Manager Systems Management

Job ID
REQ-10023582

12月 03, 2024

Spain

摘要

This role is responsible for implementing global processes and technologies to ensure compliant reporting of individual Case Safety Reports (ICSRs). This position in Patient Safety and Pharmacovigilance oversees the timely distribution and reporting of ICSRs, while ensuring quality compliance with regulatory requirements.

About the Role

Your Responsibilities Include, but are not limited to:

- Maintain and manage the reporting requirements system (T-Rex), acting as a super user for end users and a key contact for stakeholders.
- Serve as Business System Owner or Deputy System Owner to deliver global strategic initiatives and solutions for Patient Safety and Pharmacovigilance.
- Coordinate timely submission gateway implementations and submissions of ICSRs to Health

Authorities, Country Organizations, and License Partners, adhering to current regulatory standards.
- Lead or contribute to global technical projects, cross-functional workshops, and the development, testing, and validation of Safety Systems/IT applications, including drafting related documentation.
- Oversee tasks outsourced to service vendors, providing necessary guidance and training to ensure effective interaction and compliance.
- Identify compliance gaps or discrepancies in ICSR reporting and propose improvements, while ensuring inspection readiness and supporting Health Authority inspections and internal audits.

What you'll bring to the role:

- Degree in life science or computing subject
- Fluent in spoken and written English. Understanding of another major European language (French, German, Spanish) preferred
- Minimum of 7 years of experience in drug development, with at least 5 years in safety data management, and expertise in Pharmacovigilance systems and databases
- Thorough understanding of reference data for Pharmacovigilance (e.g., medical dictionaries, product and device definitions)
- Broad and in-depth knowledge of Pharmacovigilance and Drug safety business processes, along with excellent mentoring, coaching skills, and the ability to lead and deliver initiatives.

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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Alternative Location 1
Hyderabad (Office), India

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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