Medical Information Specialist

United States

Reference Number:

AIXIAL (ALTEN Group) is a CRO that has been supporting major accounts in the pharmaceutical industry in France and Europe for more than 25 years on different types of services: Insourcing (CRO) and Outsourcing (delegation of skills) in such varied environments. such as Biometrics, Clinical Research, Pharmacovigilance and Pharmaceutical Affairs.

AIXIAL is a subsidiary of the ALTEN group which has enjoyed double-digit growth for many years. Looking for continuous improvement to cope with changes in society, you can simply join a very stimulating environment.

We are currently looking for a Medical Information Specilist for a client dedicated role in the US. This role is home-based anywhere in the US.

US Medical Information support

- Support colleagues and newcomers on specific processes or topics in line with business expertise.
- Write summaries of FDA annual report clinical literature for NDA products.
- Participate in the development of specific technical/medical responses to specific situations, including but not limited to; product discontinuation, media attention, crisis situations and responses to health authorities or other organizations within the assigned therapeutic areas.

Global escalation support

- Support the GMI team with Global escalations as needed. Provide ad hoc country support on literature review and custom scientific response documents (CSRD).
- Local SRD development and oversight
- Coordination, development, and maintenance of US Standard Response Documents (SRDs) and Contact Center repository in all CHC therapeutic areas, for all products and relevant medical programs. Close collaboration with MICC vendor and other relevant departments (including, but not limited to; medical, regulatory, CMC, legal, communications) to ensure the right content is available.

Global SRD support

- Support with the creation and update of Global Standard Response Documents (SRDs) and Contact Center tools repository in all CHC therapeutic areas, for all products and relevant medical programs.
- Vendor Support and Oversight
- Coordinate, provide and monitor training of (local) products, systems, and MI to the MICC vendor.
- Other MI Activities
- Participate in global MI meetings when needed to ensure best practice sharing and transparent communication.
- Contribute to inspections and audits.
- Data analytics for MI insights/trends, KPI tracking, reporting
- Key markets MedInfo data analysis
- Generation of MI activity metrics and reports, metrics reports to teams, and responding to queries about the reports: Trends and Insights report creation (global, country, or inquiry category- or product- based, regular and upon request); management of and contributions to dashboards.
- Contribute to optimization of Global Medical Information systems.
- Provide monthly reconciliation reports to PV and QA Participate in the preparation of monthly activity reports.

Background Required

- Knowledge of local country regulations
- Must be a native English speaker
- Previous in-depth experience of pharmaceutical medical information processes
- Confirmed experience in designing and conducting literature searches using scientific literature database such as Medline, Embase, Ovid, and Medscape.
- Confirmed experience writing Medical Information documents.
- Knowledge of Microsoft Outlook, Microsoft Word, Microsoft Excel and Microsoft PowerPoint.
- Excellent communicator with a team-first approach.
- Time management and multi-tasking.
- Strong customer-centric values
- Strong analytical and synthesis aptitudes, demonstrated problem solving abilities.

Beneficial

- Understanding of the clinical development process and of the commercial environment would be an asset
- Knowledge of Veeva Vault; Sales force.
- Knowledge of data sharing platform such as e-room or SharePoint
- Some experience in hospital, community pharmacy or in a drug information center would be an asset

Your contact person
