive the timely completion of CAPAs and quality improvement actions arising from Product Quality Reviews (PQRs)

Quality Systems & Documentation

- Prepare, review, and maintain SOPs and quality-related documentation e.g. Key documents
- Act as Subject Matter Expert (SME) for the operational end-to-end management of Change Controls and Product Quality Review, supporting internal audits, customer audits, and regulatory inspections through the preparation and presentation of corresponding documentation

Collaboration & Quality Support

- Provide quality oversight and guidance to cross-functional teams (e.g. Regulatory, Technical Development)
- Proactively identify quality risks and drive mitigation strategies
- Collaborate closely with CMOs on product quality topics

Performance & KPI Management

- Support quality KPI definition, monitoring, trending, and reporting
- Contribute to continuous improvement initiatives based on operational quality metrics

Your Qualifications And Experience

- Bachelor's degree / or adequate (e.g. higher technical school in natural science) in a relevant scientific discipline
- professional certification in Quality Management / GMP is an advantage
- Min. 3 years of experience in a similar role within the manufacturing/quality department/QC of pharmaceutical industry
- Strong hands-on experience with change control management and Product Quality Report
- Solid understanding of GMP and regulatory expectations (EU, FDA, ICH guidelines)
- Structured, solution-oriented mindset with high attention to detail
- Experience working with CMOs, including the ability to challenge quality topics constructively in a professional manner
- Confident communicator, able to explain quality requirements clearly to internal/external partners
- 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.

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



Meal allowance



Company doctor



Parking spot



Healthmeasures



Employee discount

Your Contact



Kenny Trappl

Talent Acquisition Manager

Further information on our website:
aop-health.com