

Following an expansion of our activities, we are looking for a highly motivated
Senior contract Qualified/Responsible Person (QP/RP)

About infarAMA

infarAMA – a Belgian company offering a wide range of regulatory, quality, vigilance and translation services to the health care industry – is looking for highly qualified and motivated Industrial Pharmacists to act at the customer site as contracted Qualified Person/Responsible Person.

The main duties are to ensure that the customer's obligations as the Manufacturing and Import Authorization Holder (MIA- GMP) and Warehouse and Distribution Authorization Holder (WDA – GDP) are fulfilled and to provide input on regulatory GMP/GDP compliance and Quality Assurance subjects. The QP/RP will report to the Managing Director RA & Quality who will be located in a **new quality hub in Strombeek-Bever** (North of Brussels).

Responsibilities and activities

Your role as a QP/RP will be to support and contribute to the implementation and optimization of projects of the infarAMA customers. You will be responsible for a variation of aspects within their projects such as:

- Accomplish QP/RP duties according to the applicable local and EU regulations (RD 14 Dec 2006 - GMP/GDP guidelines): manage and assure continuous improvement of the pharmaceutical quality management system (QMS) and handle quality complaints, rejects, reworks, returns, recalls, change control, deviations and CAPAs
- Batch certification (QP) and release for sale (RP) as primary and back-up QP/RP
- Perform GMP/GDP compliance gap analysis and interact with other departments
- If applicable, perform GMP/GDP/QMS self-inspections and external audits
- Ensure inspection readiness and act as primary contact during Competent Authority inspections
- QA liaison with contract manufacturing organizations or third party logistic providers

Experience and Qualifications

- Preferably a minimum of **5 years working experience** in (non-)sterile manufacturing, packaging and labeling and supply chain
- **Industrial Pharmacist**, FAMHP certified (RD 14/12/2006 art. 48/EU Dir. 2001/83/EC)
- Knowledge of GMP/GDP/risk management
- Learning attitude and continuous improvement mind set
- Problem solving capabilities
- Result driven, accurate (eagle eye for details)
- Excellent organizational and planning skills
- Team player
- Customer oriented (good communicator and assertiveness)
- Fluent in English and Dutch and/or French

Are you interested and you want to apply for this job?

Please send your Curriculum Vitae and a cover letter to office.manager@infarama.be.

For more information, feel free to contact us at: + 32 11 31 26 16