Qualified Person for Biotechnological IMPs

Date posted: November 03, 2017
Location: Vienna, Austria

Position Summary:
Qualified Person with industry experience and a strong background in GxP (GCP/ GCLP/ GMP and GDP) 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 QP will lead quality improvement initiatives and 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. As the QP you will be responsible for batch reviews, certification and release of investigational medicinal products (IMPs).

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
- Ensure quality oversight and GxP compliance of manufacturing activities performed by external partners (including manufacturing, analytical testing, storage, labeling & packaging and clinical studies) from a quality perspective
- Implement, maintain and continuously improve the Electronic Document Management System
- Establish and maintain GxP status of Hookipa to meet requirements of FDA/EMEA and any other relevant competent authorities
- QP Release/Certification of IMP batches
- Ensure as QP that batches of Virus Seeds, Bulk solutions, Finished Products and IMPs (produced in EU or imported into EU via Austria from outside the EU) are manufactured, tested, labelled and packed in compliance with Product Specification and compliant to GMP and company's guidelines prior to the release and export to a third country or distribution to EU clinical trial sites.
- Review of drug product sections of Investigational Medicinal Product Dossiers.
- Perform audits of all contractors and suppliers.
- 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, preferably Pharmacy or Biochemistry
- Fulfil the requirements and duties as defined under the provision of EU Directive 2001/83/EC as well as Austrian Regulation on Medicinal Production Sites 2009 (AMBO 2009) and is registered as QP with one of the EU Regulatory Agencies
- Qualified Person status for Biotechnological IMPs
- Substantial level of experience in pharmaceutical industry
- Knowledge of EU and US GMP regulations, supported by ICH and WHO
- Excellent proactive communication skills, problem solver
- Team orientated, while able to work independently
- Previous experience of working in a GMP environment

What we offer:

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

Minimum monthly gross salary from EUR 4.500,- all-in; 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**