Senior PV Specialist

SPVS-1218

We need a qualified Senior PV specialist to continue to build Arriello´s expertise in local and global pharmacovigilance and become an integral part of team Yellow. If you're interested in becoming a new Senior PV Specialist at Arriello, this is what we're looking for:

Responsibilities

- Support PV Project Managers, Head of Local PV Unit and Head of Global PV Unit
- Maintain and improve the pharmacovigilance system and processes
- Execute project related activities and delegated activities as assigned
- Data entry and reporting of ICSRs to Competent Authorities as applicable
- Monitoring product safety in order to support benefit-risk management strategies
- Responding to product safety related requests from Competent Authorities when instructed
- Act as pharmacovigilance regulatory intelligence administrator when/if required
- Act as safety mailbox administrator when/if required
- Work on assigned activities according to various PV Unit strategies -

Different assignments may apply for each unit as follows

Global PV unit may include, but not limited to:

- Global literature monitoring
- ICSR management
- Website monitoring
- xEVMPD management
- Risk Management Plan/PSUR preparation
- Signal management

Local PV Unit: may include, but not limited to:

- Case management to Regulatory intelligence monitoring
- Safety mailbox monitoring
- Operational documents preparation
- Local literature management

- Management of local persons responsible for pharmacovigilance
- Actively build Arriello's expertise in local and/or global pharmacovigilance regulations, guidance and legislation world-wide
- Prepare for and participate in internal and external audits
- Prepare for and participate in authority inspections
- Participate during vendor audits as and when needed
- Participate in internal and external training and industry events as required
- Provide training to junior staff as needed
- Actively look for improvements in the department and day to day work
- Communicate with clients, authorities and any third parties and stakeholders as needed
- Organize and file documentation according to the company's document management system
- Use the company's databases, systems and any other IT tools applicable for the job in line with company instructions
- Work with the pharmacovigilance assistant to deliver necessary documents to clients, authorities, any other third party and stakeholders
- Ensure a high level of delivery internally that adapts to changing requirements
- Review work done by junior staff/ pharmacovigilance assistants as needed and provide them with sufficient support to execute and improve
- Identify gaps and areas for improvement and lead remedial actions and initiatives
- Participate in any related business activities, i.e. meetings with clients, trade shows, etc.
- Adhere to all company processes and systems
- Liaise with Pharmacovigilance/Regulatory Affairs/Quality Assurance/other departments and/or sub-contractors to update and exchange information on licenses and other important information

Accountabilities

- Excellent execution of assigned projects and processes
- Alignment with Pharmacovigilance (and other) partners in respect of ongoing and required activities
- Effectively build and manage working relationships with all stakeholders, based on transparency, trust and clear communication
- Excellent cross-functional teamwork with Operations colleagues to ensure full compliance

Requirements

- University degree preferably in Pharmacy, Medicine or Life sciences
- Excellent written and spoken English
- 3 years of experience in a similar position or within the same field
- Excellent communicative and organizational skills
- experience of working with external partners