Manager Systems Management

Job ID
REQ-10023582
Dic 03, 2024
España

Resumen

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.

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? https://www.novartis.com/about/strategy/people-and-culture

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

División
Development
Business Unit
Innovative Medicines
Ubicación
España
Sitio
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Hyderabad (Office), India
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work

No
Apply to Job

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

Job ID
REQ-10023582

Manager Systems Management

Apply to Job

Source URL: *https://prod1.adacap.com/careers/career-search/job/details/req-10023582-manager-systems-management*

List of links present in page

1. https://www.novartis.com/careers/benefits-rewards
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Barcelona-Gran-Va/Manager-Systems-Management_REQ-10023582-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Barcelona-Gran-Va/Manager-Systems-Management_REQ-10023582-1