U NOVARTIS

Manager Systems Management

Job ID REQ-10023582 Nov 08, 2024 Spain

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.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <u>https://www.novartis.com/careers/benefits-</u>

rewards

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Role Requirements

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Division Development **Business Unit Innovative Medicines** Location Spain Site Barcelona Gran Vía Company / Legal Entity ES06 (FCRS = ES006) Novartis Farmacéutica, S.A. Alternative Location 1 India **Functional Area Research & Development** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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