

Pharming Group N.V. is committed to the development of innovative products for the treatment of unmet medical needs. We focus on the development and production of human therapeutic proteins to provide life-changing solutions to patients.

Qualified Person

Based in: Leiden
Fulltime position

Introduction:

At this moment, the company is composed for further science, technology and new product development and commercial roll-out. The company is small (approx. 130 employees, based international) and entrepreneurial. The Qualified Person must fit in this organizational culture where integrity, entrepreneurship and flexibility are core competencies.

Overall purpose of the job:

In this position as Qualified Person you will become the direct deputy of Pharming's (first) QP but you are also an essential part of the QA team. This function requires that a year is foreseen for execution of all QA Officer tasks and personal training by the current QP, before the application for QP will be submitted to Farmatec. As part of the QA team of Pharming, you make a contribution to the implementation of and maintaining an efficient (c)GMP quality system for Pharming's biotechnological products. The quality systems apply to both internal procedures as well as systems at our contract-partners. The necessary control functions are executed by review of documentation and by performing audits on (provider's) sites. As (second) QP, you will become responsible for the legally authorized pharmaceutical release of starting materials, drug substance, drug product and final product manufactured by or under the responsibility of Pharming for commercial use or use in clinical trials.

Main general duties and responsibilities:

Implementation, execution and maintaining document- and change-control, deviation- and inspection-management and training. Review of batch records, logbooks, scientific reports, policies and procedures. Release of intermediate and final products. Auditing contract-partners and service-providers. Writing procedures, audit reports and periodic quality oversight reports.

Qualifications:

University degree pharmacy, biopharmaceutical sciences, (bio)chemistry or equivalent education, but preferably a pharmacist. Knowledge of GMP, GDP, GLP, GVP or other Quality systems (ISO 9001:2008), and preferably biotechnological production processes.

Two to three years of experience in (bio)pharmaceutical production, biotechnological R&D, auditing, quality control and/or quality assurance.

Skills:

Analytical, accurate, pro-active, independent, stress-resistant.
Effective communicator in conversation and writing, in Dutch and English.
Experienced with the use of MS-Office programs.

Apply:

Please apply via our website www.pharming.com or www.pharminggroup.heeft-vacatures.nl attn. Human Resources.

For all recruitment agencies: don't call us, we call you!
