



Quality Assurance Specialist

Date posted: January 19, 2018

Location: Vienna, Austria

Position Summary:

Quality Assurance Specialist with proven industry experience and a solid background in GxP to join our highly motivated and dedicated team at Hookipa; a Vienna-based biotechnology company developing novel recombinant viral vector vaccines against medically important infectious diseases and cancer. The Senior QA Specialist will assist continuous improvements in products and services and ensure that systems meet the appropriate regulatory standards, ensuring that customer requirements and expectations have been accurately identified and met.

Main Responsibilities:

- Ensure compliance with current GxP (Good Manufacturing Practice, Good Clinical Practice, Good Clinical Laboratory Practice, Good Laboratory Practice and Good Distribution Practice), relevant Health and Safety Regulations and other applicable current legislation
- Maintain a comprehensive quality assurance management system for all aspects of GxP activities
- Support manufacturing activities performed by external partners (including manufacturing, analytical testing, storage, labeling & packaging and clinical studies) from a quality perspective
- Review reports, manufacturing batch records for each IMP batch including batch related deviations of analysis from third party vendors performing GMP manufacturing, GMP/GLP Quality Control testing and GLP toxicology testing
- Review Technical Reports describing research/development work performed at Hookipa in support of regulatory filings
- Provide quality assurance review of regulatory submissions
- Review Pharmaceutical Quality Systems used such as Change Control, CAPA, Internal Audit, non-conformances, Quality Agreements and ensure compliance with site SOPs.

Qualifications:

- Degree in a Life Science area like Pharmacy or Biochemistry
- We expect 2 years of Experience in pharmaceutical industry in the field of QA
- Hands on knowledge of EU GMP regulations
- Demonstrable ability to analyze information in a structured manner and to be able to prepare coherent, cogently argued documents
- Excellent proactive communication skills, problem solver
- Team orientated, while able to work independently
- Excellent computer skills for the common software types office, power point, access preferred

What we offer:

- Strong team with dedicated and passionate scientists
- State of the art infrastructure
- An excellent working atmosphere
- Working in a multinational and multicultural environment

Minimum monthly gross salary from EUR 2.600,- ; depending on experience and qualification salary can be negotiated.



Contact:

If you (m/f) are interested in this challenging position, please send your CV including a cover letter summarizing your qualification and experiences to: **talent@hookipabiotech.com**

For more information on Hookipa Biotech please visit **www.hookipabiotech.com**