No Steve –
JUST JOBS

International Regulatory Specialist (m/f/d)

Our client is a **global leading Licensed Producer of pharmaceutical (RX) products** in **Neuss**, for healthcare practitioners who prescribe medical for their patients.

FRETTWORK network

Your Responsibilities:

- Assess regulatory environments and requirements of existing and new jurisdictions and markets to ensure product quality documentation is maintained throughout the entire product life cycle
- Generate accurate product quality documents, compliant with EMA regulations
- Work closely and collaboratively with the Quality Team to ensure that all product quality documentation has the applicable data set for compliance
- Understand and evaluate each market's medical cannabis regulations to ensure that product quality documents for each market are compliant with regulations
- Understand and evaluate each market's medical cannabis regulations
- Ensure that scientific data supporting submissions comply with applicable national and international regulations and guidelines
- Provide GMP-related regulatory advice to other departments
- Perform internal departmental regulatory compliance audits to facilitate sustained conformance
- Review product labels or other required documentation to ensure compliance with International requirements

PERSON OF CONTACT

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Consultant
national/international

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Xing LinkedIn

Your Qualification:

- B.Sc. degree in Biological/Life Sciences/Bioengineering or extensive experience and related training
- Post-Graduate Regulatory Certification preferred
- 3-5 years' experience working within a pharmaceutical manufacturing, and/or warehousing with cGMP-compliant Quality Management System
- Understanding of regulatory requirements for movement of controlled/uncontrolled drug products between different jurisdictions
- Knowledge of EMA regulations related to product quality (GMP, GACP, GPP)
- Understanding of product quality data generation, particularly for GMP compliance and Chemistry, Manufacturing and Controls
- Proven ability to generate a variety of technical product quality documentation
- Experience maintaining quality management systems and programs (ISO9001, GMP, HACCP) preferred
- Proficiency in English and German; Portuguese and Spanish is an advantage
- Willing to travel, approx. 20%

Our Offer:

- An innovative and international Team
- Participation in a new class of drugs with new products
- An above-average salary package, with top earning potential and corresponding success
- First-class development opportunities in an internationally renowned group

Interested?

We are looking forward to receiving your application in English, incl. starting date and your salary expectations per E-mail at: Jobs@frettwork.com

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