



QA Manager Country Quality Lead EMEA

🌐 Employees can work remotely

Full-time

Company Description

Santen is a specialized life sciences company with a proud 130-year heritage focused exclusively on ophthalmology. As a Japan-originated, global company with our footprint in over 60 countries, we are dedicated to delivering innovative treatments and digital solutions for eye health and addressing vision-related social issues for people around the world.

Job Description

Location: Paris or hybrid

Purpose of Role

In the context of team expansion within EMEA, we are looking for a QA Manager. The purpose of this role is to ensure robust quality oversight and compliance with GxP's and local regulatory requirements across the countries and affiliates assigned. This includes the Iberia region, Italy and France. The role involves collaborating with cross-functional teams to maintain and enhance the Quality Management System (QMS), while supporting business continuity and driving continuous improvement. QA Manager Country Lead will act as a subject matter expert on international pharmaceutical legislation, providing guidance to the organization. Additionally, this role is responsible for fostering and maintaining quality awareness throughout the organization.

Key responsibilities

- Ensure compliance with corporate policies, local regulations, and GDP standards across assigned affiliates.
- Oversee and maintain the Quality Management System (QMS) to ensure consistent procedures and processes.
- Monitor affiliate operations for alignment with EU and local regulations.
- Manage health authority inspections, audits, and self-inspections, including Product Quality Complaints, Deviations, CAPA, and Change Control.
- Ensure quality documentation aligns with corporate standards and regulatory requirements.
- Stay updated on local and EU regulatory changes, advising affiliates on necessary compliance updates.
- Investigate quality-related issues, implementing CAPAs, and conduct risk assessments to safeguard product integrity.
- Develop mitigation plans for risks associated with distribution channels to prevent product quality incidents.
- Deliver quality and compliance training to affiliate/s staff, ensuring understanding of GDP/GxP and corporate expectations.
- Collaborate with internal stakeholders (Manufacturing, PV, RA, SC) and foster relationships with local

regulatory authorities.

Qualifications

EDUCATION

- Degree in Pharmacy with appropriate experience
- Knowledge in relevant (European) regulations and guidance documents (GMP, GDP)
- Recognized experience by CNOP for Deputy Responsible Pharmacist (Exploitant)

EXPERIENCE

- Minimum of 5-8 years of experience in quality assurance or quality management within the pharmaceutical industry, including experience within commercial quality.
- Good understanding of Good Distribution Practices (GDP), Good Manufacturing Practices (GMP), and international regulatory requirements.
- Proven experience managing quality systems and quality investigations.
- **Spoken and written languages: English, French and Spanish**

DESIRABLE

- Knowledge of medicinal products and medical device regulations at EU and international level
- TrackWise and Veeva quality application user knowledge

Additional Information

Grow your career at Santen

A career at Santen is an opportunity to make a difference. Through our long-term vision outlined in Santen 2030, we are committed to be a Social Innovator - addressing the social and economic needs of people with visual impairments. We have team members around the world using their diverse talents to unlock new modalities and drive innovations for patient outcomes, education and treatment. At Santen, we believe in empowering all our team members with flexible ways of working and a highly inclusive work environment.

The Santen Group is an Equal Opportunity Employer. We are committed to building diverse teams and ensuring a safe and inclusive physical and virtual workplace for every one of our team members. All employment decisions are based on business needs, role requirements and individual qualifications regardless of race, color, ethnicity, national origin/ancestry, religion, sexual orientation, gender, gender identity/ expression, age, disability, medical condition, marital status, veteran status, or any other characteristic protected by law.

If you require any kind of accommodation during our recruitment process, please let the recruiter from our team know.

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