



Local Safety Officers (LSO /DSO), LPPV CZ SK

PVS-1218

We are looking for candidates for several roles within the pharmacovigilance team; Local Safety Officer (LSO), Drug Safety Officer (DSO) and Local Person for PV. Our target countries/areas include Italy, Benelux, Germany, Austria, Switzerland, Middle East but may include others.

Responsibilities

These positions are primarily responsible for overseeing the local Pharmacovigilance (PV) system in assigned country/ies and acting as a point of contact regarding PV for National Competent Authorities (NCA) in accordance with their set requirements and rules.

Activities in assigned projects may include, but are not limited to:

- Notification of the LPPV to NCA as per local requirements
- Liaising with and reporting to the Marketing Authorization Holder (MAH) and EUQPPV
- Handling safety information
- Translating ICSRs, and Medical Information Requests (MIRs) or Product Quality Complaints (PQCs) containing ADR(s), and any other safety relevant information received in local languages to English
- Performing follow-up activities for ICSRs upon request
- Handling communications between MAH and NCA
- Defining the local scientific literature monitoring strategy and selecting the appropriate journals/publications according to assigned portfolio and/or client needs
- Performing local scientific and medical literature monitoring and screening for ICSRs and other non-ICSR safety relevant information
- Monitoring changes in regulatory requirements and applicable PV legislation locally (regulatory intelligence)
- Documenting results of the local literature screening and regulatory intelligence monitoring
- Monitoring the PV compliance and ensuring the corrective and preventive actions are taken in case of non-compliance issues
- Training - performance and attendance
- Performing ad-hoc activities as and when required within the projects e.g. implementation of risk minimization measures locally, oversight of local patient support programs, review of local PV agreements etc.



- Actively building Arriello's expertise in local pharmacovigilance regulations, guidance and legislation
- Preparation for and participation in internal and external audits
- Preparation for and participation in authority inspections
- Communication with clients and other stakeholders

Requirements

- University degree preferably in Pharmacy, Medicine or Life sciences
- Excellent written and spoken English
- Russian language is a big advantage (for DSO position) and/ or other local languages e.g. Italian, French, German, Arabic, etc.
- Experience with case management a big advantage
- Excellent communication and organizational skills
- 3 - 5 years of experience in a similar position or within the same field