

Job description

Head of Quality/Responsible Person

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Table of Content

Table of Content.....	2
Company.....	3
The position as Head of Quality/Responsible person	4
Profile.....	4
Main purpose of the job / Key responsibilities	4
Tasks	4
Experience and qualifications.....	5
Personal characteristics / Required skills	5
Opportunities with the role	5
Contact	6
Application.....	6

Company

Company:	Medical Valley/Xiromed
Position:	Head of Quality/Responsible Person
Reporting to:	North Europe Head at Xiromed/CEO Medical Valley
Location:	Malmö (Höllviken)

Medical Valley/Xiromed is a fast-growing Generic Company focused on tender markets in North Europe. The aim is to deliver savings in older pharmaceutical therapies, allowing states and insurance systems to allocate more resources to newer, more efficient and costlier therapies leading to a sustainable healthcare system in North Europe.

Medical Valley/Xiromed with HQ in Höllviken is operating in 9 countries in north EU selling approx 75 different products in different therapeutic areas. Although it is an independent company it is owned by a larger developing and manufacturing pharmaceutical company, INSUD Pharma based in Spain.

For more information about the company and the products, see Medical Valley homepage <https://www.insudpharma.com/> or <http://www.medicalvalley.se/>

The position as Head of Quality/Responsible person

Profile

We are looking for a dynamic, knowledgeable and experienced Responsible Person for our wholesale license who preferably also can act Qualified Person (for release) for a few products, who has the ability to structure the function as we continue our growth and functions in a fast-paced entrepreneurial environment.

You are goal- and result-oriented, have a structured approach, are service-minded and enjoy working in teams.

Main purpose of the job / Key responsibilities

- Develop and maintain full Medical Valley/Xiromed Europe Pharmaceutical Quality Management System, including not limited to agreements, SOPs, audits
- Responsible Person for wholesale authorization in Sweden and Norway with the authority to take necessary action to fulfill the requirements for Responsible Person as listed in EU-GDP
- Manage and supervise Medical Valley/Xiromed QA and regulatory (functions and consultant coordination)
- QMS development, management and control
- Align quality mindset with group (INSUD Pharma) perspective
- Coordinate introductory and continuous GxP training of personnel
- Ensure compliance with current EU-GxP and applicable national legislation

Tasks

- Ensure that applicable accountabilities for Responsible Person are achieved according to current EU-GDP and applicable national legislation
- Escalate quality issues to senior management (CEO)
- Apply for/renewing authorizations for narcotic substances
- Create/maintain (including approval) Medical Valley QMS
- Ensure that GDP critical activities are performed (deviations, risk management, change management, training and documentation of delegations)
- Ensure proper handling of returns, recalls, PQCs, supplier qualifications
- Provide QA oversight (CMO audits, GDP/GMP compliance, protocol/report review, etc.)

- Develop and report quality metrics for performance of the Quality System, GxP, products and contractor performance
- Plan for and execute GDP/GMP audits (internal and external)
- Identify and investigate concerns arising regarding suspected non-adherence to the GxP and taking CAPA and escalation actions as necessary
- Ensure collaboration with other departments and/or business partners in cross-functional areas, in particular regulatory affairs, medical information, product quality complaints, and medical affairs, business development, supply chain and launch management

Experience and qualifications

- Pharmacist, Msc/PhD Lifesciences
- Continuous GDP and GMP training
- Fluent Swedish and English in speaking and writing
- Experienced user of Microsoft Office

Personal characteristics / Required skills

- Ability to apply expertise and technology
- Demonstrates a rapid understanding of newly presented information, gathers comprehensive information to support decision making
- Entrepreneurial mind set and innovate, produces new ideas, approaches or insights
- Focuses on customer needs and satisfaction, sets high standards for quality and quantity
- Adapts to changing circumstances, accepts new ideas and change initiatives
- Establishes good relationships with customers and staff. Builds wide and effective networks of contacts and relates well to people at all levels.

Opportunities with the role

This is a key position at the company with the great opportunity to build, lead and develop the quality initiatives for the company to secure success in the future. You will be part of an experienced and competent team focusing on collaboration and results, with possibility to influence and contribute with own ideas. Personal development within the role and at the company is highly prioritized.

Contact

*For inquiries and more information about the position, please contact:
Catharina Herbertsson or Eva Runnerström, Recruitment consultants at PeakSearch.*

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Application

Apply for the position at www.peaksearch.se

PeakSearch is a recruitment consultant company specialized in recruiting Executives, Managers and Specialists in the Nordics. We have developed a top-quality recruitment model to attract, select and deliver the optimal match to our candidates and clients. Our talent network is huge and all our consultants have a long experience from the industry. PeakSearch headquarters is situated in central Stockholm, with affiliates in Lund, Uppsala, and selected partners in the Nordic countries.