Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company focused on medical science and the development and commercialization of innovative pharmaceutical products for the treatment of rare neuromuscular diseases with high unmet medical need. For further information, please visit the Company's website www.santhera.com

Come and join our team to contribute to providing treatment options for patients with rare diseases that have a severe impact on the lives of affected children and adults. You can make a difference as:

Head Quality Management

Location: Pratteln, Switzerland

Scope of Work

The Head of Quality Management (QM) serves as a key organisational leader, responsible for defining, implementing, and monitoring a risk-based quality management strategy aligned with the company's objectives, regulatory obligations and product lifecycle. This role requires strategic oversight, a focus on operational execution excellence, and the ability to inspire a global, cross-functional quality culture.

The incumbent will act as a champion of quality excellence, ensuring that all processes comply with global laws, regulatory requirements, industry standards, and best practices. This position holds accountability for embedding a proactive, 'right-first time' quality mind-set across all levels of the organization.

Key Responsibilities

Strategic Leadership

- Serve as the primary advisor to senior leadership on quality and compliance matters, contributing to the broader organizational strategy.
- Develop and articulate a forward-thinking, risk-based quality strategy that supports both regulatory compliance and business innovation.
- Provide strategic direction and guidance to the global Quality Management Organization, ensuring alignment with corporate goals.

Operational Excellence

- Drive the design, implementation, and continuous improvement of the company's Quality Management System (QMS), ensuring it is fit-for-purpose across the product lifecycle.
- Oversee harmonization of quality processes globally, ensuring scalability and efficiency while maintaining compliance with GxP standards.
- Monitor emerging regulations, ensuring proactive adaptation to maintain global compliance.
- Define, oversee and maintain Quality related deliverables within defined timelines and budget.

Team Leadership & Collaboration

- Lead and mentor a team of quality professionals, fostering a high-performance, collaborative environment.
- Build and maintain strong relationships with internal and external stakeholders, ensuring quality initiatives align with business needs and support timely delivery of key projects.
- Promote professional growth within the team, ensuring robust succession planning and skill development.

Risk Management & Audits

- Establish and execute internal and external risk-based audit programs, ensuring readiness for regulatory inspections and audits.
- Lead initiatives to mitigate quality risks, driving a culture of proactive risk management.
- Provide critical input to Risk Management Plans, influencing decision-making at the highest levels.

Regulatory Compliance & Business Processes

- Ensure timely preparation for regulatory inspections, including hosting and follow-up activities.
- Oversee vendor and partner qualification processes and maintain compliance with GxP requirements.
- Manage validation of electronic systems to ensure adherence to global regulatory standards (including GxP document system and Learning Management Systems).
- Provide input into GxP related matters in due diligence for business opportunities.

Communication & Reporting

- Lead and chair the cross functional Santhera Quality Council with company-wide senior leadership.
- Generate and present quality metrics, trends, and status reports to senior leadership, quality status summaries and mitigation plans to Board of Directors.
- Communicate quality-related risks and issues to stakeholders, providing balanced, actionable insights.

Required Qualifications & Experience

- Advanced degree in pharmaceutical sciences or related field (PhD preferred).
- Minimum of 10 years in the pharmaceutical industry, with at least 5 years in a leadership capacity.
- Comprehensive and strong understanding of GxP, industry standards and the drug development lifecycle, with practical experience in either clinical operations, manufacturing, or pharmacovigilance.
- Proven ability to lead and influence remote, cross-functional, and international teams.
- Expertise in designing and executing quality systems and audit program.
- Fluent written and oral English (additional language skill advantageous).

Required Competencies & Skills

- **Leadership & Vision:** Demonstrated ability to inspire teams and drive organizational change.
- **Strategic Thinking:** Proficiency in developing long-term quality strategies aligned with business goals.
- **Collaboration:** Strong interpersonal skills, with the ability to build consensus among diverse stakeholders.
- **Communication:** Excellent written and oral communication skills, with the ability to convey complex ideas clearly with proficiency in MS Office suite.
- **Problem-Solving:** A proactive and pragmatic approach to addressing challenges.

For this position, the relevant working/residency permit or Swiss/EU-Citizenship is required.

If you are interested in a multicultural, challenging, and innovative working environment and your profile matches our requirements, we are looking forward to receiving your online application in English via LinkedIn or Email, at career@santhera.com

Strictly no agencies: Recruitment agencies are kindly invited to refrain from sending unsolicited CVs to Santhera.