ANMI-Job Description : Head of Quality and Regulatory Affairs
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. You will be in charge of the Quality Systems of the company. As Regulatory Affairs Head of, you will be the contact point for the Competent Authorities communication, and you will participate to the redaction and review of regulatory dossiers.

Responsibilities include but are not limited to:

- Manage the Quality System 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) in collaboration with the different head of departments
- Provide ongoing support by helping to create new documents, reviewing and revising existing documents, and verifying that the documents are aligned with relevant regulations.
- Ensure proper lifecycle of internal documentation
- Perform record reviews of batches supplied by co-manufactures.
- Review documents assess risk and create GAP analysis based on current regulations.
- Participate or lead internal quality reviews of documentation, training records, 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 product quality and specifications and documentation of the products are compliant vs national regulatory requirements.
- 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

Qualifications

- Bachelor's degree required. Orientation in pharmacy, biochemistry or science field is highly preferred.
- Minimum 8 years' experience in a pharmaceutical manufacturing environment with Good Manufacturing Practices (GMP) required.
- Minimum of 3 years' experience working in close support with R&D, Operations and Quality required.
- Audit experience required.
- Previous experience writing and reviewing with understanding SOPs and specifications required.
- Previous experience in process validation
- People management experience (direct reports) highly preferred.
- Strong written and oral communication skills required.

Contact

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