Hungarian Wholesaler Company is looking for a Responsible Person to join their team in the agglomeration zone of Budapest.

Responsibilities:

- Participate in supervising of the serialisation program from QA point of view
- Negotiate regarding Quality Agreements including responsibilities relating to especially serialisation, distribution and/or product transportation
- Ensures the implementation and maintenance of the Quality Management System. The structure, procedures and responsibilities within the Quality Management System are defined in a Quality Manual with focus on GDP.
- Ensures the GDP requirements applicable to the activities managed by the company; communicates and informs the relevant departments about corporate procedural documents related to GDP and about any update in the regulations
- Ensures that personnel are involved in distribution activities and maintained the competence in GDP through regular training.
- Ensures that medicines are supplied and traded according to GDP.
- Ensures that suppliers and customers are qualified and the personal audits are performed for markets.
- Ensures that quality of the medicinal products is guaranteed from receipt of the goods throughout the entire distribution channel to the end of the responsibility and distribution documentation is recorded and traceable.
- Lead GDP Management review activities including GDP metric review.

Skills, Education and Experience:

- Pharmacist graduation is required.
- Previous experience as Responsible Person as well as understanding of the Hungarian and European Medicine laws & regulations in accordance with the Hungarian Medicines Inspectorate (OGYÉI).
- Minimum 2 years experience in the pharmaceutical industry, preferably at a Company with GDP Warehouse responsible for receiving, storage and distribution of medicinal products, or a Company responsible for Supply Chain Management and/or Regulatory Affairs, or in a European Health Authority.
- In depth knowledge of GDP regulations in EU and other international markets.
- Knowledge of the cGMPs and regulations promulgated by EMA or equivalent regulatory Agencies.
- Extensive experience and technical knowledge in wholesale distribution operations which enables first-hand knowledge of Good Distribution Practice, transportation, quality assurance.
- Direct experience in the effective communication with Health Authorities and in the hosting of Health Authority inspections.
- Extensive experience and technical knowledge in chemical, biological and/or pharmaceutical operations which enables first-hand knowledge of manufacturing, quality control, quality assurance, regulatory affairs/sciences.
- Experience in working with global systems (e.g. serialisation softwares, SAP, Microsoft Office)
- Negotiation, communication and presentation skills across all levels both internal and external.
- Proven experience in resolution of deviations, development of effective CAPA and use of risk assessments.
- Be highly proficient in English.

Benefits:

- Competitive salary package
- Training and development opportunities
- Growing company
- Working with wide range of products
- Dynamic but friendly working environment
- Possible QP training and qualification