

Global Program Safety Lead - Immunology

Job ID
REQ-10024551
Dic 06, 2024
Reino Unido

Resumen

-Designs & develops safety surveillance strategy for products and approval. Responsible for the company's drug surveillance program including the necessary follow-up, risk assessment, and relatedness to product on adverse reaction reports, oversight of safety in clinical trials and post marketing programs. Participates in the resolution of any legal liability and complying with governmental regulations. Provides and contributes trending and safety signal detection and risk management assessment for the products' life cycle. Provides safety support to the clinical development teams.

About the Role

Global Program Safety Lead – Immunology

****Two positions available****

Primary Location: London, United Kingdom

Alternate Location(s): Barcelona or Madrid, Spain

Working model: All locations have a hybrid working model (which requires 12 days per month in the office)

Note: Novartis is not able to offer relocation support for this role. Please only apply if the location is accessible for you.

About this role:

Our Global Program Safety Lead excels as a scientific safety leader within the Immunology Medical Safety organization.

Join us and you will make a significant impact on patients' lives and contribute to Novartis' overall success through robust safety evaluation expertise and medical innovation.

Key Responsibilities:

- **Safety Input and Team Participation:** Provide expert safety input to the clinical development program for assigned projects/products and actively participate in the Global Program Team (GPT), Global Clinical Team (GCT), and Clinical Trial Team (CTT). Responsible for managing safety issues from the formation of the GPT through Life Cycle Management.
- **Signal Detection and Safety Management:** Oversee overall signal detection, monitoring, evaluation, interpretation, and appropriate management of safety information, based on data from all relevant line functions, post-marketing data, and other sources.

- **Documentation and Record Keeping:** Ensure proper documentation, tracking, and record-keeping of medical safety activities for assigned compounds.
- **Regulatory and Professional Inquiries:** Respond to inquiries from regulatory authorities or healthcare professionals regarding safety issues.
- **Safety Strategy Preparation:** Lead the preparation of the safety strategy for health authority responses and collaborate with other project team members.
- **Departmental and Functional Goals:** Contribute to and often lead the development of departmental and functional/business unit goals and objectives.
- **Marketing Samples Distribution:** Manage the distribution of marketing samples, where applicable.

Role Requirements:

- Medical Degree required
- 8+ years of experience in Big Pharma

Skills:

- Clinical Research.
- Clinical Trials.
- Functional Teams.
- Leadership.
- Medical Strategy.
- Process Safety Management.
- Regulatory Compliance.
- Risk Management.
- Safety Science.

Languages :

- Fluent English (both spoken and written) is mandatory.
- Additional languages are an advantage.

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

Sandoz

Ubicación

Reino Unido

Sitio

London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Barcelona Gran Vía, España
Alternative Location 2
Madrid Delegación, España
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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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