Turkey Jobs Expertini®

Senior Safety Officer – Pharmacovigilance

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Company: Excelya

Location: Turkey

Category: other-general

Introduction

Excelya is one of the leading CROs in Europe, founded in 2014 and headquartered in Paris. Our global team is composed of 900+ experts who understand the critical needs of clients and provide trial solutions across a broad spectrum of therapeutic areas.

We take a one-team approach to work: our shared success is the result of collaboration at every stage of a project, from regulatory affairs and clinical operations to quality assurance and strategic development.

Excelya's vision is to achieve new advances in the field of healthcare and expertise in research development. Our goal is to help our clients deliver life-changing therapies collaboratively, so we can transform tomorrow together and to become the clinical research leader in Europe.

For our team members, excelling with care means benefitting from a stimulating professional environment that encourages personal, intellectual, and operational participation so that together we can be the best in our field.

We commit to giving each Excelyate the means to express their natural talents, develop their full potential and invest their unique selves in our unique projects.

The role:

Excelya is seeking candidates to collaborate in a permanent role as a Senior Safety Officer based in Turkey.

The position involves working in local and global projects within the Pharmacovigilance (PV) and Safety department and opportunity to work in all aspects of pharmacovigilance, such

as handling adverse events, writing of aggregate reports, maintenance of the Pharmacovigilance system, implementing Risk Management Plans and handling training, medical information.
Acting as primary contact and nominated responsible person for pharmacovigilance (“Local QPPV” equivalent) notified to the local Health Authorities on behalf of Excelya Client(s).

Main Responsibilities:

Act as the national Pharmacovigilance contact for the local authorities

Responsible for PV inspections and client audits, as well as nominated as the local national Responsible Person for Pharmacovigilance (RPP/QPPV) for CHC products where applicable according to national regulations. Also, designated a backup who assumes responsibilities in their absence from the office

Serve as the key leader representing the client in all pharmacovigilance (PV) related endeavors at the national level, encompassing comprehensive responsibilities such as case management, local safety surveillance, signal detection, risk management, and mitigation activities. Additionally, oversee PV aspects of patient support programs and market research initiatives related to pharmacovigilance.

Ensures that local pharmacovigilance activities in the assigned country comply with relevant regulations, as well as Excelya and Client’s global pharmacovigilance policies and procedures. Additionally, ensures adherence to global, regional, and local pharmacovigilance regulations to ensure the safe and appropriate use of consumer healthcare (CHC) products in the assigned country.

Establishes and maintains robust and efficient local pharmacovigilance (PV) systems in the designated country by ensuring the availability and implementation of proper systems, procedures, tools, and training. Provides support to the Qualified Person for Pharmacovigilance (QPPV) in overseeing PV activities in the country.

Responsible for supporting the CHC Head of Safety with regards to local budget planning and management.

Responsible for fostering close and robust relationships and collaboration with in-country partner Client functions, which include but are not limited to Medical, Regulatory, Quality, Commercial, Legal, and Country Manager.

Act as Deputy Pharmacovigilance person CSH for a partner to other country(ies).

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