Introduction:
Pharming Group N.V. develops innovative protein therapeutics for the treatment of genetic disorders. The company is poised for further scientific, technological and new product development and additional commercial roll-outs. The company is small (approx. 200 employees, based internationally) and growing quickly. As a result of this growth, we are looking for a:

Quality Systems Specialist

Overall purpose of the job:
As part of the Quality Assurance (QA) team, you provide support on the efficient automated (C)GMP quality systems for Pharming's products. The quality systems apply to both internal procedures as well as systems at our contract-partners and service providers including their cloud solutions. The necessary control functions are executed by active governance and review of documentation and by performing audits.

Main duties and responsibilities:

- The main initial task consists of the configuration, validation, implementation and maintenance of Master Control. After implementation, you remain, as the Sys Admin, responsible for the yearly updates and revalidation, including addition of new applications to the (C)GMP quality systems.
- Provide service to all users of the (C) GMP quality systems, investigate and solve issues when required, in a timely manner
- Technical support and interaction with vendors
- You have a leading role in setting up and maintaining an integrated data interaction between the (C)GMP quality systems and other internal and external management systems (Regulatory, Clinical, LIMS, ERP, etc..).

Qualifications:

- Bachelor's degree in biotechnology, biopharmaceutical sciences, (bio)chemistry, ICT or alike.
- Knowledge of quality systems (such as ISO 9001:2008), pharmaceutical Quality systems ((C)GxP) and in particular EU-GMP Annex 11, US-CFR21 part 11 and GAMP-5
- Two to three years of experience in (bio)pharmaceutical production, quality control or quality assurance and at least three years of experience with automated Documentation and Quality Management system(s). In particular experience with MasterControl or similar automated quality systems (TrackWise, Veeva, etc.) will add value to the application.

Skills:

- Analytical, accurate, pro-active, independent.
- Effective communicator in conversation and writing, in Dutch and English.
- Experienced with the use of MS-Office programs. Affinity and preferably also experience with ERP or SAS systems.

Are you interested? Please e-mail your CV and letter of motivation to: vacatures@pharming.com.


Pharming