Compliance Regulatory Affairs Manager

Job ID
REQ-10024114

10月 03, 2024

United Kingdom

摘要

Role essential for efficient and effective national publishing operations for Marketing Authorisation submissions; reporting of regulatory status in the relevant UK RA Quality Management systems and supporting proactive compliance to key RA procedures with the ability to demonstrate this when required and particularly when called upon at Health Authority inspections and internal audits.

About the Role

Major accountabilities:

- Co-ordinate UK RA publishing operations to ensure effective management of workload within the UK RA Compliance Team
- Drive the development and implementation of end-to-end best practice relating to country publishing activities to ensure the efficient transmission of technically high-quality

submissions are consistently made to UK HA

- Support onboarding and act as mentor of UK Regulatory Publishing and Compliance Associates
- UK Regulatory Information Management (RIM) Subject Matter Expert, ensuring UK data compliance in the global RIM system
- Actively representing UK RA in the Global RA Process Improvement and Excellence Network
- Support the preparation and involvement of UK RA in internal global audits and external inspections, including CAPA management
- Support project management and implementation of pan-portfolio regulatory initiatives to ensure efficient and compliant outcome to ensure business continuity
- Support Regulatory Compliance and Process Lead to address potential quality issues and emerging compliance concerns and recommend solutions, providing backup support, as needed with quality incidents/deviations in the appropriate system

Key performance indicators:

KPIs as identified during annual objective setting

Minimum Requirements:

Life Science Degree or equivalent in education and experience
Work Experience:

- Dependent on individual aptitude, but would expect a minimum of 2-3 years ' experience of a broad range of regulatory work in the ethical pharmaceutical industry

Skills:

Knowledge of operational aspects of regulatory affairs

Compliance and Quality mind-set

Ability to be innovative and a creative problem solver with quality and compliance approach.

Excellent communication and interpersonal skills

Languages :

- English.

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部门
Development

Business Unit
Innovative Medicines

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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