Safety Physician

SP-1218

Are you an expert with medical terminology in clinical or industry practice? Are you excellent at executing assigned projects and processes? Can you effectively build and manage working relationships with stakeholders, based on transparency, trust and clear communication? We may have the ideal job for you.

Responsibilities

- Involved in continuous safety assessment, evaluation and risk management of products under Arriello's responsibility (where Arriello is MAH or Arriello performs activities on behalf of Clients, further as "Arriello products")
- Involved in the evaluation of adverse events and adverse reactions and other safety information on Arriello products
- Provide medical support to the EU QPPV/deputy EU QPPV and other Global pharmacovigilance department employees
- Maintains current knowledge on the safety profiles of Arriello products
- Is involved in the Quality management system (QMS) and activities related to medical processes
- Has an overview and supports the continuous evaluation of the benefit-risk profiles of Arriello products
- Provides support in the preparation and review of CCDS/SmPC/PIL as/if required
- Perform medical reviews of ICSRs and adverse events from clinical trials (causality and expectedness assessment, MedDRA coding, clinical evaluation and accuracy of reports, case narrative review etc.)
- Provide medical expertise into signal management activities
- Provide medical input into Periodic Safety Update Reports (PSUR) and Development Safety Update Reports (DSUR)
- Provide medical input into Risk Management Plans (RMP)
- Provide medical input and has awareness of risk minimisation measures (RMMs)
- Provide medical input into Non-interventional studies documentation
- Provide medical input into clinical trial documentation
- Participates in the preparation of responses to Authority requests (i.e. EMA, NCAs)
- Provide medical expertise on Emerging safety issues identification and response
- Maintain knowledge of current PV and related regulations (i.e. Good vigilance practice)
- Prepares training materials and performs training on medical related issues both for Arriello internal personnel and Client/Vendor personnel
- Serve as a company medical expert
- Performs any other related activities as assigned

Accountabilities

- Excellent execution of assigned projects and processes
- Precise alignment with partners in respect of ongoing and required activities
- Effectively manage and build working relationships with all stakeholders, based on transparency, trust and clear communication

Requirements

- Medical degree (M.D.)
- Expert understanding of the use of medical terminology in clinical or industry practice
- Knowledge of life science industry and medicinal product lifecycle
- Excellent written and spoken English
- Fluent in Czech (native speaker or upper intermediate is a must)
- Previous experience within a similar or the same position