Regulatory Affairs Specialist

The role performs the coordination and preparation of document packages for regulatory submissions in Belarus and Armenia for new and mature products to ensure alignment and compliance with local and regional registration requirements as well as with company policies from all areas of the company as well as internal audits and inspections.

Key responsibilities include:

- Support in implementation and maintenance of regulatory, quality and safety compliance for IVD medical devices and support in providing guidance for regional and local business partners;
- Preparation of all materials required in submissions processes in both countries (Belarus and Armenia), license renewal and annual registrations;
- Communicating effectively with distributors' contacts, global and local quality/ regulatory groups on a daily basis with regards to regulatory and quality aspects;
- Support in monitoring regulatory intelligence and acting proactively on identified changes to regulatory requirements (i.e. support with submissions);
- Playing an active role in post-registration quality activities and support;
- Working on improvement opportunities for regulatory processes, policies and systems;
- Playing an active role in interaction with regulatory agencies on defined matters;
- Playing an active role in product quality issues, including medical devices vigilance, in order to minimize the impact on business;
- Providing support for all audits and inspections as needed and participating/ conducting internal audits.

As an ideal candidate, you have the following skills and competencies:

- 3 years proven experience in regulatory in medical or pharma market;
- Knowledge and working experience on regulatory operations and regulatory intelligence activities;
- Experience with preparing, performing, reporting and following on regulatory processes;
- Strong organizational skills and attention to detail required;
- Ability to work in a cross-functional, highly interdependent team structure;
- Results and goal oriented;
- High degree of initiative with the ability to work independently;
- Excellent command of written and spoken English;
- Ability to clearly convey or exchange information with internal and external stakeholders;
- Ability to address and resolve conflict by creating an atmosphere of openness and trust;
- Basic understanding of National and EU medical devices and IVD medical devices directives, regulations and requirements;
- Ability to work independently with limited supervision,
- Flexibility to travel, 10% travel based on business needs

Qualification:

- University degree in Healthcare related fields and/or Legal

To send your CV in English or enquire more details, contact:

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