ANMI-Job Description : Head of Quality and Regulatory Affairs / Qualified Person
Type : Full-time
Location : Liege, Belgium
Date : Immediate

About ANMI S.A.

ANMI S.A. is a pharmaceutical company developing innovative radiopharmaceutical solutions and a global service provider in the nuclear medicine field, located in Liège, Belgium. ANMI's vision is focused on increasing patient access to new highly specific theranostic radiopharmaceuticals through streamlined and cost-effective production processes. Since end 2018 ANMI is part of Telix Pharmaceuticals Limited ("Telix"), a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR). Telix is headquartered in Melbourne and is listed on the Australian Securities Exchange (ASX:TLX). For more information visit www.telixpharma.com

Description

The core deliverable of the role is to lead the quality and regulatory affairs department of the company ANMI SA based in Liege following cGMP requirements. As Qualified Person and Head of QA, you will have the Quality Assurance responsibility related to release activities for the products. As Regulatory Affairs Head you will be the contact point for the Competent Authorities communication, and you will participate to the redaction and review of regulatory dossiers. Your presence on site in Liège is largely required in the regulatory context and highly desirable from a management and collaboration standpoint. Responsibilities include but are not limited to:

- Manage the AFMPS interactions (inspection, information,…)
- Release of the Product
- Manage the day to day activities of the QMS and its continuous improvement, ensure its application and follow up
- Develop and manage the training program to ensure the ongoing training of current staff
- Develop and implement product specifications and standard operating procedures (SOPs) according to company wide requirements
- Review protocols, summary reports, SOPs, and internal specifications to ensure that documentation is accurate and complete.
- Perform record reviews of batches supplied by co-manufactures.
- Review documents assess risk and create GAP analysis based on current regulations.
- Maintain electronic document management system.
- Participate or lead internal quality reviews of documentation, training records, stability programs, CAPA's
- Investigate and resolve product and process problems related to quality issues.
- Participate in investigations of customer complaints; working with manufactures and operations to resolution.
- Ensure CAPA's are properly documented and corrective actions taken
- Understand and adhere to GMP policies and Procedures.
- Provide ongoing technical assistance and problem solving with existing manufacturers and suppliers, leveraging industry experiences and best practices.
- Participate in communication with the regulatory agencies as needed
- Report on a regular basis to the Director of Quality and Regulatory Affairs of the parent group based in Australia

Qualifications

- Bachelor's degree required. Orientation in pharmacy, biochemistry or science field is highly preferred.
- QP certification
- Minimum 8 years' experience in a pharmaceutical manufacturing environment with Good Manufacturing Practices (GMP).
- Minimum of 3 years' experience working in close support with R&D, Operations and Quality, this in an international matrix organization.
- Audit experience.
- Experience in radiopharmaceuticals is a plus
- Fluent in English
- Previous experience writing and reviewing with understanding SOPs and specifications.
- People management experience (direct reports) highly preferred.
- Strong written and oral communication skills required.
- Languages: English and French fluency.

Contact

For further information about the role, as well as expressions of interest, please contact ANMI HR at info@anmi.be.